

# Grand Bargains for Big Data: The Emerging Law of Health Information

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## GRAND BARGAINS FOR BIG DATA: THE EMERGING LAW OF HEALTH INFORMATION

FRANK PASQUALE\*

### ABSTRACT

*Health information technology can save lives, cut costs, and expand access to care. But its full promise will only be realized if policymakers broker a “grand bargain” between providers, patients, and administrative agencies. In exchange for subsidizing systems designed to protect intellectual property and secure personally identifiable information, health regulators should have full access to key data those systems collect.*

*Successful data-mining programs at the Centers for Medicare & Medicaid Services (“CMS”) provide one model. By requiring standardized collection of billing data and hiring private contractors to analyze it, CMS pioneered innovative techniques for punishing fraud. Now it must move beyond deterring illegal conduct and move toward data-driven promotion of best practices.*

*With this aim in mind, CMS is already subsidizing technology, but more than money is needed to optimize the collection, analysis, and use of data. Policymakers need to navigate intellectual property and privacy rights skillfully. They must condition current (and future) government support for providers and insurers on better collection and dissemination of health information. If they succeed, the law of health information might better incorporate public values than information law generally.*

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## I. INTRODUCTION

Quantitative analysis of large information sets (“big data”) has spurred scientific and business breakthroughs.<sup>1</sup> Better collection and analysis of health data may save lives, cut costs, and expand access to care. Congress has allocated billions of dollars for health information technology since 2009,<sup>2</sup> but more than subsidies are needed to assure optimal collection, analysis, and use of data in medicine. Policymakers need to skillfully navigate areas of law often used to stop the sharing of data, including intellectual property rights and contractual obligations.

By siloing data, health insurers and providers have impeded the types of large-scale analysis common in other industries. Providers have kept vital information about price, quality, and access secret to maintain a competitive advantage or hide shortcomings.<sup>3</sup> For example, insurers keep secret many of the prices they pay.<sup>4</sup> Each major drug company’s “data exclusivity”<sup>5</sup> may mean that rivals waste vast amounts of money pursuing leads that have already proven to be dead ends. Health information technology systems may not be interoperable, leaving them unable to “talk to one another” and share data.<sup>6</sup>

Though the inherent inefficiencies of intellectual property (“IP”) law may be acceptable in ordinary markets, they raise serious questions in the life-and-death domain of health care.<sup>7</sup> Federal and state authorities are pushing back against aggressive deployment of IP protections by health care providers and insurers. Sometimes the pushback involves reporting requirements attached to subsidies;<sup>8</sup> in

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1. See Steve Lohr, *The Age of Big Data*, N.Y. TIMES, Feb. 11, 2012, at A1 (surveying “revolution[s] in measurement” made possible by an “explosion of data”). “Big data” is shorthand for advancing technological trends that allow for the collection, analysis, and use of an ever-increasing flood of data. *Id.*

2. See *infra* notes 113–116 and accompanying text.

3. See *infra* Part II.

4. See *infra* Part II.C.

5. See *infra* Part II.A.

6. See *infra* Part II.D; see also David Blumenthal, *Implementation of the Federal Health Information Technology Initiative*, 365 NEW ENG. J. MED. 2426, 2428 (2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMSr1112158> (describing how the technical requirements in the HITECH Act “are vital to ensuring that [electronic health records] can communicate with one another (or interoperate)”).

7. See *infra* notes 268–272 and accompanying text.

8. See *infra* notes 113–117.

other cases, IP law itself is simply declared inapplicable or directly limited in the medical context.<sup>9</sup> Federal and state agencies are imposing a new bargain on insurers and providers: In exchange for persistent subsidies and government support, they must reveal key data about their activities.<sup>10</sup> Sometimes, as in the case of health information technology's "meaningful use" regulations,<sup>11</sup> the activities themselves must change to reflect public values. Federal and state agencies need to require providers and insurers to reveal key data in exchange for government support, while minimizing the possibility of improper uses of that data. The proper balance between privacy and innovation, or openness and proprietization, will depend on the end goal of particular government data initiatives. Sometimes the aim will be the creation of new—or repair of old—markets for data. In other instances, the goal will be an information commons. The challenge is to rationalize complex, often conflicting legal frameworks as the stakes rise. Increasing computer power means that both uses and misuses of data are becoming more important.

The increasing power of data to be used for both good and ill arises from powerful trends within industry and computing science. Increasingly, complete digital copies of health providers' business practices exist in cloud-based storage services.<sup>12</sup> Purchases, expenses, business strategies, and other documents coexist in ever-cheaper and more easily copied files. Individuals are also taking advantage of the new technology. For example, members of the "Quantified Self" movement could insert verified tracking of average pulse, sleep time, weight, and meters walked per day, based on smartphone-enabled self-monitoring.<sup>13</sup> An era of "big data" promises exhilarating and frightening opportunities to cure and exploit human vulnerabilities.<sup>14</sup>

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9. See *infra* notes 279, 311 (discussing Food and Drug Administration ("FDA") access to aggregate data while allowing data partners to retain control over proprietary, patient level data).

10. See *infra* text accompanying notes 113–121.

11. See *infra* text accompanying notes 113–121 (discussing meaningful use). Other scholars have defined "meaningful use" of electronic health records ("EHRs") as "the level of use that providers would have to attain to qualify for incentive payments under the HITECH Act." Blumenthal, *supra* note 6, at 2426.

12. Cloud computing transfers "application software and server-based databases to centralized, large data centers." Jared A. Harshbarger, *Cloud Computing Providers and Data Security Law*, 16 J. TECH. L. & POL'Y 229, 230–31 (2011).

13. Anita Allen, *Dredging Up the Past: Lifelogging, Memory, and Surveillance*, 75 U. CHI. L. REV. 47, 52 (2008) ("The lifelog could easily store data pertaining to purely biological

Legal scholars have responded by analyzing how current law will govern data flows.<sup>15</sup> These existing rules include limits on disclosure posed by the proprietary interests of corporations.<sup>16</sup> Recent developments suggest that these legal regimes, primarily concerned with the *restriction* of information flows, may impede innovation and undermine public health.<sup>17</sup> They may also provide illusory assurances: In case of an emergency or breach, even the best-protected data flows will likely be subject to multiple forms of collection, analysis, and use.<sup>18</sup> Is there a way to take advantage of rapidly increasing capacities to store and analyze data while protecting proprietary information?

Software-based automation has raised living standards dramatically in the developed world. It makes factories more efficient, renders vast amounts of information accessible, and improves the quality

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states derived from continuous self-monitoring of, for example, heart rate, respiration, blood sugar, blood pressure, and arousal.”); Emily Singer, *The Measured Life*, MIT TECH. REV., July/Aug. 2011, available at <http://www.technologyreview.com/featured-story/424390/the-measured-life/> (“The new generation of devices rely on inexpensive, low-power wireless transceivers that can automatically send data to the wearer’s cell phone or computer. Compared with the limited snapshot of health that is captured during an annual visit to the doctor’s office, these tools and techniques could reveal the measures of someone’s health in context, and with a much richer resolution.”).

14. See Randal E. Bryant, Randy H. Katz, & Edward D. Lazowska, *Big-Data Computing: Creating Revolutionary Breakthroughs in Commerce, Science, and Society* (Dec. 22, 2008), [http://www.cra.org/ccc/docs/init/Big\\_Data.pdf](http://www.cra.org/ccc/docs/init/Big_Data.pdf) (arguing that big-data computing can and will transform the way many sectors of our society operate).

15. See *infra* note 271–272.

16. See *infra* Parts II.A., II.D.

17. See Victoria Stodden, *Enabling Reproducible Research: Licensing for Scientific Innovation*, INT’L J. COMM. L. & POL’Y Winter 2009, at 12, available at [http://www.ijclp.net/files/ijclp\\_web-doc\\_1-13-2009.pdf](http://www.ijclp.net/files/ijclp_web-doc_1-13-2009.pdf) (noting that copyright laws create a block for generating new scientific research and discoveries).

18. See, e.g., Sara A. Needles, *The Data Game*, 88 N.C. L. REV. 267, 296–97 (explaining that HIPAA “permits broad exceptions in health care providers’ privacy policies to allow disclosure pertaining to the protection of public health, essential government functions, law enforcement purposes, and as authorized by programs such as workers’ compensation”). Similar exceptions also limit state laws that offer stronger privacy protections than HIPAA. See Jason Sterzer, *The Good, the Bad, and the Ugly: A 50-State Survey Exploring Federal and State Firearm Regulations Related to Mental Health*, 33 J. LEGAL MED. 171, 196 (2012) (“[S]tate privacy laws . . . have exceptions for disclosure of personal health information to specified individuals/entities without consent pursuant to mandatory reporting requirements, specifically to law enforcement.”).

of daily life in barely noticeable ways. To realize these types of advances in health care, government needs to catalyze better data collection, retention, and analysis in the industry.<sup>19</sup> Government itself is scarcely a model here; the information technology systems of many government agencies are years behind even the sclerotic computing capacities of struggling hospitals.<sup>20</sup> Nevertheless, agencies like CMS have a proven track record of contracting technically savvy private entities to interpret data to detect and deter fraud.<sup>21</sup> Such public-private surveillance partnerships should have a much larger role in health care.

Unfortunately, trade secrecy and some other IP protections now prevent the realization of the full scale of efficiencies possible in an era of big data.<sup>22</sup> The cost of excess IP protection is a persistent theme in IP scholarship.<sup>23</sup> Scholars seek to reshape doctrine so that it respects the unique economic conditions (and moral imperatives) related to specific industries.

One way to do so is to insist on the autonomy of a subject matter-defined legal field (versus the trans-substantive aspirations of, say, contract, tort, or property law). Private law scholars assailed that autonomy by warning about the distortionary effects of applying different laws to different sectors,<sup>24</sup> and health law professors have shared

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19. *See infra* Part III.D.

20. Sometimes the lag can be counted in decades. *See, e.g.*, Mary L. Schapiro, Opening Speech at the SEC Open Meeting—Consolidated Audit Trail (May 26, 2010), available at <http://www.sec.gov/news/speech/2010/spch052610mls-audit.htm> (“The technology for collecting data and surveilling our markets is often as much as two decades behind the technology currently used by those we regulate.”). For a theoretical perspective on the challenges to governance raised by information lag, see generally WILLIAM SCHEUERMAN, LIBERAL DEMOCRACY AND THE SOCIAL ACCELERATION OF TIME (2004).

21. *See infra* notes 408–409 and accompanying text.

22. *See infra* notes 99, 274–275.

23. *See, e.g.*, CHRISTOPHER SPRIGMAN & KAL RAUSTIALA, THE KNOCKOFF ECONOMY (2012) (calling for more measured IP protections); JAMES BESSEN & MICHAEL MEURER, PATENT FAILURE 4 (2008) (acknowledging that the American patent system is broken). For a more radical perspective, see Peter Frase, *Four Futures*, JACOBIN (Winter 2012), <http://jacobinmag.com/winter-2012/four-futures/> (“The embryonic form of class power in a post-scarcity economy can be found in our systems of intellectual property law.”).

24. Frank H. Easterbrook, *Cyberspace and the Law of the Horse*, 1996 U. CHI. LEGAL F. 207, 208 (1996). The phrase “law of the horse” is meant to embody the idea “that the best way to learn the law applicable to specialized endeavors is to study general rules.” *Id.* at 207. This critique is summed up well by a rhetorical question Easterbrook posed in his

such concerns<sup>25</sup> But those anxieties ought to fade as a distinct field of health care economics develops and lawyers interpret the massive Health Information Technology for Economic and Clinical Health Act (“HITECH”) and Patient Protection and Affordability Care Act (“PPACA”) legislation passed in 2009 and 2010.<sup>26</sup> The field is sufficiently unique that it demands not only distinctive treatment in the common law, but also sufficient latitude in the statute-driven world of intellectual property, data protection, and cyberlaw to reflect the importance of new health information flows.

The law of health information is neither more “open” nor more “closed” than information law generally. Free access should be dictated in areas of extreme personal or societal need; in other cases, it may be right to force high payments—either ex ante via taxes, or ex post via high prices—from those with the ability to pay. Privacy should play a far more important role here than it does in the usual Wild West of Internet data collection and processing. But once data is truly anonymized, the research imperative for access is perhaps more pressing here than in any other area of law (except, perhaps, national security). Health professionals and patients believe the medical field deserves some autonomy from the normal laws of IP.

The stage is now set for a distinctive law of “health information” to emerge, as government uses its leverage in the sector to tamp down proprietary strategies that undermine the public weal. Over a decade ago, Bill Sage complained that both supporters and critics of information-based regulation in health care “have overlooked serious operational issues and misunderstood some of the best uses of information.”<sup>27</sup> Sage argued that disclosure must be “properly designed

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article: “If we are so far behind in matching law to a well-understood technology such as photocopiers—if we have not even managed to create well-defined property rights so that people can adapt their own conduct to maximize total wealth—what chance do we have for a technology such as computers that is mutating faster than the virus in *The Andromeda Strain*?” *Id.* at 210.

25. See Theodore W. Ruger, *Health Law’s Coherence Anxiety*, 96 GEO. L.J. 625, 625 (2008) (“No one has expressed the perceived incoherence of health law more comprehensively than many of the nation’s leading health law scholars themselves . . .”).

26. Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148, § 6301, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 1320(e) (2010)); Title VIII (“HITECH”) of the American Recovery and Reinvestment Act of 2009 (“ARRA”), Pub. L. No. 111-5, 123 Stat. 115, 226–79 (2009) (codified in various sections of 42 U.S.C.).

27. William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1710 (1999).

and implemented” in order to improve outcomes, and he worried that the disclosure movement of the 1990s was ill-equipped to provide actionable information to patients and providers.<sup>28</sup> This Article will document computational and legislative advances that should assuage many of Sage’s concerns, if policymakers at key government agencies can properly implement laws like HITECH and PPACA.

The argument will proceed as follows. Part II will present failures in the current health information order, ranging from suppressed data about drug safety to hidden prices of procedures. Part III will lay out the types of efficiencies that could be attained in each area if health care shared the productivity gains characteristic of mature information industries. Part IV will explain how existing public-private surveillance partnerships should inform regulatory developments here. Part V will conclude by situating the argument in a larger context, explaining the normative concerns that need to be balanced in the emerging law of health information.

## II. INFORMATION GAPS IN AMERICAN HEALTH CARE

Classic economic theory directly relates the competitiveness of a market to the amount of information available about the products and services exchanged in it.<sup>29</sup> Health care, however, is one of many areas where intermediaries consider information gathering either a commodifiable service in itself, or an aspect of their own competitive strategy. There is an important divide between researchers who have access to critical medical research and those who do not.<sup>30</sup> While the market value of intermediaries who ration access to data may have been clear in an era of laborious paper gathering and transcribing, it

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28. *Id.*

29. See George A. Akerlof, *The Market for “Lemons”: Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488, 500 (1970) (discussing economic models involving “trust” and uncertain quality); Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 947, 965–66 (1963) (discussing behaviors influenced by information inequality in a medical context).

30. See JOHN WILLINSKY, *THE ACCESS PRINCIPLE: THE CASE FOR OPEN ACCESS TO RESEARCH AND SCHOLARSHIP* 5 (2005) (describing challenges to individuals and institutions); see generally OPEN ACCESS TO SCIENTIFIC, TECHNICAL, AND MEDICAL INFORMATION (Anthi Katsirikou ed., 2011) (describing numerous articles that discuss varying strategies to address the issue).

must be questioned in today's market, where computing capacity makes data capture an almost trivially easy proposition.<sup>31</sup>

Experts suggest that as much as a third of health care spending in the United States may be wasted on inappropriate, useless, or even harmful care.<sup>32</sup> This massive misallocation of resources may be attributed, in part, to failures to act on current data, but it also occurs because useful data is not available, does not exist, or is actively hidden.<sup>33</sup> The emerging field of agnotology studies such lacunae by examining the “structural production of ignorance, its diverse causes and conformations, whether brought about by neglect, forgetfulness, myopia, extinction, secrecy, or suppression.”<sup>34</sup> The following Sections explore the problem of missing data in health care from an agnotological perspective, focusing on strategies for hiding or destroying knowledge.

#### A. *Suppressed Data*

There is a remarkable amount of undisclosed health data about the effects of pharmaceuticals.<sup>35</sup> Companies push to keep exclusive access to their own data, even when serious concerns arise about their products. As Ernest House observed, companies have repeatedly denied permission for the reporting of negative information.<sup>36</sup> A lead-

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31. See VIKTOR MAYER-SCHÖNBERGER, *DELETE: THE VIRTUE OF FORGETTING IN THE DIGITAL AGE* 14 (2009) (describing declining costs of data capture and storage, and the “the technical developments—digitization, cheap storage, easy retrieval, and global access—that have altered the economics of remembering and facilitated the demise of forgetting”).

32. See SHANNON BROWNLEE, *OVERTREATED: WHY TOO MUCH MEDICINE IS MAKING US SICKER AND POORER* 5 (2007) (stating that “a third of the medicine we receive is unnecessary”); MAGGIE MAHAR, *MONEY-DRIVEN MEDICINE* 78 (2006) (lamenting the “laissez-faire chaos of the marketplace” in health care).

33. See *infra* Parts II.A, II.D.

34. Robert N. Proctor, *Agnotology: A Missing Term to Describe the Cultural Production of Ignorance (and Its Study)*, in *AGNOTOLOGY: THE MAKING AND UNMAKING OF IGNORANCE* 3 (Robert N. Proctor & Londa N. Schiebinger eds., 2008).

35. See Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 *J. AM. MED. ASS'N* 308, 308–10 (2007) (reviewing undisclosed medical information related to Vioxx, Baycol, Redux, Paxil, Rezulin, Propulsid, Bextra, and Zyprexa).

36. See Ernest R. House, *Blowback: The Consequences of Evaluation for Evaluation*, 29 *AM. J. EVAL.* 416, 418 (2008) (“One review of 122 articles in the *Journal of the American Medical Association* found that 65% of harmful effects were not completely reported . . . . Authors

ing firm has been accused of suppressing negative data about Celebrex,<sup>37</sup> Zoloft, and Cymbalta.<sup>38</sup> The Food and Drug Administration (“FDA”) has long protected the secrecy of key data.<sup>39</sup> These are only a few examples of disturbing patterns in misleading data collection, presentation, and analysis by the industry.<sup>40</sup>

cherry-picked results. Researchers are subject to binding contracts that allow companies to determine what can be revealed from the study . . . .” (citation omitted)). The FDA has not adequately responded to these suspect practices. See, e.g., James M. Wood & Roxanne M. Gariby, *Hoarding Away Science: Towards a More Transparent View of Health and Online Registries for Independent Postmarket Drug Research*, 60 FOOD & DRUG L.J. 547, 547–50 (2005) (criticizing data secrecy at the FDA); Editorial, *Next Stop, Don’t Block the Doors: Opening Up Access to Clinical Trials Results*, 5 PLOS MED. 1007, 1007 (2008) (supporting FDA requirements to make results from clinical trials publically available on the Internet).

37. See Arthur Schafer, *Biomedical Conflicts of Interest: A Defence of the Sequestration Thesis: Learning from the Cases of Nancy Olivieri and David Healy*, 30 J. MED. ETHICS 8, 18–19 (2004), available at <http://jme.bmj.com/content/30/1/8.full> (describing how drug manufacturer Pharmacia withheld six months of data regarding Celebrex testing results).

38. See DAVID HEALY, *THE ANTI-DEPRESSANT ERA* 24 (1997) (concluding that “the discovery of antidepressants has been the invention of and marketing of depression”); Jeanne Lenzer, *What the FDA Isn’t Telling*, SLATE (Sept. 27, 2005, 6:38 AM), [http://www.slate.com/articles/health\\_and\\_science/medical\\_examiner/2005/09/drug\\_secrets.html](http://www.slate.com/articles/health_and_science/medical_examiner/2005/09/drug_secrets.html) (detailing how the FDA refused to provide information about duloxetine after a college student, who was acting as a test subject in a clinical trial of the drug, committed suicide).

39. See Howard Mann, *Hidden Data at the FDA*, BIOETHICS F. (June 15, 2006), available at [www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=184](http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=184) (criticizing FDA’s long-standing policy of declining to disclose results of drug trials). According to the Critical Path Institute, outdated methods of assessing drug safety may also be discouraging innovation. See *Predictive Safety Testing Consortium*, CRITICAL PATH INST., <http://www.c-path.org/pstc.cfm> (last visited Mar. 25, 2013) (“The tests used to determine drug safety have not changed in decades. Although companies have developed newer safety testing methods, these are not generally accepted by FDA or EMA as proof of safety. This is due, in part, because the methods used for testing are often different from company to company. That discrepancy leaves regulatory scientists uncertain about which methods should be preferred. Another key factor is that the tests have not, in the past, been independently validated. PSTC now . . . serves as a neutral third party to assess drug safety tests.”).

40. See BEN GOLDACRE, *BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS* 15 (2013) (“[U]nflattering trial data can simply be withheld from doctors and patients . . . .”); Donald W. Light, *Bearing the Risks of Prescription Drugs*, in *THE RISKS OF PRESCRIPTION DRUGS* 15–17 (Donald W. Light ed., 2010) (describing “five institutional practices” that lead to what Light refers to as the “risk proliferation syndrome”). Efthimios Parasidis has summarized Light’s findings. See Efthimios Parasidis, *Patients over Politics: Ad-*

The medical community is becoming increasingly skeptical about the amount and value of information provided by pharmaceutical firms. According to one commentator, “[s]elective publication and reporting in studies sponsored by the pharmaceutical industry exaggerate the efficacy of some medications while minimizing their side effects.”<sup>41</sup> Overseas trials can give firms maximum discretion to pick

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*dressing Legislative Failure in the Regulation of Medical Products*, 5 WIS. L. REV. 929, 975–76 (2011). The author lists industry tactics including:

1. Excluding patients with profiles that are judged to be more likely to suffer adverse health events;
2. Structuring clinical trials with short durations so latent effects are less likely to be uncovered;
3. Limiting the number of participants in clinical trials so as to reduce the likelihood of uncovering all adverse health effects;
4. Recording only selective side effects;
5. Excluding patients who removed themselves from clinical trials because they could not tolerate the side effects;
6. Selectively publishing study results to disproportionately favor positive research findings;
7. Removing patients who have strong placebo responses;
8. Testing some patients before the trial officially begins and selecting only those patients who have an initially positive response to the product under evaluation;
9. Secretly un-blinding interim results midway through a clinical trial and altering the trial design prior to re-blinding the study;
10. Conducting trials in countries where quality and ethical oversight is lacking;
11. Utilization of ingredients from sources where FDA oversight is minimal or precluded;
12. Ghost writing scientific articles;
13. Ghost managing academic research;
14. Off-label promotion absent evidence of safety and efficacy

*Id.* Goldacre has promoted the website AllTrials.net to require creation of new (and enforcement of extant) rules to assure that “[a]ll trials past and present . . . be registered, and the full methods and the results reported.” ALLTRIALS.NET, <http://www.alltrials.net/> (last visited Mar. 23, 2013).

41. Gilbert Melander et al., *Evidence B(i)ased Medicine*, 326 BRIT. MED. J. 1171, 1173 (2003); see also Marc A. Rodwin, *Independent Clinical Trials: The Neglected Reform*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 113, 114 (2012) (“[C]onflicts of interest persist because the firm that seeks to market a drug designs and controls the clinical trials used to test its safety and efficacy.”).

and choose which trial data to report.<sup>42</sup> This “non-system” not only endangers the clinical subjects exploited by unscrupulous contract researchers, but also leads to misuse of “rescue countries”—areas with researchers who are reputed to be most likely to come back with positive results.<sup>43</sup>

An integral part of the *value* of a drug is knowledge about how well (and for whom) it works.<sup>44</sup> An information environment selectively curated by those with the most to gain from sales of drugs does not assure the drugs’ proper use.<sup>45</sup> If researchers are connected to the company whose drug is evaluated, the findings are four times more likely to be favorable to the product than when researchers have no connections.<sup>46</sup>

Even as the United States suffers serious drug shortages and counterfeiting problems, problematic manufacturing processes are also emerging.<sup>47</sup> Many commentators have blamed the FDA for fail-

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42. See Donald L. Barlett & James B. Steele, *Deadly Medicine*, VANITY FAIR, Jan. 2011, available at <http://www.vanityfair.com/politics/features/2011/01/deadly-medicine-201101> (“[M]ost clinical trials are conducted overseas—on sick Russians, homeless Poles, and slum-dwelling Chinese—in places where regulation is virtually nonexistent, the F.D.A. doesn’t reach, and ‘mistakes’ can end up in pauper’s graves . . .”).

43. See *id.* (“There’s even a term for countries that have shown themselves to be especially amenable when drug companies need positive data fast: they’re called ‘rescue countries.’”).

44. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 347 (2007) (describing the importance of gathering data about drugs’ efficacy and side effects).

45. See House, *supra* note 36, at 418 (noting that, in a study of 370 randomized drug trials, “studies recommended the experimental drug as the ‘treatment of choice’ in 51% of trials sponsored by for-profit organizations compared to 16% sponsored by nonprofits”).

46. See Marcia Angell, *The Truth About the Drug Companies*, N.Y. REV. BOOKS, July 15, 2004, available at <http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/?pagination=false> (advocating reforms to end “the inappropriate control drug companies have over the evaluation of their own products”).

47. See Kevin Born, *Time and Money: An Analysis of the Legislative Efforts to Address the Prescription Drug Shortage Crisis in America*, 33 J. LEGAL MED. 235, 241 (2012) (“As drug manufacturing becomes more global with 40% of drugs being made outside of the United States and 80% of domestically manufactured drugs containing an active pharmaceutical ingredient (API) from a foreign supplier, the drug supply becomes more susceptible to any disruption in the supply chain or production process, even in remote parts of the world.”); *Securing the Pharmaceutical Supply Chain: Hearing Before the S. Comm. on Health, Education, Labor and Pensions*, 112th Cong. 5–11 (2011) (statement of Deborah M. Autor, Esq., Deputy

ing to adequately monitor plants, and congressional proposals would empower the agency to require drug manufacturers to report on predicted supply disruptions.<sup>48</sup> Congress, however, has added dozens of duties to the FDA's docket without commensurately increasing staffing or funding.<sup>49</sup> Moreover, many manufacturing processes are moving overseas.<sup>50</sup> The end result is complex supply chains that are hard to monitor even within firms, let alone outside them.<sup>51</sup> Data integrity problems are brewing for many companies.<sup>52</sup>

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Comm'r for Global Regulatory Operations and Policy, Food and Drug Administration), available at <http://www.help.senate.gov/hearings/hearing/?id=3fe78bef-5056-9502-5da8-cf290af9c334> (discussing access and audit capabilities of other nations).

48. Born, *supra* note 47, at 242–45.

49. See Parasidis, *supra* note 40, at 931–32 (“[G]ross underfunding restricts the ability of regulators to monitor and enforce post-market obligations. . . . [T]he FDA epitomizes ‘the hollow government syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.’” (citation omitted)); Eisenberg, *supra* note 44, at 348 (“Congress has repeatedly fine-tuned the FDA’s mandate . . .”).

50. See BARRY LYNN, *END OF THE LINE: THE RISE AND COMING FALL OF THE GLOBAL CORPORATION* 15–17 (2005) (describing the complexity and fragility of many supply chains); Elizabeth Dwoskin, *Your Food Has Been Touched by Multitudes*, BLOOMBERG BUSINESSWEEK (Aug. 25, 2011), <http://www.businessweek.com/magazine/your-food-has-been-touched-by-multitudes-08252011.html> (“Congress put off perhaps the most useful tool for quickly heading off outbreaks [of food poisoning]: A rule requiring food companies to keep records about where their ingredients come from was left out of the final bill.”).

51. See Jaime Moss, *Patients at Risk: The Need to Amend the Food, Drug, and Cosmetic Act to Ensure the Safety of Imported Prescription Drugs*, 33 T. JEFFERSON L. REV. 297, 307–09 (describing the need for regulators to know more “details regarding the country of origin of the raw materials or other aspects of” supply chains); Frank Pasquale, *Audit Trails: The Corporate Surveillance We Need*, BALKINIZATION (Aug. 28, 2011, 5:42 PM), <http://balkin.blogspot.com/2011/08/audit-trails-corporate-surveillance-we.html> (“Purposeful avoidance of tracking may well indicate a corporate plan to destroy evidence of wrongdoing.”).

52. See Moss, *supra* note 51, at 308–11 (describing several disturbing cases); MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 3–9 (2004) (describing how pharmaceutical companies manipulate science and politics to make more money); Jim Edwards, *FDA Has Only 2 Inspectors Watching Drug Factories in China*, CBS MONEY WATCH (Dec. 4, 2009, 3:14 PM), [http://www.cbsnews.com/8301-505123\\_162-42843667/fda-has-only-2-inspectors-watching-drug-factories-in-china/](http://www.cbsnews.com/8301-505123_162-42843667/fda-has-only-2-inspectors-watching-drug-factories-in-china/) (“[T]he fact that the FDA has just two people to cover [China,] a territory 3.7 million square miles in size[,] raises questions about how often those factories and labs will be in-

Even within reported clinical trials, irregularities or biased results can be engineered. For example, choosing a placebo as a comparator can make a drug look far more useful than it actually is.<sup>53</sup> Those organizing the trial may choose subjects designed to minimize side effects, or fail to report the full effects of the drug.<sup>54</sup> For instance, “Merck did not count subjects who dropped out of the treatment group because Vioxx was making them ill if these people didn’t have heart attacks or strokes within fourteen days of dropping out, even if they had coronary events soon after.”<sup>55</sup> Selective publication can also distort or hide a drug’s true effects.<sup>56</sup> Finally, there is evidence that postmarketing surveillance has been inadequate.<sup>57</sup> The Food and

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spected to make sure the drugs they are producing are safe for Western—or indeed any—patients.”).

53. See MAHAR, *supra* note 32, at 78 (“[D]rug-makers tend to avoid head-to-head clinical trials, preferring to test their newest nostrums against placebos rather than comparing them to existing, often less expensive treatments.”).

54. See Margaret Gilhooley, *Vioxx’s History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 964–65 (2007) (“Long-term clinical tests provide the best evidence about the safety risks of drugs . . . [but] ‘clinical trials are designed primarily with efficacy,’ not safety outcomes in mind.”); Barbara Martinez et al., *Expiration Date: Merck Pulls Vioxx from Market After Link to Heart Problems*, WALL ST. J., Oct. 1, 2004, at A1 (describing Merck & Co.’s failure to conduct trials to study potential heart-safety issues with the drug Vioxx, despite knowledge that an alarming number of patients taking the drug suffered heart attacks or strokes).

55. House, *supra* note 36, at 417; see also Cathy O’Neil, *How Big Pharma Cooks Data: The Case of Vioxx and Heart Disease*, NAKED CAPITALISM (Feb. 15, 2012), <http://www.nakedcapitalism.com/2012/02/25244.html> (concluding that “the clinical trials for drugs should not be run or reported on by the drug companies themselves [and t]here has to be a third party which is in charge of testing the drugs”).

56. See THOMAS O. MCGARITY & WENDY WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* 76 (2008) (describing “selective reporting of favored results”); Frank Pasquale, *Human Farming & the Limits of Medical Research*, HEALTH REFORM WATCH (Dec. 16, 2010), <http://www.healthreformwatch.com/2010/12/16/human-farming-the-limits-of-medical-research/16,2010> (describing a “litany of poorly controlled or ramshackle studies” and other reasons for doubting medical research).

57. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-090-866, *NEW DRUG APPROVAL: FDA NEEDS TO ENHANCE ITS OVERSIGHT OF DRUGS APPROVED ON THE BASIS OF SURROGATE ENDPOINTS* (2009) (“Concerns have been raised about FDA’s . . . oversight of postmarketing studies”); Jordan Paradise, *Reassessing Safety for Nanotechnology Combination Products: What Do Biosimilars Add to Regulatory Challenges for the FDA*, 56 ST. LOUIS U. L.J. 465, 483 (2012) (“[P]roblems with industry adherence to post-market requirements linger.”).

Drug Administration Amendments Act of 2007 was intended to advance transparency in drug research, but remains inadequately implemented.<sup>58</sup>

Many other western countries have tried to address these agency problems by establishing authoritative centers to gather information, such as the National Institute for Clinical Excellence in Britain.<sup>59</sup> Recent developments in the United States follow these steps in small ways,<sup>60</sup> but congressional interventions have also deterred many efforts to impose similar discipline.<sup>61</sup>

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58. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.); FDA, GUIDANCE FOR INDUSTRY: POSTMARKETING STUDIES AND CLINICAL TRIALS—IMPLEMENTATION OF SECTION 505(O) (3) OF THE FEDERAL FOOD, DRUG, AND COSMETICS ACT (2011), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf>. The Act includes provisions FDCA § 505(k)/21 U.S.C. § 355(k) (regarding records of clinical experience); FDCA § 505(o)/21 U.S.C. § 355(o) (regarding postmarket studies and clinical trials); FDCA § 505-1/21 U.S.C. § 355-1 (regarding risk evaluation and mitigation strategies); FDCA § 505(5)/21 USC § 355(r) (regarding postmarket drug safety information for patients and providers, including a website for drug safety information). Nevertheless, critics contend that much more needs to be done to assure public and medical community understanding of the implications (and limits) of disclosed information. Deborah A. Zarin & Tony Tse, *Moving Toward Transparency of Clinical Trials*, 319 SCI. 1340, 1342 (2008).

59. See Nicholas Timmins, *Letter from Britain: Across the Pond, Giant New Waves of Health Reform*, 29 HEALTH AFF. 2138, 2140–41 (2010) (describing the National Institute for Health and Clinical Excellence (NICE), which is at the cutting edge of an evidence-based movement aimed at reducing health care costs and getting value for money). But see MICHAEL SCHLANDER, GALEN INSTITUTE, COMPARATIVE EFFECTIVENESS PROGRAMS: A GLOBAL PERSPECTIVE: DISCUSSING GERMANY AND THE UK 11-16 (2009) (offering more critical perspectives).

60. The Agency for Healthcare Research and Quality (“AHRQ”) has long studied effectiveness. See *AHRQ’s Career Development and Postdoctoral Training Awards for Comparative Effectiveness Research*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, <http://www.ahrq.gov/fund/training/cdpostcer10.htm> (last visited Oct. 23, 2012). It received some funding for comparative research via the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, 2438–41 (2003) (codified at 42 U.S.C. § 299b-7(e) (2006)). The Patient Protection and Affordable Care Act (“PPACA”) authorized the establishment of the Patient-Centered Outcomes Research Institute (“PCORI”), which will complete important research on effectiveness. See Patient Protection and Affordable Care Act § 6301(a), Pub. L. No. 111-148, 124 Stat. 119, 727 (2010); see also Chris Fleming, *New Health Affairs Issue: Comparative Effectiveness Research*, HEALTH AFFAIRS BLOG

Problems like the ones mentioned above have provoked the Cochrane Collaboration, a widely respected advocacy group, to demand free access to all data from clinical trials.<sup>62</sup> Their work, as well as that of Victoria Stodden and the open science movement generally, is a worthy extension of an access-to-knowledge movement that is well-known for its opposition to patent and copyright maximalism.<sup>63</sup> The question now is whether government will use the power of the purse to force more openness. Failing that, it can at least use the advanced data analysis suggested in Part III to create an information environment less polluted by bias than the present one.

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(Oct. 5, 2010, 7:36 AM), <http://healthaffairs.org/blog/2010/10/05/new-health-affairs-issue-comparative-effectiveness-research> (“A national push on comparative effectiveness research is underway as a result of federal stimulus and health reform legislation.”). *But see* Peter J. Neumann and Milton C. Weinstein, *Legislating Against Use of Cost Effectiveness Information*, 363 NEW ENG. J. MED. 1495 (2010) (discussing ACA restrictions on the PCORI’s use of QALYs).

61. *See* Steven D. Pearson & Peter B. Bach, *How Medicare Could Use Comparative Effectiveness Research in Deciding on New Coverage and Reimbursement*, 29 HEALTH AFF. 1796, 1796–97, 1802–03 (2010) (endorsing modest steps toward value-based purchasing, and describing legal barriers to it).

62. *See The Cochrane Collaboration Supports Free Access to All Data from All Clinical Trials, Cochrane Policies*, COCHRANE COLLABORATION (Oct. 5, 2011), <http://www.cochrane.org/about-us/our-policies/support-free-access-to-all-data-from-all-clinical-trials> (“Selective reporting of trial results occurs frequently, leading to exaggerated findings of the beneficial effects of healthcare interventions and underestimates of their harms. As a consequence, many patients are unknowingly treated with interventions that have little or no effect, and may be harmed unnecessarily. This is unethical and has been said to violate the implicit contract between healthcare researchers and patients, where the aim of research is to improve treatment of future patients.”); Gary Price, *Cochrane Collaboration Urges Free Access to All Data from All Clinical Trials: End to Selective Reporting Can Reduce the Risk of Harm to Patients*, LIBR. J. INFODOCKET (Oct. 5, 2011), <http://infodocket.com/2011/10/05/cochrane-collaboration-urges-free-access-to-all-data-from-all-clinical-trials-end-to-selective-reporting-can-reduce-the-risk-of-harm-to-patients/> (explaining how and why Cochrane Collaboration has petitioned for mandatory free access to all data from all clinic trials).

63. *See* Stodden, *supra* note 17, at 2 (“[P]revailing scientific norms . . . provide both that results be replicated before accepted as knowledge, and that scientific understanding be built upon previous discoveries for which authorship recognition is given.”).

*B. Misleading Quality Indicators*

Internet-savvy patients aim to find high quality doctors in a world of uneven care.<sup>64</sup> Insurers also aim to direct resources to reliable providers.<sup>65</sup> As Ellen Nakashima has reported, “data-driven surveillance offers the prospect of using incentives to steer patients to care that is both effective and sensibly priced.”<sup>66</sup> The data can have important results. According to one survey, “users who picked a top-performing hospital or surgeon from the latest available report had approximately half the chance of dying as did those who picked a hospital or surgeon from the bottom quartile.”<sup>67</sup>

But the quality of Internet reviews of doctors has been questioned.<sup>68</sup> Moreover, more formal rating systems can have perverse consequences, encouraging doctors to shun the sickest patients. For example, a cardiac surgeon may turn away very ill patients in order to keep the mortality rate associated with his practice low.<sup>69</sup> At least one journalist has contended that gaming of ratings was common in New York after the state “ma[d]e public the mortality rates of its heart surgeons.”<sup>70</sup> In the few years after this public reporting standard was adopted, the Cleveland Clinic “received 31 percent more referrals from New York hospitals than they had previously received,” and these referrals were “sicker than those who were referred from other

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64. See *infra* note 66.

65. See *infra* note 66.

66. Ellen Nakashima, *Doctors Rated but Can't Get a Second Opinion*, WASH. POST, July 25, 2007, at A1.

67. Ashish K. Jha & Arnold M. Epstein, *The Predictive Accuracy of the New York State Coronary Artery Bypass Surgery Report-Card System*, 25 HEALTH AFF. 844, 844 (2006).

68. See Ron Lieber, *The Web Is Awash in Reviews, but Not for Doctors. Here's Why*, N.Y. TIMES, Mar. 10, 2012, at B1 (discussing patients' “unquestioning mind-set that may cause such low participation (or disproportionately positive reviews) at many review sites”).

69. See, e.g., Robert Kolker, *Heartless*, N.Y. MAG., Oct. 16, 2005, available at <http://nymag.com/nymetro/health/features/14788/> (“An anonymous 1999 survey of bypass surgeons revealed that 62 percent of cardiac surgeons refused to treat at least one patient in the preceding year who was perceived to be high risk.”). For related problems, see Rachel M. Werner & David A. Asch, *The Unintended Consequences of Publicly Reporting Quality Information*, 293 J. AM. MED. ASS'N 1239, 1239 (2005).

70. *Id.*; see also Frank Pasquale, “Best Doctors.” *Shaming Shirkers or Shunning the Sickest?*, CONCURRING OPINIONS (July 28, 2007), [http://www.concurringopinions.com/archives/2007/07/doctor\\_ratings.html](http://www.concurringopinions.com/archives/2007/07/doctor_ratings.html) (providing specific examples of “gaming” that took place in New York).

states.”<sup>71</sup> The statistics suggested a consistent effort to game the system by focusing care on the patients most likely to enjoy positive outcomes.<sup>72</sup>

Risk adjustments can solve simple gaming; for example, mortality figures can be adjusted to reflect the sickness of patients or the complexity of a procedure.<sup>73</sup> But risk adjustments themselves can be gamed.<sup>74</sup> Doctors might even add unnecessary procedures during a routine surgery to avoid reputational damage once the patient takes an unexpected turn for the worse.<sup>75</sup>

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71. Pasquale, *supra* note 70 (“In the first few years after the report-card program began, the Cleveland Clinic received 31 percent more referrals from New York hospitals than they had previously received—and the study verified that the New York patients were sicker than those who were referred from other states . . . . David Dranove of Northwestern released a study in 2003 suggesting that the patients being selected for surgery in New York were simply healthier than elsewhere.”).

72. *Id.*

73. See Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215, 229 (2009) (“[I]n an ideal world, report card measures would focus on clinical outcomes. Patients care about outcome measures such as lower mortality rates, not whether physicians are board-certified or the frequency of beta blocker prescriptions in hospital settings. These alternative measures are imperfect at best, and are used mainly because it can be costly and difficult to measure outcomes and to risk-adjust them properly, so that they reflect the providers’ quality, rather than underlying patient characteristics. In practice, very few report cards measure outcomes, and the outcomes they capture tend to be a limited subset of what patients may care about.”).

74. For more on the problem of manipulation of ratings in health care, see Nic Terry, *Fear of Facebook: Private Ordering of Social Media Risks Incurred by Health Care Providers*, 90 NEB. L. REV. 703, 746-47 (2012) (discussing “sockpuppetry” and “astroturfing.”).

75. See Kolker, *supra* note 69. The author states:

David Brown of SUNY–Stony Brook remembers a patient from 1999, a man in his early fifties who was athletic, a bicyclist, whom he referred to surgery for a bypass. On paper, the man was a low-risk patient—young, healthy, with just one vessel that needed repair. For some reason, however, the man went into cardiac arrest while being put under anesthesia. If he had died, the Department of Health would have scored the death with a very high mortality and no risk adjustment. But the man survived, and a week later Brown glanced at the report and noticed that the surgeon had performed an additional procedure while the patient was on the table. ‘He did a mitral annuloplasty, which is putting a little ring around the mitral valve,’ Brown says. Because of this surgery, this patient no longer could be considered for the state data; he was knocked out of the sample. If the patient died, it wouldn’t affect that surgeon’s mortality rate. “I called him,

Not only state and federal authorities, but also private insurers are trying to rate doctors' quality.<sup>76</sup> Insurers and other raters try to make reams of tables and graphs accessible to consumers by boiling them down into grades and scores.<sup>77</sup> Highly rated physicians appreciate the publicity and endorsement but others "say that the data often contain errors and that doctors often lack the ability to correct them."<sup>78</sup> Conflicts proliferate, including "a lawsuit in Seattle" and a "physician revolt in St. Louis"<sup>79</sup> These acts of resistance reflect both guild protectionism and legitimate concerns about misleading characterization or unfair stigmatization of high-quality physicians.

Fearing an unfair tiering of its members, the Washington State Medical Association filed suit against Regence BlueShield, an insurance company that evaluated doctors using allegedly inaccurate and outdated information.<sup>80</sup> The doctors claimed that Regence used four-

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and he sort of hemmed and hawed about it," Brown remembers. "I was going to report it, because I thought it was assault. Certainly it was done strictly to manipulate the data."

*Id.*

76. See Kristin Madison, *Defragmenting Health Care Delivery Through Quality Reporting*, in *THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS* 87, 97 (Einer Elhauge ed., 2010) (discussing various entities that are developing ways to measure performance quality within the health care industry). I have also called for more data development as a goal of health care policy in an essay on specialty hospitals. See Frank Pasquale, *Ending the Specialty Hospital Wars: A Plea for Pilot Programs as Information—Forcing Regulatory Design*, in *THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS* 140, 165, 235, 250–51 (Einer Elhauge, ed., 2010) (describing research commissioned by the U.S. government in efforts to rate level of care provided by specialty hospitals).

77. See Ann Marie Marciarille, "How's My Doctoring?" *Patient Feedback's Role in Assessing Physician Quality*, 14 *DEPAUL J. HEALTH CARE L.* 361, 362 (2012) ("User-generated feedback on physicians has found multiple fora on the Internet, including: Angie's List, Yelp, and specialty sites like RateMDs.com.").

78. Nakashima, *supra* note 66.

79. *Id.*

80. See Amy Lynn Sorrel, *Washington Doctors Sue Blues Plan over Performance Standards*, *AM. MED. NEWS*, Oct. 16, 2006, available at <http://www.ama-assn.org/amednews/2006/10/16/prsd1016.htm> ("The Washington State Medical Assn. is suing Regence BlueShield, claiming the health plan defamed physicians when it told thousands of patients that their doctors didn't meet the 'quality and efficiency' standards needed to be included in the insurer's new performance-based network."); Judith VandeWater, *Doctors Level Charges at Health Insurer*, *ST. LOUIS POST-DISPATCH*, May 26, 2005, at A1; see also *Lawsuit: Insurance Commission Physician Tiering Program Flawed*, *SURGISTRATEGIES* (June 25, 2008),

year-old data, small sample sizes, and focused on the cost of claims rather than the quality of care.<sup>81</sup> The complaint alleged defamation and violation of the Consumer Protection Act, among other causes of action.<sup>82</sup> After ten months of litigation, Regence agreed to settle with the Washington State Medical Association “in an effort to better understand physician concerns,”<sup>83</sup> voluntarily withdrawing the Select Network program. The settlement agreement, effective for at least two years, promises transparency in evaluations and fair methodology.<sup>84</sup>

To the extent that insurance companies are rating and ranking doctors to guide members to the most effective care, they should be free to use properly anonymized claims data and freely publish their results. If such rating systems are primarily driven by commercial concerns of the insurers to steer patients away from the high cost of doctors, however, that effort needs to be disclosed and perhaps deterred. Quality regulators have already adopted some of these principles, but they need to be more clearly articulated as rating sites proliferate.

In New York, then-Attorney General (and now Governor) Andrew Cuomo launched an investigation of insurers’ physician ratings

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<http://www.surgicenteronline.com/hotnews/insurance-commission-physician-tiering.html> (describing the lawsuit).

81. See Judith VandeWater, *BJC Warns It May Drop United Healthcare*, ST. LOUIS POST-DISPATCH, Mar. 18, 2005, at A1 [hereinafter VandeWater, *BJC Warns*] (describing physician concerns); *Doctors Outraged at Ratings*, OREGONIAN, May 26, 2006, at D4.

82. VandeWater, *BJC Warns*, *supra* note 81.

83. Judith VandeWater, *BJC, Health Insurer Resolve Dispute*, ST. LOUIS POST-DISPATCH, June 24, 2005, at A1.

84. *Id.* Had the suit gone to trial, First Amendment defenses may have been raised. See Frank Pasquale, *Beyond Innovation and Competition: The Need for Qualified Transparency in Internet Intermediaries*, 104 NW. U. L. REV. 105, 117–19 (2010) (discussing the successful First Amendment defense of the Avvo lawyer ratings site). There were several possible causes of action. See CHRISTINE C. RINN, AM. HEALTH LAWYERS ASS’N, TIERED PHYSICIAN NETWORKS: A NEW TWIST ON AN OLD ISSUE 4–7 (2008), available at [http://www.crowell.com/documents/Tiered\\_Physician\\_Networks\\_AHLA\\_Rinnpdf.pdf](http://www.crowell.com/documents/Tiered_Physician_Networks_AHLA_Rinnpdf.pdf) (discussing potential causes of action in ranking and rating cases, including: “breach of contract;” “defamation;” “consumer protection violations;” “unfair insurance practices;” “tortious interference with contractual relations;” “fraud;” and “conspiracy”); Lawrence P. Casalino et al., *Will Pay-for-Performance and Quality Reporting Affect Health Care Disparities?*, 28 HEALTH AFF. (WEB EXCL.) w405, w405–12 (2007) (suggesting design elements likely to help create fair evaluation methods).

that culminated in settlement agreements in 2007. Cuomo claimed that the evaluation programs were confusing and unfair to both physicians and consumers.<sup>85</sup> After negotiating with his office, insurance companies eventually agreed to follow the ranking guidelines in a national model provided by the Office of the Attorney General (in cooperation and consultation with the American Medical Association and other provider trade organizations).<sup>86</sup> The model agreements required “insurers to fully disclose to consumers and physicians all aspects of their ranking system.”<sup>87</sup> Since there is mandatory disclosure of all data and methodologies, the problem of the “black box” evaluation system is greatly reduced under the model agreements. Larger insurers capitulated to state demands, starting a trend toward transparent, quality-based rankings with public methodologies.<sup>88</sup> A Patient Charter for Physician Performance Measurement has also emerged as a project of the Consumer-Purchaser Disclosure Project.<sup>89</sup> The specific terms of the charter call for evaluations that are “meaningful to consumers” and bar decontextualized ratings based solely on cost.

These developments are encouraging, but even the regulated rating systems are far from reaching their potential. Patients may seek more granular data. For example, a group that does very well with one subset of patients (say, diabetics) may not be as adept at treating others. Moreover, as Kristin Madison has argued, “particularly for process-oriented and outcome-oriented measures, limitations on available data and statistical techniques complicate efforts to develop statistically reliable quality measures that differentiate providers suffi-

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85. See Agreement Between Andrew M. Cuomo, Attorney Gen. of the State of N.Y., and CIGNA Healthcare of N.Y., Inc., Concerning Physician Performance Measurement, Reporting and Tiering Programs 3 (Oct. 29, 2007), available at <http://www.ag.ny.gov/sites/default/files/press-releases/archived/CIGNA%20Settlement%20Final.pdf> (“The Attorney General finds that any initiatives to measure quality and cost-efficiency of physicians . . . have the potential to cause confusion . . . and could result in a violation of law.”).

86. Press Release, N.Y. Att’y Gen. Office, Attorney General Cuomo Announces Doctor Ranking Agreement with GHI and HIP (Nov. 20, 2007), available at <http://www.ag.ny.gov/press-release/attorney-general-cuomo-announces-doctor-ranking-agreement-ghi-and-hip>.

87. *Id.*

88. See E-mail from Linda Lacewell, Chair of the N.Y. Att’y Gen. Health Care Task Force, to Frank Pasquale (Oct. 27, 2008) (on file with author) (“CIGNA and other plans have agreed to disclose their methodologies to the public.”).

89. See *id.*

ciently to make quality ratings meaningful.”<sup>90</sup> The developing national health information infrastructure, as well as state level health information exchanges and system-level network building, need to address this data drought.

### C. *Perplexing Prices*

Given the potential complexity of medical interventions, it is perhaps understandable that quality information is difficult to gather, analyze, and disseminate.<sup>91</sup> Even pricing information has proven elusive for patients, and sometimes even for doctors, hospitals, and insurers. Each of these health care players can obscure the costs of their services to maximize opportunities for price discrimination or even price gouging.<sup>92</sup>

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90. Madison, *supra* note 73, at 228. A quick consultation of sites like Hospital Compare and Nursing Home Compare helps validate Madison’s contention here. Very disparate entities can appear almost indistinguishable given the crudeness of the categories used to assess quality. Conversely, something like Google’s Zagat ratings, now applied to some hospitals, wraps a non-transparent process of evaluation in a patina of objectivity, and in my experience has applied mysterious and unjustified scores to health care entities.

91. In the context of a discussion of rationing and insurance companies efforts to devise approved lists of interventions, one health law textbook suggests that a mapping of possible condition-treatment combinations “would require rigorous scientific information on each of the almost 10,000 diagnostic entries in the *International Classification of Diseases* (9th ed. 1979) (known as “ICD-9”) and for each of the 10,000 medical interventions listed in the AMA’s *Common Procedural Terminology* (known as “CPT” codes).” MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, *HEALTH CARE LAW AND ETHICS* 345 (7th ed. 2007). The ICD-10, which should be adopted in the U.S. in 2014, having long been the standard in other industrialized nations, has about seven times more codes than ICD-9. Press Release, Health & Human Servs., HHS Issues Final ICD-10 Code Sets and Updated Electronic Transaction Standards Rules (Jan. 15, 2009), *available at* <http://www.hhs.gov/news/press/2009pres/01/20090115f.html>; *see also* Dan Bowman, *New ICD-10 Deadline Proposed for 2014*, FIERCEHEALTHIT (Apr. 9, 2012), <http://www.fiercehealthit.com/story/new-icd-10-deadline-proposed-2014/2012-04-09>.

92. Mark A. Hall and Carl E. Schneider, *Price-Gouging by Doctors and Hospitals*, HEALTH REFORM WATCH (July 19, 2009), *available at* <http://www.healthreformwatch.com/2009/07/19/price-gouging-by-doctors-and-hospitals/> (“Providers routinely double, triple, or even quadruple prices for unprotected patients.” (emphasis omitted)); Gerard F. Anderson, *From ‘Soak the Rich’ to ‘Soak the Poor’: Recent Trends in Hospital Pricing*, 26 HEALTH AFF. 780, 780 (2007) (explaining that rates charged to many “uninsured and other ‘self-pay’ patients” for hospital services were often “2.5 times what most public and private health insurers actually pay”).

There is a remarkable lack of uniformity in health care prices in many U.S. markets. For example, the *Boston Globe* reported that coronary bypass procedures generated median insurance company payments over \$17,000 more at Massachusetts General Hospital than at the Boston Medical Center.<sup>93</sup> Imaging services, such as MRIs, CT-scans, and ultrasounds, featured similar spreads between the highest- and lowest-cost providers.<sup>94</sup> Though Massachusetts General Hospital is reputed to be one of the best hospitals in the world, experts claimed that the differences in price did not reflect commensurate differences in quality. Rather, the market power of Massachusetts General Hospital as a “must-have” hospital for private insurers let it charge much more for its services.<sup>95</sup>

In ordinary markets, publicity would tend to narrow the price differential between similar quality services. In health care, however, there is a triple layer of agency between care and patients whose physicians’ recommendations are often constrained by an insurer that is chosen by the patient’s employer or government.<sup>96</sup> Even if we assume away the agency problems in such an arrangement, it is difficult for buyers and sellers to truly understand “market” dynamics. As health economist Uwe Reinhardt has observed, “[o]nly a handful of Americans truly comprehend the complex payment system for U.S. hospitals—mostly those whose job it is to set, negotiate, and study hospital prices.”<sup>97</sup>

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93. *Comparable Quality, Different Prices*, BOS. GLOBE (Nov. 16, 2008), <http://www.boston.com/news/health/articles/2008/11/16/differentprices/>.

94. *See id.*

95. For example, an MRI of the ankle that costs around \$1,100 at Boston Children’s Hospital would only be around \$500 at Boston Medical Center. Scott Allen & Marcella Bombardieri, *A Healthcare System Badly Out of Balance*, BOS. GLOBE, Nov. 16, 2008, at A1. The health policy literature has documented wide price variations throughout the United States. Todd P. Gilmer & Richard G. Kronick, *Differences in the Volume of Services and in Prices Drive Big Variations in Medicaid Spending Among U.S. States and Regions*, 30 HEALTH AFF. 1316, 1317 (2011) (“We find substantial variations both in the volume of services and in prices.”).

96. Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 819–20 (2011); *see also* Peter J. Hammer & William M. Sage, *Monopsony as an Agency and Regulatory Problem for Health Care*, 71 ANTITRUST L.J. 949, 949 (2004) (describing a “three-level model of industrial production—comprised of provider-suppliers, insurer-producers, and patient-consumers”).

97. Uwe E. Reinhardt, *The Pricing of U.S. Hospital Services: Chaos Behind a Veil of Secrecy*, 25 HEALTH AFF. 57, 57–58 (2006).

In theory, an “info-mediary” could work for consumers and try to interpret the data to offer simpler accounts of what care actually costs. The rise of a movement advocating “consumer-directed health reform” during the Bush administration led to some small steps toward pricing transparency. Yet trade secrecy law still enables obfuscation of critical data.<sup>98</sup> Even aspects of Medicare spending have remained opaque.<sup>99</sup>

Perhaps a coalition of insurers could band together to gain enough bargaining power to demand transparency, carefully avoiding the antitrust questions that could arise if such coordination became too aggressive. Other intermediaries might also arise. But the record of at least one such intermediary, Group Purchasing Organizations (“GPOs”), is not promising. GPOs are supposed to use purchasing

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98. *Id.* at 62 (“[A]ctual dollar payments [paid by insurers to hospitals] have traditionally been kept as strict, proprietary trade secrets by both the hospitals and the insurers. Recently Aetna announced that it will make public the actual payment rates it has negotiated with physicians in the Cincinnati area. That this small, tentative step toward transparency made national news speaks volumes about the state of price-transparency in U.S. health care.”); see also Annemarie Bridy, *Trade Secret Prices and High-Tech Devices: How Medical Device Manufacturers Are Seeking to Sustain Profits by Propertizing Prices*, 17 TEX. INTELL. PROP. L.J. 187, 188 (2009) (discussing claims by the medical device manufacturer Guidant/Boston Scientific that the actual prices its hospital customers pay for implantable devices, including cardiac pacemakers and defibrillators, are protectable as trade secrets under the Uniform Trade Secrets Act).

99. See *Consumer’s Checkbook Loses Appeal in Medicare Data Case*, FINDLAW (Feb. 2, 2009), <http://commonlaw.findlaw.com/2009/02/consumers-checkbook-loses-appeal-in-medicare-data-case.html> (reporting that a consumer group’s attempt to access Medicare payment records as a means of evaluating doctor performance failed in court). It must be acknowledged, however, that Medicare releases a great deal of information at low costs that might be ten to twenty times more expensive in the hands of a company like IMS Health. See Mark Schoofs & Maurice Tamman, *In Medicare’s Data Trove, Clues to Curing Cost Crisis*, WALL ST. J., Oct. 26, 2010, at A1 (“Federal investigators use the database to find fraud; academic researchers mine it to compare the cost and utilization of various services; and consultants make a business out of analyzing the data for a wide variety of health-care companies.”); Ricardo Alonso-Zaldivar, *Feds to Allow Use of Medicare Data to Rate Doctors*, MINN. NPR (Dec. 5, 2011), <http://minnesota.publicradio.org/display/web/2011/12/05/feds-allow-medicare-data-to-rate-doctors/> (“Medicare’s database is considered the mother lode of health care information. Tapping it has largely been forbidden because of a decades-old court ruling that releasing the information would violate the privacy of doctors. . . . [PPACA] changed federal law to explicitly authorize release of the information.”).

clout on behalf of buyers (like hospitals) to drive down prices from sellers.<sup>100</sup> It appears, however, that these intermediaries are often more interested in fees and payments from the sell-side than they are in helping the buy-side. As one analyst testified before the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”), “the compensation of most GPO management is almost always based on . . . fee income [from suppliers] rather than on the real savings to hospital members.”<sup>101</sup> Such intermediaries are often tempted to put their own profits ahead of the entities they are ostensibly serving. In the endless battle for compensation between providers, hospitals, and insurers, there are many profitable opportunities to shift alliances.

Complex contracts may also limit the transparency of pricing. As Uwe Reinhardt has documented:

Relative to hospitals paid under the much simpler national health insurance schemes in other countries, the contracting and billing departments of U.S. hospitals . . . are huge enterprises, often requiring large cadres of highly skilled

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100. Robert E. Litan, Hal Singer & Anna Birkenbach, *An Empirical Analysis of Aftermarket Transactions by Hospitals*, 28 J. CONTEMP. HEALTH L. & POL’Y 23, 36 (2011) (“GPOs play an important role in brokering transactions between hospitals and medical device suppliers. Our empirical findings suggest that hospitals can achieve significant savings relative to the GPO-negotiated price through participation in medical-device aftermarkets.”). *But see* S. PRAKASH SETHI, GROUP PURCHASING ORGANIZATIONS: AN UNDISCLOSED SCANDAL IN AMERICAN HEALTH CARE xiv (2009) (calling for “greater transparency and accountability” in the industry); S. COMM. ON FINANCE, 111TH CONG., EMPIRICAL DATA LACKING TO SUPPORT CLAIMS OF SAVINGS WITH GROUP PURCHASING ORGANIZATIONS 6 (2010), *available at* <http://grassley.senate.gov/about/upload/2010-09-24-GPO-Report.pdf>.

101. Elizabeth Weatherman, Testimony at FTC/DOJ Hearing (Sept. 26, 2003), *in* DEP’T OF JUSTICE & FED. TRADE COMM’N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION 38 (2004), *available at* <http://www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf>. As Mariah Blake explains: “[I]n 1986 Congress passed a bill exempting GPOs from the anti-kickback provisions embedded in Medicare law. This meant that instead of collecting membership dues, GPOs could collect ‘fees’—in other industries they might be called kickbacks or bribes—from suppliers in the form of a share of sales revenue.” Mariah Blake, *Dirty Medicine*, WASH. MONTHLY, July–Aug. 2010, *available at* <http://www.washingtonmonthly.com/features/2010/1007.blake.html>; *see also* EINER ELHAUGE, ANTITRUST ANALYSIS OF GPO EXCLUSIONARY AGREEMENTS (Sept. 26, 2003), [http://www.law.harvard.edu/faculty/elhaug/pdf/statement\\_ftcdoj.pdf](http://www.law.harvard.edu/faculty/elhaug/pdf/statement_ftcdoj.pdf) (“Serious anti-trust concerns remain about exclusionary agreements that charge higher prices to GPOs or hospitals that won’t commit to limiting purchases from rivals of dominant manufacturers to a small (often 5–10%) percentage of their purchases.”).

workers backed up by sophisticated computer systems that can simulate the revenue implications of the individual contract negotiations.<sup>102</sup>

Given that U.S. doctors' administrative costs are four times more than Canadian doctors' costs, consumers might expect a clearer picture of the financial landscape.<sup>103</sup> Instead, complexity mainly serves to protect the business models of established players. If consumer-driven health care advocates ask hospitals to reveal more, a plaintive chorus will respond that true prices are irredeemably opaque. For what is market freedom if it does not include the right to contract into a dynamically multivariate payment scheme where the cost of a service constantly changes because it depends on dozens of factors?

Doctors and insurers are not the only ones obscuring health care costs. As Steve Pearlstein has observed, "[t]he prescription drug market . . . is renowned for its lack of transparency."<sup>104</sup> Drug companies not only refuse to reveal their wholesale prices, but in contracting with pharmacy chains and Pharmacy Benefits Management ("PBMs") they insist on contracts that prohibit either party from revealing prices to anyone else.<sup>105</sup> As Annemarie Bridy has shown, a medical device manufacturer may claim that "the actual prices its hospital customers pay for implantable devices, including cardiac pacemakers and defib-

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102. Reinhardt, *supra* note 97, at 59.

103. Dante Morra et al., *U.S. Physician Practices Versus Canadians: Spending Nearly Four Times As Much Money Interacting With Payers*, 30 HEALTH AFF. 1443, 1443 (2011) ("Total health spending per capita in the United States, adjusted for differences in purchasing power, is 87 percent more than in Canada (\$7,290 compared to \$3,895 per year). Many factors contribute to the high cost of health care in the United States, but there is broad consensus that administrative costs in the health care system are high and could be reduced. Interactions between physician practices and health insurance plans are one prominent component of administrative costs."). For concrete examples of the inefficiencies involved, see Steven Ringel, *Practicing Medicine Versus Pushing Paper*, 30 HEALTH AFF. 1200, 1200 (2011) ("I've completed the same form several years in a row. Every year the answers are the same—the message does not change: Kyle is profoundly weak, is restricted to a wheelchair, and needs assistance with all activities of daily living . . . . Yet if I don't fill out this year's form, the services Kyle relies on will be denied.").

104. Steven Pearlstein, *Sunday Pearlstein: End of the 'Anything Goes' Era of Antitrust?*, WASH. POST: EZRA KLEIN'S WONKBLOG (Dec. 11, 2011, 8:11 AM), [http://www.washingtonpost.com/blogs/ezra-klein/post/sunday-pearlstein-end-of-the-anything-goes-era-of-antitrust/2011/12/11/gIQAEUcJmO\\_blog.html](http://www.washingtonpost.com/blogs/ezra-klein/post/sunday-pearlstein-end-of-the-anything-goes-era-of-antitrust/2011/12/11/gIQAEUcJmO_blog.html).

105. *Id.*

rillators, are protectable as trade secrets under the Uniform Trade Secrets Act.”<sup>106</sup>

Rebecca Busch has documented how complex relationships between providers, employers, insurers, vendors, and patients create ample opportunities for fraud.<sup>107</sup> They have also created unfortunate opportunities for powerful or crafty players in the industry to block accountability. Can a market work when buyers are kept in the dark about the prices they will pay? The question is increasingly urgent for those who believe market forces can improve outcomes and reduce health care spending. In theory, consumers could force doctors and hospitals to compete by shopping around for services. But informed consumption is more easily described than implemented.

#### *D. Missing Electronic Health Records*

Combine the opacity described above with the bargaining power enjoyed by many American health care’s key players, and inexplicably varied (and sometimes astronomical) costs are a foregone conclusion.<sup>108</sup> An MRI that costs, on average, \$1,080 in America costs \$280 in France.<sup>109</sup> That average figure also hides wide variations within the United States. A 2004 study showed massive dispersion in California hospital prices: A blood test that costs less than \$200 in San Francisco

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106. Bridy, *supra* note 98, at 206 & n.109.

107. REBECCA S. BUSCH, HEALTHCARE FRAUD: AUDITING AND DETECTION GUIDE 52 (2012) (discussing “15 layers of fragmentation” in health care); Robert Radick, *Claims Data and Health Care Fraud: The Controversy Continues*, FORBES, Sept. 25, 2012, available at <http://www.forbes.com/sites/insider/2012/09/25/claims-data-and-health-care-fraud-the-controversy-continues>; *New Technology To Help Fight Medicare Fraud*, FIERCE HEALTHIT (June 22, 2011), available at <http://www.fiercehealthit.com/press-releases/new-technology-help-fight-medicare-fraud>.

108. Joseph White, *Markets and Medical Care: The United States, 1993–2005*, 85(3) MILBANK Q. 395, 413 (2007) (describing bargaining power imbalances and their effect on prices in U.S. health care).

109. Ezra Klein, *Why an MRI costs \$1,080 in America and \$280 in France*, WASH. POST: EZRA KLEIN’S WONKBLOG (Mar. 3, 2012, 12:08 PM), [http://www.washingtonpost.com/blogs/ezra-klein/post/why-an-mri-costs-1080-in-america-and-280-in-france/2011/08/25/gIQAVHzt0R\\_blog.html?fb\\_ref=NetworkNews](http://www.washingtonpost.com/blogs/ezra-klein/post/why-an-mri-costs-1080-in-america-and-280-in-france/2011/08/25/gIQAVHzt0R_blog.html?fb_ref=NetworkNews) (“Medicare and Medicaid negotiate prices on behalf of their tens of millions of members and, not coincidentally, purchase care at a substantial markdown from the commercial average. But outside that, it’s a free-for-all.”).

might be \$1,500 at Doctors Medical Center in Modesto.<sup>110</sup> One need not be a devotee of all-payer rate settings to conclude that these differences may result more from bargaining power than from actual differences in quality.

Better technology could help regulators and consumers understand the true value proposition of insurers, doctors, and providers. It could also cut costs from duplicative tests and uncoordinated care. But electronic health record adoption has lagged in the United States. As Nicolas Terry has observed, “by 2009 only seventeen percent of U.S. doctors and ten percent of hospitals had even basic Electronic Medical Record systems” and “fewer than two percent of U.S. hospitals had comprehensive systems.”<sup>111</sup> There is a strange disconnect between the wonders of Silicon Valley, where the United States leads the world in search and social networking, and the dismal midden of faxes and manila folders littering many doctors’ offices.<sup>112</sup> While other industries have been spending ten percent or so of annual costs on information technology, the health care industry has barely spent more than two percent of its annual costs.

Despite the polarized health policy landscape, a consensus emerged in 2009 around the need to subsidize electronic health records. The United States took a major step toward establishing such an infrastructure in the HITECH Act of 2009.<sup>113</sup> The Act established

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110. Lucette Lagnado, *California Hospitals Open Books, Showing Huge Price Differences*, WALL ST. J., Dec. 27, 2004, at A1.

111. Nicolas Terry, *Anticipating Stage II: Assessing the Development of Meaningful Use and EMR Deployment*, 21 ANNALS HEALTH L. 103, 103 (2012) [hereinafter Terry, *Anticipating*]; see also Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1631 (2009) (concluding that only 1.5% of U.S. hospitals have a comprehensive electronic records system); Richard Hillested et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFF. 1103, 1103 (2005) (noticing that most records “are still stored on paper”); Robert H. Miller and Ida Sim, *Physicians’ Use of Electronic Medical Records: Barriers and Solutions*, 23 HEALTH AFF. 116, 117–18 (2004) (detailing the results of a study on physicians’ EMR usage).

112. See Catherine M. DesRoches et al., *Electronic Health Records in Ambulatory Care: A National Survey of Physicians*, 359 NEW ENG. J. MED. 50, 54 (2008) (reporting a dearth of electronic record usage); Jha, *supra* note 111, at 1631 (same).

113. American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 115 (2009); Mark Faccenda and Lara Parkin, *Meaningful Use—What Does It Mean To You?*, 23 HEALTH L. 10, 10 (2011) (citing ARRA, Title IV, Subtitles A and B). *But see generally* Larry Wolf, Jennie Harvell and Ashish K. Jha, *Hospitals Ineligible for Federal Meaningful-Use Incentives*, 23 HEALTH AFF. 1103, 1103 (2005) (arguing that many hospitals are ineligible for incentives).

incentive programs for eligible hospitals and professionals adopting and meaningfully using certified electronic health record (“EHR”) technology.<sup>114</sup> Computational innovation may improve health care by creating stores of observational data to complement traditional clinical research.<sup>115</sup> President Obama called HITECH “an investment that will take the long overdue step of computerizing America’s medical records to reduce the duplication and waste that costs billions of health care dollars and medical errors that cost thousands of lives each year.”<sup>116</sup>

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*tives Have Dismally Low Rates of Adoption of Electronic Health Records*, 31 HEALTH AFF. 505 (2012) (discussing providers explicitly excluded from incentive programs).

114. Bob Brown, *What Is a “Certified EHR?”* 12 J. HEALTH CARE COMPLIANCE 31, 31 (2010); *see generally* Nicolas P. Terry, *Certification and Meaningful Use: Reframing Adoption of Electronic Records as a Quality Imperative*, 8 IND. HEALTH L. REV. 43 (2011) [hereinafter Terry, *Certification and Meaningful Use*] (examining meaningful use as the condition for receiving EHR subsidy funds).

115. OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., DEP’T OF HEALTH AND HUMAN SERVS., ACCELERATING THE ADOPTION OF HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION (2010), *available at* [http://www.hhs.gov/recovery/reports/plans/onc\\_hit.pdf](http://www.hhs.gov/recovery/reports/plans/onc_hit.pdf); SAMHSA, SUBSTANCES ABUSE AND MENTAL HEALTH ADMIN., SAMHSA’S WEEKLY FINANCING NEWS PULSE: NATIONAL EDITION, July 23, 2010, at 3, *available at* [http://www.samhsa.gov/financing/file.axd?file=2010%2f10%2f2010\\_10\\_WeeklyFinancingNewsPulseNationalEditionfinal20100723.pdf](http://www.samhsa.gov/financing/file.axd?file=2010%2f10%2f2010_10_WeeklyFinancingNewsPulseNationalEditionfinal20100723.pdf) (reporting that the new program will direct \$27 billion for CMS and \$2 billion for the ONC). About \$30 billion in subsidies were appropriated for this purpose. *CMS Medicare and Medicaid EHR Incentive Program Timeline*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Nov. 15, 2010), <https://www.cms.gov/EHRIncentivePrograms/Downloads/EHRIncentProgTimeline508V1.pdf>.

116. President Barack Obama, Remarks at Stimulus Bill Signing (Feb. 17, 2009), *available at* <http://www.sequelmed.com/Stimulus/>; *see also* Federico Girosi, Robin Meili & Richard Scoville, *Extrapolating Evidence of Health Information Technology Savings and Costs*, RAND CORP. MONOGRAPH (2005), [http://www.rand.org/pubs/monographs/2005/RAND\\_MG410.pdf](http://www.rand.org/pubs/monographs/2005/RAND_MG410.pdf). *But see* Steve Lohr, *Digital Records May Not Cut Health Costs, Study Cautions*, N.Y. TIMES, Mar. 5, 2012, at B1 (citing more recent data); CONGRESSIONAL BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 4 (2008), *available at* <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/91xx/doc9168/05-20-healthit.pdf> (criticizing the RAND study). Given such conflicting findings, it is reassuring to note that a meta-study concluded that ninety-two percent of recent articles on health IT did find positive benefits overall. M.B. Buntin et al., *The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results*, 30 HEALTH AFF. 464, 465 (2011).

The Act has already catalyzed diffusion of electronic medical records by providing billions of dollars in subsidies to hospitals and physicians.<sup>117</sup> The American Recovery and Reinvestment Act of 2009 (“ARRA”) does more than subsidize; it conditions funding on the “meaningful use” of electronic medical records.<sup>118</sup> “Meaningful use” regulations define how functional an EHR system has to be before its user can receive subsidies.<sup>119</sup> Electronic health records are to include basic information such as patient demographics, clinical health information, and medical history.<sup>120</sup> The law focuses on incentives to improve quality, safety, efficiency, and care coordination; engage patients and families; and improve population health, all while protecting privacy, confidentiality and security.<sup>121</sup> Meaningful use requirements are phased in over a six-year period, in three stages. Stage 1 focuses on basic information and demographics.<sup>122</sup>

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117. An electronic health record (“EHR”) is “an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.” 42 U.S.C. § 17921 (2006). This paper uses the terms EHR and EMR (electronic medical record) interchangeably, though in the future an EHR might more accurately designate a more comprehensive record (relating to all pieces of information related to one’s health, as opposed to mere medical care). This appears to be the ONC’s view. See Peter Garrett and Joshua Seidman, *EMR vs. EHR*, HEALTHITBUZZ (Jan. 4, 2011, 12:07 PM), <http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/> (describing the difference between using EHR and EMR).

118. Camella B. Boateng, *Federal Electronic Health Records Incentive Programs: What They Mean for Compliance Officers*, 12 J. HEALTH CARE COMPLIANCE 17, 18 (2010) (“The meaningful use objectives are divided into two groups: (1) core set and (2) menu set objectives. The core set contains 14 required objectives that eligible hospitals must fulfill to receive bonus payments. The menu set has 10 objectives, and hospitals must select and meet five objectives for payment purposes.”).

119. David Blumenthal & Marilyn Tavenner, *The “Meaningful Use” Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 501 (2010); Terry, *supra* note 111.

120. 42 U.S.C. § 300jj(13)(2006).

121. Nicolas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV. 681, 691–96.

122. See Medicare and Medicaid Programs, 75 Fed. Reg. 44,314, 44,328 (proposed July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422) (listing the “core set of meaningful use objectives” for Stage 1). Capabilities include: recording smoking status and body mass index; present clinical data on individual patients, including medication list, medication allergy list, problem and current diagnosis list, and a clinical summary; generate lists of patients by specific condition and allows communication with patients for reminders

The HITECH Act also mandated that the Department of Health and Human Services (“HHS”) establish procedures for certifying health information technology so that providers can be assured that their technology meets basic standards.<sup>123</sup> The “Standards Rule” focuses on basic benchmarks for data entry and portability.<sup>124</sup> Such certified EHRs must include capacities that “enable providers to achieve meaningful use as it is currently constituted in Phase 1 of HHS’ regulations.”<sup>125</sup> The Office of the National Coordinator for Health Information Technology (“ONC”) delegates certification authority to Authorized Testing and Certification Bodies (“ATCBs”), which will follow standards developed by the International Organization for Standardization.<sup>126</sup>

The meaningful use and certification standards are a comprehensive, complex effort to create the rules and standards that can support a twenty-first-century health IT infrastructure. The standards have succeeded in many ways,<sup>127</sup> despite the fact that David Blumenthal has conceded that CMS and ONC “were in many ways unprepared to undertake” the task of leading “the creation of a nationwide, interoperable, private, and secure electronic health information sys-

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and such; allow patients timely access to their EMR that the system allow providers to submit claims for payment and information to public health authorities electronically. *Id.*

123. 45 C.F.R. § 170 (2010); Proposed Establishment of Certification Programs for Health Information Technology, 75 Fed. Reg. 11,328 (proposed March 10, 2010) (to be codified at 45 C.F.R. pt. 170); Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590 (proposed July 28, 2010) (to be codified at 45 C.F.R. pt. 170).

124. Brown, *supra* note 114, at 66.

125. Sharona Hoffman & Andy Podgurski, *Meaningful Use and Certification of Health Information Technology: What About Safety?*, 39 J.L. MED. & ETHICS s77, s78 (Supp. 2011) [hereinafter Hoffman & Podgurski, *Meaningful Use*].

126. *Id.*

127. David J. Brailer, *David Brailer & Farzad Mostashari: Two National Health IT Czars Compare Notes*, 31 HEALTH AFF. 475, 475 (2012) (“In mid-February 2012, Secretary of Health and Human Services Kathleen Sebelius announced that nearly 2,000 US hospitals and more than 41,000 doctors have now met the standards for achieving meaningful use of health information technology and have received \$3.1 billion in federal incentive payments as a result.”).

tem” in 2009.<sup>128</sup> Blumenthal has argued that “the HITECH Act may have spurred a rapid increase in the adoption of EHRs.”<sup>129</sup>

Unfortunately, other developments in health information technology threaten to undermine policies of openness.<sup>130</sup> According to Phillip Longman, subsidies could be directed to proprietary systems that prevent widespread study and utilization of health records.<sup>131</sup> Longman worried that several proprietary systems increase the chance of medical error due to restrictive licensing agreements that prohibit users from fully understanding aspects of the system that cause problems.<sup>132</sup>

In 2011, EHR experts Sharona Hoffman and Andy Podgurski sounded another note of alarm about the development of digitized health infrastructure.<sup>133</sup> They argued that early rounds of regulations relating to health information technology failed to address safety concerns: “General system safety is a property that is attainable only through rigorous processes for development and evaluation. The

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128. Blumenthal, *supra* note 6. Blumenthal was National Coordinator of Health Information Technology in charge at the time the ARRA was adopted. He has confirmed that consultation with outside experts helped the process along. *Id.* ONC and CMS were fortunate that the HITECH Act created two new federal committees to advise them: a Health Information Technology Policy Committee (“HITPC”) and a Health Information Technology Standards Committee (“HITSC”). The former was to provide general policy advice, and the latter to help with developing standards, implementation specifications, and certification criteria for EHRs. In hundreds of open meetings of the HITSC, the HITPC, and its many working groups, scores of experts contributed tens of thousands of free hours to helping HHS make the HITECH Act work. *Id.*

129. Blumenthal, *supra* note 6, at 2427–28.

130. Cost of implementation is the first impediment; one study estimated that the first sixty days of implementation in a primary care setting would cost over \$30,000 and consume 134 hours of physician time. N.S. Fleming et al., *The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices*, 30 HEALTH AFF. 481, 482 (2011).

131. Phillip Longman, *Code Red: How Software Companies Could Screw Up Obama’s Health Care Reform*, 41 WASH. MONTHLY 19, 20–22 (2009).

132. *Id.* at 23 (“Perversely, license agreements usually bar users of proprietary health IT systems from reporting dangerous bugs to other health care facilities. In open-source systems, users learn from each other’s mistakes; in proprietary ones, they’re not even allowed to mention them.”).

133. Hoffman & Podgurski, *Meaningful Use*, *supra* note 125. These concerns were anticipated in Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L.J. 1523, 1527 (2009).

regulations, however, do not address certification of EHR vendors' software development processes or even require vendors to analyze and mitigate potential safety hazards."<sup>134</sup>

A critical mass of incidents has demonstrated the dangers of malfunctioning and insecure software.<sup>135</sup> Though health care settings are often beset with urgent developments, ATCBs will use testing requirements that do not even attempt to approximate the "varied operating conditions" that will challenge systems over the long term.<sup>136</sup> Since a system that is "safe at one facility can experience safety problems when customized by other users," this may prove a serious source of preventable errors and substandard care.<sup>137</sup>

Whereas Hoffman and Podgurski critiqued the certification process for *technology* for lack of rigor, Nicolas Terry has focused on meaningful use requirements for *providers* that similarly shrink from genuine accountability.<sup>138</sup> Terry has worried that even "meaningful use" of EHRs may leave data trapped in silos and inaccessible for many important purposes.<sup>139</sup> Without "metadata that provides patient identifying information, privacy protocols, and provenance relating to that data element," EHRs could not live up to their full potential in monitoring and improving aggregate health outcomes.<sup>140</sup> Though ONC has begun to develop such standards for summary care records,<sup>141</sup> it may be a case of too little, too late. Excessive solicitude to-

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134. Hoffman & Podgurski, *Meaningful Use*, *supra* note 125, at s78 (footnote omitted).

135. *Bad Health Informatics Can Kill*, INST. OF HEALTH INFORMATICS (Oct. 19, 2012), available at <http://iig.umit.at/efmi/badinformatics.htm> (providing "summaries of a number of reported incidents in healthcare where [insecure software] was the cause or a significant factor"); Steven Lohr, *Seeing Promise and Peril in Digital Records*, N.Y. TIMES, July 17, 2011, at BU3.

136. Hoffman & Podgurski, *Meaningful Use*, *supra* note 125, at s78.

137. *Id.* at s79.

138. See Terry, *Certification and Meaningful Use*, *supra* note 114, at 48 (citing the "lack of provider enthusiasm for investing in EHR technology").

139. Terry, *Anticipating*, *supra* note 111, at 110 ("Where PCAST was insightful (and clearly differed from the CMS/ONC approach) was in viewing data exchange as a major priority (for patient care, health research, and to create network value and so stimulate adoption) and in its skepticism for useful data exchange emerging from the current generation of EMRs, even when supported by Health Information Exchanges ("HIE").").

140. *Id.* at 111.

141. See 45 C.F.R. § 170 (2010) (creating Metadata Standards To Support Nationwide Electronic Health Information Exchange).

ward IT vendors may be compromising the effectiveness of the emerging EHR infrastructure.<sup>142</sup>

Moreover, patients' perspectives have not been adequately acknowledged and incorporated into standards.<sup>143</sup> Many patients want to download their health data onto their own computers and applications.<sup>144</sup> Several entities have provided platforms for doing so,<sup>145</sup> promoting "personal health records" ("PHRs").<sup>146</sup> Despite a growing "quantified self"<sup>147</sup> movement that embraces such records, incompatible data entry standards have stymied even the most technologically advanced companies. For example, consider the story of one "tech-savvy" kidney cancer survivor featured in the *Boston Globe*.

When Dave deBronkart . . . tried to transfer his medical records from Beth Israel Deaconess Medical Center to Google Health, a new free service that lets patients keep all their health records in one place and easily share them with new doctors, he was stunned at what he found. Google said his

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142. For a case study in vendor resistance to more ambitious standards, see Anthony Guerra, *Health IT Advisers Blast Data Exchange Policies*, INFORMATIONWEEK (Apr. 1, 2011), <http://www.informationweek.com/healthcare/leadership/health-it-advisers-blast-data-exchange-p/229400737> (discussing tensions between PCAST and the approach to fair information practices being developed by Tiger Team (Workgroup on Privacy and Security)).

143. HEALTH RESEARCH INST., PUTTING PATIENTS INTO "MEANINGFUL USE" 3 (2011), available at <http://www.pwc.com/us/en/health-industries/publications/putting-patients-into-meaningful-use.jhtml> (finding that "[p]atient awareness of and access to available health IT tools is low").

144. Office of the Nat'l Coordinator for Health Info. Tech., Dep't of Health & Human Servs., Roundtable: Personal Health Records, Understanding the Evolving Landscape (Dec. 3, 2010), available at [http://www.healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_personal\\_health\\_records\\_-\\_phr\\_roundtable/3169](http://www.healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_personal_health_records_-_phr_roundtable/3169) (transcript).

145. See MICROSOFT HEALTHVAULT, [www.microsoft.com/en-us/healthvault/](http://www.microsoft.com/en-us/healthvault/) (last visited Oct. 25, 2012); AETNA CAREENGINE, <http://www.aetna.com/showcase/phr/> (last visited Oct. 25, 2012); MY HEALTHEVET, <https://www.myhealth.va.gov/index.html> (last visited Nov. 17, 2012); BLUE BUTTON, <http://www.va.gov/bluebutton/> (last visited Oct. 25, 2012).

146. A Personal Health Record is "an electronic record . . . that is managed, shared, and controlled by or primarily for the individual." 42 U.S.C. § 17921(11) (2006); see also 16 C.F.R. § 318.2(d) (2012); Office of the Nat'l Coordinator for Health Info. Tech., *supra* note 144 (describing the range of personal health record systems).

147. See, e.g., QUANTIFIED SELF, <http://quantifiedself.com/> (last visited Dec. 14, 2012) ("A place for people interested in self-tracking to gather, share knowledge and experiences, and discover resources.").

cancer had spread to either his brain or spine—a frightening diagnosis deBronkart had never gotten from his doctors—and listed an array of other conditions that he never had, as far as he knew, like chronic lung disease and aortic aneurysm. A warning announced his blood pressure medication required “immediate attention.” “I wondered, ‘What are they talking about?’” said deBronkart . . . . [He] eventually discovered the problem: Some of the information in his Google Health record was drawn from billing records, which sometimes reflect imprecise information plugged into codes required by insurers.<sup>148</sup>

According to one doctor consulted by the *Globe*, “an inaccurate diagnosis of gastrointestinal bleeding on a heart attack patient’s personal health record could stop an emergency room doctor from administering a life-saving drug.”<sup>149</sup> For the critically or chronically ill, the record is literally a life-or-death matter.

Stories like deBronkart’s also suggest the limits of a personalized health record model. The Center for Democracy and Technology has recommended that HHS require PHR vendors “to provide opportunities for consumers to amend, correct or annotate information in a PHR,” and “to have policies for handling disputes concerning information in the PHR.”<sup>150</sup> If regulators followed the same model as credit reporting, patients should be able to review their reports without charge, and make corrections.<sup>151</sup>

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148. Lisa Wangsness, *Electronic Health Records Raise Doubt*, BOS. GLOBE, Apr. 13, 2009, at C1. Google Health has since ceased operations. See David Talbot, *How A Broken Medical System Killed Google Health*, MIT TECH. REV. (June 29, 2011), <http://technologyreview.com/news/424535/how-a-broken-medical-system-killed-google-health/> (noting that Google “is unwilling, for perfectly good business reasons, to engage in block-by-block market solutions to health-care institutions one by one . . . and expecting patients to actually do data entry is not a scalable and workable solution.” (internal quotation omitted)).

149. Wangsness, *supra* note 148.

150. CTR. FOR DEMOCRACY & TECH., COMMENTS OF THE CENTER FOR DEMOCRACY & TECHNOLOGY TO THE OFFICE OF THE NATIONAL COORDINATOR’S PHR ROUNDTABLE 3, 19 (2010), [http://www.cdt.org/files/pdfs/CDT\\_Comment\\_to\\_ONC\\_PHR\\_Roundtable.pdf](http://www.cdt.org/files/pdfs/CDT_Comment_to_ONC_PHR_Roundtable.pdf) (arguing the need to build in a number of consumer safeguards to assure that other stakeholder interests do not trump patients’ interests).

151. For a discussion of the Fair Credit Reporting Act model, see Frank Pasquale, *Reputation Regulation*, in THE OFFENSIVE INTERNET 111 (Martha Nussbaum & Saul Levmore eds., 2010).

Conversely, the more control individuals have over a PHR (and the more verified it becomes), the more possibility there is that “[e]mployers, health plans, and others” might require “individuals to open PHR accounts as a condition of employment, membership, or for any other reason.”<sup>152</sup> To verify participation in a wellness program, an employer may want access to an employee’s PHR, particularly if it is much easier for its own computer systems to read and understand than the “objective health record” existing in the health care system itself. Yet the employer may also want to ensure that the PHR is populated by materials validated by third parties, such as doctors’ offices, fitness clubs, scales, or blood sugar monitors.

Presently, this is not a major issue; Nicolas Terry’s 2009 observation that “sharing or exchange of data between PHRs and providers or their EHRs is as speculative as it is controversial” is still an accurate characterization of most patients’ experience.<sup>153</sup> There are a few pioneer programs that are leading the way here, but they tend to be integrated into well-established health systems that have focused on information technology for decades.<sup>154</sup> One has to look to other countries for more advanced adoption of health information technology.<sup>155</sup> At their best, PHRs may help patients better manage their own conditions and join communities of interest online. For example, social networks like PatientsLikeMe.com have proven invaluable sources of support and advice.<sup>156</sup>

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152. CTR. FOR DEMOCRACY & TECH., *supra* note 150.

153. Nicolas P. Terry, *Personal Health Records: Directing More Costs and Risks to Consumers?*, 1 DREXEL L. REV. 216, 226 (2009).

154. *Id.* at 217 nn.10–11.

155. News Release, The Commonwealth Fund, 100 Percent of Primary Care Doctors in Denmark Use Electronic Medical Records (Mar. 11, 2010), *available at* <http://www.commonwealthfund.org/~media/Files/News/News%20Releases/2010/Protiti%20Release%20Final%203910.pdf> (“All primary care doctors in Demark use electronic medical records”); THE COMMONWEALTH FUND, INTERNATIONAL HEALTH POLICY SURVEY OF PRIMARY CARE PHYSICIANS IN ELEVEN COUNTRIES (2009) (noting that the United States is near the bottom in measures of electronic medical record penetration and use among primary care physicians).

156. PATIENTSLIKEME, <http://www.patientslikeme.com> (last visited Dec. 16, 2012). Of course, these networks raise some difficult legal issues once patients’ privacy rights are considered. For example, PatientsLikeMe was subject to a “scraper” which connected health information to some site users’ handles. Julia Angwin & Steve Stecklow, ‘Scrapers’ Dig Deep for Data on Web, WALL ST. J., Oct. 11, 2010, at A1. Sites like Spokeo can in turn re-connect handles back to individuals. SPOKEO, <http://www.spokeo.com/> (last visited Nov.

Technological advances could promote PHRs with inputs from providers, apps, and even radio frequency identification chips.<sup>157</sup> What happens if an employer tries to condition participation in a wellness program on an employee's agreement not to try to change whatever is reported by those trusted third parties?<sup>158</sup> Patients must "buy in" to EHR for it to work effectively, and many will avoid any data-sharing environment where medical history can lead to denial of opportunities.<sup>159</sup>

As ONC promulgates rules governing meaningful use, it is important that voices like deBronkart's are heard. So far, public dialogue on the process has been limited, and the main commenters are industry players.<sup>160</sup> A predictable pattern has developed: HHS announces ambitious goals in proposed rules, commenters raise concerns about technical feasibility, and requirements are scaled back somewhat in final rules.<sup>161</sup> The broader purposes of health information technology remain in the background.

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17, 2012). For a compelling analysis of how to address these concerns, see Nicolas P. Terry, *Physicians and Patients Who "Friend" or "Tweet": Constructing a Legal Framework for Social Networking in a Highly Regulated Domain*, 43 IND. L. REV. 285, 286 (2010) (discussing both tort and administrative models of protection).

157. Scott Peppet, *Unraveling Privacy: The Personal Prospectus and the Threat of a Full-Disclosure Future*, 105 NW. U. L. REV. 1153, 1153–56 (describing data gathering apps); MIREILLE HILDEBRANDT, *PROFILING THE EUROPEAN CITIZEN* 15 (2009) (describing ubiquitous health data gathering apps).

158. Frank Pasquale, *The End of "Notice and Consent" as Meaningful Privacy Protection*, CYBERLAW JOTWELL (Feb. 3, 2012), <http://cyber.jotwell.com/the-end-of-notice-and-consent-as-meaningful-privacy-protection/> (offering an overview of the likely responses of data subjects).

159. *See id.* (discussing patient distrust over privacy of personal data and examining three possible responses to avoid the harms of full disclosure).

160. *See* HEALTH RESEARCH INST., *supra* note 143, at 1 (noting that "[t]he industry" has expressed concerns that the proposed requirements and timelines for Stage 2 of meaningful use may be too aggressive).

161. Blumenthal & Tavenner, *supra* note 119, at 502 (noting that the final regulations for Stage 1 of meaningful use incorporated changes in response to comments that the regulations were too demanding).

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### III. ENVISIONING HEALTH CARE AS AN INFORMATION INDUSTRY

Information gaps persistently compromise the delivery of high-quality health care.<sup>162</sup> Some of the gaps persist for good normative, legal, or technical reasons.<sup>163</sup> Nevertheless, there can be little doubt that a good part of the hundreds of billions of dollars wasted in American health care annually is due to information failures.<sup>164</sup>

The American health care industry must change: From Wall Street to Silicon Valley, from the Manhattan Institute to the Roosevelt Institute, that message is a constant. By the time Tim Jost magisterially cataloged the failings of the U.S. health care system in his 2006 article, *Our Broken Health Care System and How to Fix It*, experts on health information had reached a policy consensus.<sup>165</sup> Providers and insurers alike needed to use information technology to prevent error and improve efficiency. This Part explores several proposals for addressing the information gaps described in Part II.

#### A. *Characteristics of Information Industries: Search, Analytics, and Co-Creation*

The twin rise of information industries and globalization has led to a startling imbalance in American political economy. As manufactured goods and many services decline in price, health care costs remain stubbornly high.<sup>166</sup> Within the United States, many commentators have argued that more intensive and extensive use of information

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162. See Robert John Kane, *Information Is the Key to Patient Empowerment*, 11 ANNALS HEALTH L. 25, 34 (2002).

163. See *id.* at 31 (discussing the Health Insurance Portability and Accountability Act (“HIPAA”), which requires that health care information be kept private and confidential in accordance with universal privacy standards).

164. Elise Viebeck, *Institute of Medicine Says U.S. Healthcare System in Need of Giant Overhaul*, HEALTHWATCH (Sept. 6, 2012, 11:21 AM), <http://www.thehill.com/blogs/healthwatch/other/247929-iom-us-healthcare-needs-giant-overhaul>.

165. Timothy Jost, *Our Broken Health Care System and How to Fix It: An Essay on Health Law and Policy*, 41 WAKE FOREST L. REV. 537, 608–13 (2006) (proposing a reform agenda that was very similar to many of the programs enacted in the Affordable Care Act of 2010).

166. See Frank Pasquale, *The Hippocratic Myth*, 32 J. LEGAL MED. 529, 535 (2012) (reviewing M. Gregg Bloche’s book, *The Hippocratic Myth* (2011) and examining “bloated” health care costs).

technology can improve quality and contain costs.<sup>167</sup> It is helpful to review the key transformative aspects of information technology before discussing how it might address the problems raised in Part II.

### 1. Search Capacity

Economic sociologist David Stark has observed that “search is the watchword of the information age.”<sup>168</sup> We are now so reliant on information technology in daily life that it can be hard to remember how complex and costly tasks were before its diffusion.<sup>169</sup> Consider, for instance, the location and purchasing of a book. The 1990s were a decent time to find a specialized, old, or out-of-print work if you had access to a large university library.<sup>170</sup> If not, the search could be quite laborious.<sup>171</sup> Scarcely two decades later, this market has been revolutionized.<sup>172</sup> Sites like Amazon not only offer low prices and rapid shipping for most volumes, but they also provide something of a plat-

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167. See e.g., Gerard F. Anderson et. al., *Health Care Spending and Use of Information Technology in OECD Countries*, 25 HEALTH AFF. 819, 821 (2006) (proposing the adoption of health IT as a method of controlling health spending).

168. DAVID STARK, THE SENSE OF DISSONANCE: ACCOUNTS OF WORTH IN ECONOMIC LIFE I (2009). “With a few keywords at the toolbar, we can access enormous databases to find an obscure article by a long-distant colleague, identify the supplier of a critical component, read about the benefits and side effects of new pharmaceutical products or medical procedures, or find the fact that immediately settles a dispute about the performance of an opera, an athlete, or a mutual fund.” *Id.*

169. *Id.*

170. Robert P. Holley & Kalyani Ankem, *The Effect of the Internet on the Out-of-Print Book Market: Implications for Libraries*, 29 LIBR. COLLECTIONS, ACQUISITIONS, & TECHNICAL SERVS. 118, 119 (2005), available at <http://www.sciencedirect.com/science/article/pii/S1464905505000278> (arguing that before the 2000s, libraries were the primary source of out-of-print books, whereas the Internet has increased the efficiency of the out-of-print book market, thereby increasing availability and access).

171. For one account of search methods, see Douglas Duchin & Celia Scher Wagner, *Trials and Tribulations: Out-of-Print 101*, 20 LIBR. ACQUISITIONS: PRAC. & THEORY 341, 342–43 (1996), available at <http://www.sciencedirect.com/science/article/pii/0364640896000506>; see also Mary Eldredge, *Comparison of Out-of-Print Searching Methods*, 17 LIBR. ACQUISITIONS: PRAC. & THEORY 427, 432 (2002), available at <http://www.sciencedirect.com/science/article/pii/036464089390006R>.

172. See *supra* note 170; see also Michael Seringhaus, *E-Book Transactions: Amazon “Kindles” the Copy Ownership Debate*, 12 YALE J.L. & TECH. 147, 149 (2009) (discussing how Amazon Kindle is revolutionizing the way we buy and read books).

form for their own competitors—for example, used booksellers and other retailers.<sup>173</sup> These sellers compete not only on price but also on quality, occasionally demanding a few more dollars for a book in “excellent” (as opposed to “used”) condition.<sup>174</sup> The competitive pressures are enormous, bringing a range of volumes within reach of consumers who would otherwise be extremely inconvenienced to find them.<sup>175</sup>

Just as Amazon has revolutionized the publishing industry, Apple has remade the world of online music by designing simple interfaces and providing instant access to products.<sup>176</sup> A little over a decade ago, digital music was mired in conflicts over rights, balky technology, and annoying digital rights management.<sup>177</sup> Now Apple’s iPod, iTunes, iPhone, and iPad have combined to unleash an ecosystem of innovation.<sup>178</sup> The power of a well-maintained and popular platform is enormous. As Amar Bhide has argued, “innovations that sustain modern prosperity have a variety of forms and are developed and used through a massively multiplayer, multilevel, and multiperiod

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173. Frequently, the biggest competition is Amazon itself. See Richard Russo, *Amazon’s Jungle Logic*, N.Y. TIMES, Dec. 13, 2011, at A35 (discussing Amazon’s price-check app which allows shoppers in physical book stores to scan a bar code and see if they can get a better price online through Amazon).

174. Fred Bernstein, *Unloading His Books, but Not His Conscience*, N.Y. TIMES, Apr. 11, 2002, at G5 (describing how the price of a resold book on Amazon is dependent on its condition).

175. Barry Lynn and Steven Pearlstein present more skeptical views. Barry C. Lynn, *Killing the Competition: How the New Monopolies Are Destroying Open Markets*, HARPER’S BAZAAR, Feb. 1, 2012, at 27 (illustrating how monopolistic capitalism is destroying various markets); Steven Pearlstein, *Pick Your Monopoly: Apple or Amazon*, WASH. POST, Mar. 10, 2012, at G1 (“So which is better: a market in which Amazon uses low prices to maintain its e-book monopoly and drive brick-and-mortar bookstores out of business, or one in which the major book publishers, in tacit collusion with Apple, break Amazon’s monopoly and raise prices?”).

176. Randy Lewis, *Steve Jobs Revolutionized the Music Industry*, L.A. TIMES (Oct. 6, 2011), <http://www.articles.latimes.com/2011/oct/06/entertainment/la-et-jobs-music-20111007>; Matthew Fagin, Frank Pasquale & Kimberlee Weatherall, *Beyond Napster: Using Antitrust Law to Advance and Enhance Online Music Distribution*, 8 B.U. J. SCI. & TECH. L. 451, 460 (2002) (describing in detail the state of the digital music industry as of 2002).

177. *Id.*

178. John Markoff, *Steven P. Jobs 1955–2011; Redefined the Digital Age as the Visionary of Apple*, N.Y. TIMES, Oct. 6, 2011, at A1.

game.”<sup>179</sup> Pervasive search capacity allows the players to find one another and cooperate over time.<sup>180</sup>

Labor can also be the object of search capacity. Analyzing task-matching programs like Amazon’s Mechanical Turk, LiveOps, and TxtEagle, Jonathan Zittrain has observed that “[w]e are in the initial stages of distributed human computing that can be directed at mental tasks the way that surplus remote server rackspace or Web hosting can be purchased to accommodate sudden spikes in Internet traffic . . . .”<sup>181</sup> The resulting distributed labor force offers unparalleled flexibility for enterprises. Zittrain presents a compelling account of how the day-to-day phenomenology of labor, supervision, and monitoring can be technologically transformed via computing capacity.<sup>182</sup>

## 2. *Predictive Analytics and Personalization*

Massive stores of data can also be used to tailor offerings to customers. One data broker alone, Acxiom, has at least 1,600 pieces of information about ninety-eight percent of U.S. citizens, quietly gathered from thousands of sources.<sup>183</sup> Driven by marketing opportunities, intermediaries track and record nearly all online activity. Secondary uses of data are ubiquitous. Marketers can easily repurpose the data, assessing whose behavioral profiles match those of tax evaders, insurance cheats, or terrorists. Private companies are also joining the “data-driven” bandwagon, digitizing reputation assessment systems.

Privy to an ever expanding store of transactions, credit card companies are at the vanguard of predictive analytics. Credit card

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179. AMAR BHIDE, *THE VENTURESOME ECONOMY: HOW INNOVATION SUSTAINS PROSPERITY IN A MORE CONNECTED WORLD* 9 (2008).

180. A prescient legal academic recognition of the need for such capacity in health care was the discussion of “common exchange representation” by Hoffman and Podgurski. Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Records*, 22 HARV. J.L. & TECH. 103, 153 (2008).

181. Jonathan Zittrain, *Ubiquitous Human Computing*, 366 PHIL. TRANSACTIONS: MATHEMATICAL, PHYSICAL, & ENG’G SCI. 3813, 3813–21 (2008). Zittrain’s work on privication was a prescient response to privacy dilemmas raised later in this Article.

182. Frank Pasquale, *Banana Republic.com*, CYBERLAW JOTWELL (Jan. 10, 2011), <http://cyber.jotwell.com/2011/01/>.

183. See generally ELI PARISER, *THE FILTER BUBBLE* (2011); DAN SOLOVE, *THE FUTURE OF REPUTATION* (2008).

purchase records are a data geek's dream.<sup>184</sup> Quantitative analysts correlate various forms of behavior to uncover hidden relationships.<sup>185</sup> Billing data may identify buying patterns that associate with profitable customers. One company determined that buyers of cheap automotive oil were worse risks than those who paid for a brand-name oil.<sup>186</sup> Drinking beer at a sketchy bar, installing chrome-skull car accessories, or subscribing to *Soldier of Fortune* magazine might lead to higher interest rates or lower credit limits.<sup>187</sup> One researcher has bragged that his firm considers over 300 characteristics to pinpoint delinquency risks.<sup>188</sup>

In a 2006 *Businessweek* cover story, Stephen Baker described the spread of quantitative analysis in leading industries.<sup>189</sup> "Partnerships between mathematicians and computer scientists are pulling into whole new domains of business and imposing the efficiencies of math," he reported.<sup>190</sup> Over the next several years, Baker focused on the extensive implementation of tracking and analysis at IBM.<sup>191</sup> Ian Ayres has also hailed the role of "supercrunchers" in promoting more efficient business practices.<sup>192</sup>

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184. Charles Duhigg, *What Does Your Credit Card Company Know About You?*, N.Y. TIMES MAG., May 12, 2009, at 40. ("Just a little more than two decades ago, the credit-card business was a quiet, slightly boring industry dominated by banks looking for easy revenue. Card issuers made money by collecting annual dues and interest payments from cardholders as well as fees from merchants each time a customer used a card. Then the math whizzes arrived.")

185. SCOTT PATTERSON, *THE QUANTS: HOW A NEW BREED OF MATH WHIZZES CONQUERED WALL STREET AND NEARLY DESTROYED IT* 31, 45 (2010) (discussing data crunching).

186. Duhigg, *supra* note 184, at 40 ("[P]eople who bought cheap, generic automotive oil were much more likely to miss a credit-card payment than someone who got the expensive, name-brand stuff.")

187. *Id.*; see also Frank Pasquale, *Online Health Data in Employers' and Insurers' Predictive Analytics*, CONCURRING OPINIONS (Nov. 19, 2010, 11:20 AM), <http://www.concurringopinions.com/archives/2010/11/online-health-data-in-employers-and-insurers-predictive-analytics.html> ("Many have complained about inaccuracy in these new forms of profiling, and consumers' inability to review and correct digital dossiers collected about them.")

188. Pasquale, *supra* note 187.

189. Stephen Baker, *Math Will Rock Your World*, BLOOMBERG BUSINESSWEEK (Jan. 22, 2006), <http://www.businessweek.com/stories/2006-01-22/math-will-rock-your-world>.

190. *Id.*

191. STEPHEN BAKER, *THE NUMERATI* 20–40 (2009).

192. IAN AYRES, *SUPERCRUNCHERS* 16 (2007).

### 3. *Customers Promote Innovation via Co-Creation of Value*

A thriving information economy does not just need innovative firms. It also crucially depends on active consumers, people willing to take the time to learn how to use a new product and to broaden its range of uses.<sup>193</sup> Sometimes called “prosumers” (producing consumers) or “playborers” (those whose play generates the value usually associated with labor), early adopters and proselytizers of new technologies can catalyze a chain reaction of networked product and service use.<sup>194</sup> Think back to the first time you used an MP3 player—the device needed to be connected to your computer and its software installed, sometimes with instructions only found in online “manuals” created by other users. The seamless interface design of Apple and its best applications (“apps”) have not always helped the digital consumer find his way. Rather, persistent profits could only be built on a base of largely unpaid labor by enthusiastic early users.<sup>195</sup>

The spectacular growth of apps within Apple’s hardware is one of today’s economy’s greatest success stories.<sup>196</sup> When someone like Marco Arment develops a useful app like Instapaper, he does not merely make at least a few hundred thousand dollars for himself; he also draws in first-time users to explore and learn about how other

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193. Yochai Benkler, *Coase’s Penguin*, 112 YALE L.J. 369 (2002) (describing the importance of peer production within and outside marketized social relations).

194. TYLER COWEN, *CREATE YOUR OWN ECONOMY: THE PATH TO PROSPERITY IN A DISORDERED WORLD* 158 (2009) (“America has created a very special environment for nurturing the creativity of diverse talents.”). *But see generally* TREBOR SCHOLZ & LAURA LIU, *FROM MOBILE PLAYGROUNDS TO SWEATSHOP CITY* (2012), [http://www.situatedtechnologies.net/files/ST7-MobilePlaygrounds\\_SweatshopCity.pdf](http://www.situatedtechnologies.net/files/ST7-MobilePlaygrounds_SweatshopCity.pdf) (examining how “communication, attention, and physical movement generate financial value for a small number of private stakeholders”).

195. In *The Venturesome Economy*, Amar Bhide has described the traits of consumers that lead to such cooperative and iterative innovation. BHIDE, *supra* note 179, at 27. Examining the “technostructure” behind over 100 innovative businesses, Bhide has observed that “[a] new ‘diskless’ (or ‘thin client’) computer, for instance, will generate revenue for its producer and value for its users only if it is effectively marketed by the former and properly deployed by the latter,” and that “Microsoft profited enormously from pioneers’ efforts to educate customers and create a market for spreadsheets.” *Id.* at 8, 17.

196. Mobile health is one of the fastest growing areas in medicine. Elizabeth Dougherty, *Mobilizing a Revolution: How Cell Phones are Transforming Public Health*, HARV. PUB. HEALTH REV., Winter 2012, available at <http://www.hsph.harvard.edu/news/magazine/mobilizing-a-revolution/>.

software could make their lives easier.<sup>197</sup> Kevin Kelly has suggested that the “technium,” an assemblage of connected, smart, motivated users, can improve outcomes in unexpected ways.<sup>198</sup> Communities and companies are already coalescing around health data openness initiatives.<sup>199</sup>

*B. Search and Analytics for the Health Information Technology of Quality Assessment*

There are at least two major barriers to the optimal use of search and analytics in health care. First, powerful incumbent firms can use secrecy to frustrate efforts to understand the true value of their services.<sup>200</sup> As noted above, a pharmaceutical company may reduce or deny access to data;<sup>201</sup> an insurer may offer hundreds of slightly different plans to make informed shopping impossible; even health IT companies themselves may use licensing agreements that forbid disclosure of defects in their software.<sup>202</sup> Second, the privacy concerns of

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197. See Farhad Manjoo, *iPhone Apps to Organize Your Life*, N.Y. TIMES, July 9, 2009, at B5 (discussing “the best apps to keep your life running smoothly”).

198. KEVIN KELLY, WHAT TECHNOLOGY WANTS 14 (2011).

199. See, for example, the Department of Health and Human Services’ management of the Community Health Data Initiative (“CHDI”). Community Health Data Initiative, HHS.GOV/OPEN, <http://www.hhs.gov/open/plan/opengovernmentplan/initiatives/initiative.html> (last visited Apr. 14, 2013) (“Since the debut of our initial Open Government Plan, the public-private Community Health Data Initiative collaboration has already attracted companies, nonprofit organizations, advocacy groups, and innovators of all stripes to utilize the data HHS is providing and develop applications for the public.”); *Proceedings*, HHS NCVHS, June 17, 2010 (unedited transcript), <http://www.ncvhs.hhs.gov/100617tr.htm> (“What the folks at Asthmopolis have done is to put little tiny GPS trackers on inhalers for asthma patients. What they are doing is both enabling providers to track what is happening to their asthma patients, but through crowd sourcing they are able to identify regions in parts of cities where the air is bad on a particular day, because they are picking up a whole lot of inhaler use in a particular part of a city on a particular day.”).

200. See Frank Pasquale, *Restoring Transparency to Automated Authority*, 9 J. TELECOMM. & HIGH TECH. L. 235, 239–43 (2011) [hereinafter Pasquale, *Restoring Transparency*] (arguing that industry secrecy obfuscates critical data failing to reveal the true costs of health care).

201. See Kesselheim & Avorn, *supra* note 35.

202. Jonathon H. Roth, *Regulating Your Medical History Without Regulations: A Private Regulatory Framework to Electronic Health Record Adoption*, 91 B.U. L. REV. 2103, 2124–25 (2011).

patients have slowed adoption of some digital records.<sup>203</sup> Moreover, where privacy concerns have been ignored (as in the rapid dissemination of pharmacy dossiers), they have led to unfair, invasive, and irremediable violations of the privacy of the individual.<sup>204</sup>

Key parts of the PPACA of 2010 and the ARRA of 2009 reduce barriers to health IT deployment related to secrecy prerogatives and privacy and security concerns.<sup>205</sup> The PPACA's insurance regulations promote transparency; its quality improvement mechanisms are designed to make providers more easily comparable; and its Patient-Centered Outcomes and Research Institute ("PCORI") and Independent Payment Advisory Board ("IPAB") are calculated efforts to

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203. See generally Roger S. Magnusson, *The Changing Legal and Conceptual Shape of Health Care Privacy*, 32 J.L. MED. & ETHICS 680, 685 (2004). Patient concerns are not hypothetical; data breaches have been on the rise. *Reported Health Data Breaches Rose by 97% in 2011*, IHEALTHBEAT (Feb. 1, 2012), <http://www.ihealthbeat.org/articles/2012/2/1/health-data-breaches-increased-by-97-in-2011-report-finds.aspx>; Scott Gibson, *Stolen Medical Records One of the Most Lucrative Forms of ID Theft*, HEALTHCARETECHREVIEW (Dec. 13, 2011), <http://healthcaretechreview.com/stolen-medical-records-lucrative/>.

204. Over twenty-one million patients have suffered data security breaches reported to the federal government over the past three years. See section 13402(e)(4) of the HITECH Act, in HEALTH INFO. SERVS., DEP'T OF HEALTH AND HUMAN SERVS., BREACHES AFFECTING 500 PATIENTS OR MORE, available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachtool.html> (last visited Nov. 11, 2012). Even non-breached data can lead to serious negative consequences. See, e.g., Chad Terhune, *They Know What's in Your Medicine Cabinet*, BLOOMBERG BUSINESSWEEK (July 22, 2008), [http://www.businessweek.com/magazine/content/08\\_31/b4094000643943.htm](http://www.businessweek.com/magazine/content/08_31/b4094000643943.htm) ("Two-thirds of all health insurers are using prescription data—not only to deny coverage to individuals and families but also to charge some customers higher premiums or exclude certain medical conditions from policies, according to agents and others in the industry."); Sarah Ludington, *Reining in the Data Traders: A Tort for the Misuse of Personal Information*, 66 MD. L. REV. 140, 162 (2006) ("Without consent, CVS Pharmacy, Inc. (CVS) mined its customer prescription records for the purpose of sending its customers mailings targeted to their specific medical conditions . . ."). There are also legitimate worries about discriminatory uses of information either not covered by extant privacy or anti-discrimination laws, or undetectable by workers. Sharona Hoffman, *Employing E-Health: The Impact of Electronic Health Records on the Workplace*, 19 KAN. J.L. & PUB. POL'Y 409, 422 (2010) (raising the possibility of a growing use of "complex scoring algorithms based on EHRs to determine which individuals are likely to be high-risk and high-cost workers").

205. See Arielle Yaffee, *Financing the Pulp to Digital Phenomenon*, 7 J. HEALTH & BIOMEDICAL L. 325, 340–41 (2011) (discussing the privacy regulations of HITECH under ARRA and the privacy provisions in PPACA).

generate objective information about drugs and devices free of the conflicts of interest and shadowy pecuniary ties that render suspect so much sponsored research.<sup>206</sup> The ARRA tries to protect patients from misuse of their medical data by requiring the use of “audit trails” to record each instance of access to a record and creating incentives for the use of encryption and other best practices.<sup>207</sup>

These statutory provisions are now being implemented in an epic series of rulemakings. As they continue, predictable counterattacks have been launched by affected industries. This Article focuses on two lines of attack as particularly worth addressing. First, all the providers mentioned above have insisted that complexity in their fields can never truly be grasped by regulators or rendered clear to con-

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206. Nan D. Hunter, *Health Insurance Reform and Intimations of Citizenship*, 159 U. PA. L. REV. 1955, 1990–91 (2011) (noting that a key goal of PPACA’s exchanges is “to facilitate easy plan comparison, to maximize transparency, and to boost competition”); Scott Lindstrom, *Health Care Reform and Rural America: The Effect of the Patient Protection and Affordable Care Act on the Rural Economy and Rural Health*, 47 IDAHO L. REV. 639, 645 (2011) (“PPACA calls for the creation of state health insurance . . . [that] will provide information to potential insurance enrollees about the costs and benefits of various plans and provide ratings based on relative quality and price to allow comparison of individual and small group health insurance options.”); Lance Gable, *The Patient Protection and Affordable Care Act, Public Health, and the Elusive Target of Human Rights*, 39 J.L. MED. & ETHICS 340, 351 (2011) (“The IPAB recommendations for best practices and cost-effective treatments also could have a positive impact on quality.”).

207. Sandra Nunn, *Managing Audit Trails*, 80 J. AM. HEALTH INFO. 44, 44 (2009) (“Audit trails are records with retention requirements.”); John W. Hill et al., *A Proposed NHIN Architecture*, 48 AM. BUS. L.J. 503, 517 (2011) (“HITECH expanded the reach of HIPAA’s Privacy Rule. Patients must now be notified when their PHI is disclosed or used without their authorization. HITECH closed the loophole for business associates, established patients’ right to access and control of their PHI (including obtaining an audit trail showing all electronic disclosures), and prohibited companies from selling PHI without authorization.”). The audit trail is a sine qua non for technological due process. Danielle Keats Citron, *Technological Due Process*, 85 WASH. U. L. REV. 1249, 1305–06 (2008) (exploring the due process implications of automated system determinations and arguing that technological due process requires the inclusion of audit trails into automated systems). Nevertheless, even this mechanism of protection must be carefully implemented so that the audit process itself does not create its own potential for breaches. See, e.g., Dom Nicastrò, *HIPAA Auditor Involved in Own Data Breach*, HEALTHLEADERS MEDIA (Aug. 8, 2011), <http://www.healthleadersmedia.com/page-1/PHY-269480/HIPAA-Auditor-Involved-in-Own-Data-Breach> (reporting that a firm hired to conduct audits lost an unencrypted flash drive with 4,500 patient records).

sumers.<sup>208</sup> Second, they have accused HHS of engaging in stealth industrial policy, picking winners and losers in the health care field by effectively outlawing certain business models and promoting others.<sup>209</sup>

As HHS considers comments on the emerging information law of health reform, it should focus on moving from *transparency* to *intelligibility* in industry data. Rather than merely opening up the black box of presently maintained information, policymakers need to focus on developing the types of data entry standards and contractor-based analysis that can make that data actionable.

In 2010, the President's Council of Advisors on Science and Technology ("PCAST") warned against health information technology adoption that is uninspired by a vision for data use and sharing that would allow health care to enjoy the quality and efficiency gains characteristic of information industries.<sup>210</sup> Unfortunately, the EHR industry's rejection of the PCAST approach has stifled debate here.<sup>211</sup> The next Sections make a case for reviving PCAST's (and others') ambitious goals for health IT systems, based on the successes of IT in other parts of the economy. Effective health information technology depends on sophisticated surveillance: watching, recording, and analyzing patients, populations, and providers.<sup>212</sup>

### C. Monitoring Quality in Accountable Care Organizations

The history of American health care is littered with cost-reduction ideas that ran into the buzz saw of quality concerns, provider resistance, or patient rebellion.<sup>213</sup> While capitation promised to incentivize cost discipline, the many health maintenance organizations

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208. See *infra* note 264 and accompanying text.

209. See *infra* Part IV.

210. PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD 14 (2010), available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>.

211. Terry, *Anticipating*, *supra* note 111, at 111–12.

212. See Kenneth W. Goodman, *Ethics, Information Technology, and Public Health: New Challenges for the Clinician-Patient Relationship*, 38 J.L. MED. & ETHICS 58 (2010) (arguing that surveillance is necessary to ensuring useful health information is not ignored).

213. See, e.g., GREGG BLOCHE, *THE HIPPOCRATIC MYTH* (2010) (examining the conflicted history of American health care); Frank Pasquale, *The Hippocratic Math: How Much Should Society Spend on Health Care?*, 32 J. LEGAL MED. 529 (2012) (reviewing Gregg Bloche's book, *The Hippocratic Myth* (2010), and critiquing some cost reduction efforts).

(“HMOs”) charged with implementing the concept faced a backlash in the 1990s as they attempted to implement aggressive utilization review.<sup>214</sup> More recently, the less controversial ideas behind gainsharing ran into a number of legal obstacles.<sup>215</sup>

The PPACA has emphasized Accountable Care Organizations (“ACOs”) as a relatively ambitious form of cost cutting.<sup>216</sup> Implemented as part of a Medicare shared savings program,<sup>217</sup> ACOs are net-

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214. Thomas H. Greaney, *Managed Care: From Hero to Goat*, 47 ST. LOUIS U. L.J. 217, 217 (2003) (examining managed care in the 1990s); Joe White, *Markets and Medical Care: The United States, 1993–2005*, 85 MILBANK Q. 395, 426 (2007) (“Utilization reductions were part of the reason that cost increases slowed in the mid-1990s. Group/staff HMOs certainly did reduce hospitalization rates . . . . Moreover, health insurers did retreat from many of the methods of utilization controls that they had emphasized in the mid-1990s.” (citations omitted)).

215. Gainsharing is a financial arrangement that permits physicians to share in the savings that result when they alter practice patterns. Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 147 (2003). For example, a group of surgeons may engage in bulk purchasing to obtain discounts on surgical equipment, rather than each choosing instruments individually. Start-ups like Groupon and Living Social have exploited this savings model, but residual quality concerns have impeded its adoption in health care settings. Some recent pilot programs have indicated the potential for savings from gainsharing. Mike Kalison, Presentation at the Seton Hall Law Symposium on ACOs (Oct. 28, 2011).

216. PPACA § 3022(a)(1), 124 Stat. 119, 395 (codified at 42 U.S.C. § 1395jii(a)(1)); Frank Pasquale, *Accountable Care Organizations in the Affordable Care Act*, 42 SETON HALL L. REV. 1371, 1371 (“The Medicare Shared Savings Program (MSSP) . . . depends on Accountable Care Organizations (ACOs) to coordinate care for large groups of Medicare beneficiaries and reduce their overall costs while maintaining quality.”).

217. PPACA § 3022(a)(1), 124 Stat. 119, 395 (codified at 42 U.S.C. § 1395jii(a)(1)). The term ACO originated in a 2006 exchange. Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w56 n.7 (2007), <http://content.healthaffairs.org/content/26/1/w44.full>. It is designed to solve a classic “chicken and egg” problem in health care reform: whether to start with payment or delivery system reform. See KELLY DEVERS AND ROBERT BERENSON, URBAN INST., CAN ACCOUNTABLE CARE ORGANIZATIONS IMPROVE THE VALUE OF HEALTH CARE BY SOLVING THE COST AND QUALITY QUANDARIES? (2009), available at [http://www.urban.org/uploaded/pdf/411975\\_accountable\\_care\\_orgs.pdf](http://www.urban.org/uploaded/pdf/411975_accountable_care_orgs.pdf) (“Many believe that to bend the cost curve while improving quality, we must reform the provider payment system first, because it pays for volume rather than value. Others hold that it is impossible to change the payment system to achieve the desired objectives unless delivery system reform first produces organizations capable of handling an altered payment system. To avoid the quandary of where to start

works of providers and hospitals<sup>218</sup> that are charged with coordinating care for a group of at least 5000 Medicare beneficiaries.<sup>219</sup> As of early 2012, HHS had already named thirty-two “health care organizations and providers that are already experienced in coordinating care for patients across care settings” as pioneer ACOs.<sup>220</sup> ACOs can be physician-centered, hospital-centered, or some combination of the two.<sup>221</sup> CMS will reward the provision of quality care by giving providers participating in the ACO a share of the savings if risk-adjusted, per-beneficiary spending levels come in below a benchmark set by the agency at the outset.<sup>222</sup> For example, if benchmark spending was

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first—provider payment or delivery system reform—the ACO concept attempts to combine them.”); Sarah Klein, *Building Accountable Care Organizations that Improve Quality and Lower Costs—A View from the Field*, COMMONWEALTH FUND NEWSLETTER, June/July 2010, available at <http://www.commonwealthfund.org/Content/Newsletters/Quality-Matters/2010/June-July-2010/In-Focus.aspx>.

218. Bruce Merlin Fried et al., *Accountable Care Organizations: Navigating the Legal Landscape of Shared Savings and Coordinated Care*, 4 J. HEALTH & LIFE SCI. L. 88 (2010) (“A wide range of professionals may work together to establish ACOs, including physicians in group practice arrangements, networks of individual physician practices, hospitals, and partnerships or joint ventures between hospitals and physician groups. [Accountable Care Organizations] also may include other forms of groups as the HHS Secretary (Secretary) deems appropriate. By forming an ACO, these healthcare providers commit to being held accountable for the quality, cost, and overall care of Medicare beneficiaries.”).

219. Peter Fise, *Prognosis for Synergy Between Accountable Care Organizations and Bundled Payments in Medicare*, 28 J. CONTEMP. HEALTH L. & POL’Y 296, 297 (2012) (“Under Congress’ vision for ACOs, the program will encourage providers to establish new health care entities that coordinate care for an assigned group of at least 5,000 Medicare beneficiaries . . .”). ACOs have also been called “amorphous cluster[s] of possible collaborative models,” where hospitals are bound to remain central because “the largest avoidable Medicare costs are hospital related” and “in many communities, the hospital is the only organized care delivery entity capable of executing the model.” Jeff Goldsmith, *Accountable Care Organizations: The Case For Flexible Partnerships Between Health Plans And Providers*, 30 HEALTH AFF. 32, 33 (2011).

220. *Pioneer ACO Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://innovations.cms.gov/initiatives/aco/pioneer/> (last visited July 12, 2012).

221. Physician-centered ACOs could include multispecialty group practices (“MSGs”) and interdependent physician organizations (“IPOs”), also known as independent practice associations (“IPAs”). Wasif Ali Khan, *Accountable Care Organizations: A Response to Critical Voices*, 14 DEPAUL J. HEALTH CARE L. 309, 320–23 (2012).

222. See generally RTI INT’L, ACCOUNTABLE CARE ORGANIZATION 2012 PROGRAM ANALYSIS 1–2 (2012), available at <http://www.cms.gov/medicare/medicare-fee-for-service->

\$10,000 apiece for 10,000 beneficiaries in 2014, and the ACO reduced the spending to \$9,000 while maintaining quality levels, \$10 million in savings could be attained, some of which would compensate participants in the ACO for cutting costs while maintaining or improving quality.

Elliott Fisher, director of the Center for Health Policy Research at Dartmouth Medical School, has described the “three key attributes” of ACOs: “organized care, performance measurement, and payment reform.”<sup>223</sup> Fisher has argued that insurers are not well-positioned to improve the quality of health care because they “have largely focused on negotiating favorable prices within relatively open networks of providers” instead of trying to improve the health care their members received.<sup>224</sup> He believes that a “virtual organization” of physicians could do a better job if they teamed up with hospitals.<sup>225</sup> ACO refers to this legal alliance, which would be entitled to receive payments in exchange for cutting costs or improving quality.<sup>226</sup>

In an ACO, an “extended hospital medical staff” (or “a hospital-associated multispecialty group practice”) can join forces with a hospi-

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payment/sharedsavingsprogram/downloads/aco\_qualitymeasures.pdf (describing the shared savings program); see also Jackson Williams, *The “Shared Accountability” Approach to Physician Payment: Four Options for Developing Accountable Care Organizations*, 7 IND. HEALTH L. REV. 185 (2010) (describing the fee-for-service approach for Accountable Care Organizations).

223. Craig Schneider, *A Primer on Accountable Care Organizations*, MASS. MED. SOC'Y, <http://www.massmed.org/Content/NavigationMenu2/ContinuingEducationEvents/NewCourses/AccountableCareOrganizations101APrimer/Introduction/introduction.htm> (last visited Nov. 17, 2012) (citing Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44 (2007)).

224. Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w45 (2007). Private insurers have little incentive to keep current subscribers healthy over the long term, since at least half of subscribers on average churn into different plans within three years of signing up with a given plan. See Randall D. Cebul et al., *Organizational Fragmentation and Care Quality in the U.S. Healthcare System*, 22 J. ECON. PERSPECTIVES 93, 97 (2008) (arguing that shortening the insurer-policy holder relationship will lead to fewer investments in future health).

225. See Fisher et al., *supra* note 224, at w45.

226. See, e.g., Jackson Williams, *The “Shared Accountability” Approach to Physician Payment: Four Options for Developing Accountable Care Organizations*, 7 IND. HEALTH L. REV. 185, 186 (2010) (arguing that shared accountability occurs by “grouping doctors and hospitals together into discrete payment pools, through which collective performance could be rewarded as a unit”).

tal and agree to be compensated via a lump sum payment.<sup>227</sup> If the group manages to keep overall costs beneath the lump sum payment, it can share the gains among its members. Each part of the team also has an incentive to work together to keep those they care for healthy.<sup>228</sup> In an ideal world, the ACO responds to the concerns about fragmentation, as discussed by several health law experts.<sup>229</sup>

Nonetheless, there are skeptics. Jeff Goldsmith has worried about shadowy new pressures on providers that patients will not be aware of:

Consumers would not be aware that they were being treated by ACOs. Rather, they would be “attributed” to them: virtual patients of virtual organizations. Aggregate health spending for attributed patients would be tracked, and increases in that spending would be capped using a form of “shadow capitation.” ACOs that lived within the caps would get their fees increased. Those that overspent would see their fees reduced or frozen.<sup>230</sup>

Gail Wilensky believes that hospitals may dominate ACOs: “[I]f [hospitals] are the only entities receiving the payment, [there] will [be] a bad imbalance between groups of physicians and the hospitals.”<sup>231</sup> Robert Pear has also reported that a potential “frenzy of mergers involving hospitals, clinics and doctor groups eager to share costs

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227. Khan, *supra* note 221, at 317 (“An ACO under the Extended Medical Staff model would essentially be a hospital-associated, multispecialty group practice that is empirically defined by direct or indirect referral patterns to a hospital.”).

228. Williams, *supra* note 226.

229. See THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS (Einer Elhauge ed., 2010).

230. Jeff Goldsmith, *The Accountable Care Organization: Not Ready for Prime Time*, HEALTH AFF. BLOG (Aug. 17, 2009), <http://healthaffairs.org/blog/2009/08/17/the-accountable-care-organization-not-ready-for-prime-time/>; see also Craig Evan Pollack & Katarina Armstrong, *Accountable Care Organizations and Health Care Disparities*, 305 J. AM. MED. ASS'N 1706, 1707 (2011) (expressing concern that ACOs will avoid high-need areas); Jessica Mantel, *Accountable Care Organizations: Can We Have Our Cake and Eat It Too?*, 42 SETON HALL L. REV. 1393, 1405 (2012) (adducing evidence to demonstrate that it is sometimes very difficult to disincentivize unnecessary care without also discouraging needed interventions).

231. *Perspective Roundtable: Creating Accountable Care Organizations*, NEW ENG. J. MED. (Oct. 7, 2010), <http://www.nejm.org/doi/full/10.1056/NEJMp1009040> (transcript download available).

and savings” worries consumer advocates and antitrust scholars.<sup>232</sup> “The new law is already encouraging a wave of mergers, joint ventures and alliances in the health care industry,” as antitrust expert Thomas Greaney has noted.<sup>233</sup> He has stated: “The risk that dominant providers and dominant insurers may exercise their market power, individually or jointly, has never been greater.”<sup>234</sup>

ACOs also implicate fraud and abuse laws, since anti-kickback statutes and other prohibitions can hamstring efforts to create relevant financial incentives.<sup>235</sup> At a recent government workshop on ACOs, participants addressed “circumstances under which collaboration among independent health care providers in an ACO permits ACO providers to engage in joint price negotiations with private payers without running the risk of engaging in illegal price fixing under the antitrust laws.”<sup>236</sup> HHS also explored “the different ways in which

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232. Robert Pear, *As Health Law Spurs Mergers, Risks Are Seen*, N.Y. TIMES, Nov. 20, 2010, at A1 (“In an environment where health care providers are financially rewarded for keeping costs down,” [a lawyer for the Consortium for Citizens with Disabilities] said, “anyone who has a disability or a chronic condition, anyone who requires specialized or complex care, needs to worry about getting access to appropriate technology, medical devices and rehabilitation. You don’t want to save money on the backs of people with disabilities and chronic conditions.”); Tara Ragone, *Structuring Medicaid Accountable Care Organizations to Avoid Antitrust Challenges*, 42 SETON HALL L. REV. 1443, 1445 (2012) (discussing potential antitrust issues in an article primarily aimed at addressing them).

233. Pear, *supra* note 232; see also Thomas Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 843–44 (2011); Cory Capps & David Dranove, *Market Concentration of Hospitals*, BATES WHITE (June 2011), available at <http://www.ahipcoverage.com/wp-content/uploads/2011/06/ACOs-Cory-Capps-Hospital-Market-Consolidation-Final.pdf> (illustrating recent merger trends in the health care field).

234. Pear, *supra* note 232. There have been some recent wins for federal enforcers against certain major mergers, but the overall record of the past two decades has been one of consolidation. See, e.g., Joe White, *Markets and Medical Care: The United States, 1993–2005*, 85 MILBANK Q. 143 (2007) (“Hospital managers consolidated systems in order to strengthen their bargaining power with insurers, and studies show that consolidation did indeed enable hospitals to extract higher-than-average price increases.”).

235. Khan, *supra* note 221, at 326 (“Besides antitrust concerns, ACOs raise significant . . . fraud and abuse concerns.”).

236. Agenda, Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (“CMP”) Laws (Oct. 5, 2010), available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads/100510\\_Meeting\\_Agenda.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads/100510_Meeting_Agenda.pdf).

the Secretary may exercise waiver authority or create new exceptions and safe-harbors related to the physician self-referral law, the Anti-kickback statute and the CMP law in order to encourage the creation and development of ACOs.”<sup>237</sup> The American Medical Association (“AMA”) has pushed for “explicit exceptions to the antitrust laws” for participating doctors.<sup>238</sup> And, as Pear has reported, the president of the Federation of American Hospitals believes that “the fraud and abuse laws should be waived altogether.”<sup>239</sup>

Some scholars may share that skeptical view of fraud and abuse laws, at least as those laws pertain to the types of economic transactions necessary to make ACOs work.<sup>240</sup> Over the past twenty years, regulation of fraud and abuse has waxed and waned.<sup>241</sup> In 1996, James F. Blumstein concluded that “the modern American healthcare industry is akin to a speakeasy—conduct that is illegal is rampant and countenanced by law enforcement officials because the law is so out of sync with the conventional norms and realities of the marketplace.”<sup>242</sup> Nevertheless, as Joan Krause has shown, there are important public purposes behind these laws, and it is troubling to see a hospital leader advocating for them to be swept away *tout court*, as in the case of ACOs.<sup>243</sup> Policymakers should also be cautious about granting overly broad antitrust exemptions to ACOs in a field where competition law’s prerogatives have already been whittled away.<sup>244</sup>

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237. *Id.*

238. AM. MED. ASS’N, AMERICAN MEDICAL ASSOCIATION TALKING POINTS: CMS OPEN DOOR FORUM ON ACOS (2010), available at <http://www.ama-assn.org/ama1/pub/upload/mm/399/talking-points-acos.pdf>.

239. Pear, *supra* note 232.

240. See, e.g., Khan, *supra* note 221, at 337–40 (noting that “ACO waivers are a significant departure from the requirements of existing fraud and abuse laws”).

241. See, e.g., V. Michel Magloire Marcoux, *Why Healthcare Fraud and Abuse Laws Should Allow Appropriate Hospital Gainsharing*, 59 ALA. L. REV. 539, 540 (2008) (“Departing from its previously distrustful view of hospital gainsharing agreements, OIG issued an Advisory Opinion in January 2005 promising not to impose sanctions for violations of healthcare fraud and abuse statutes on a hospital’s gainsharing program . . .”).

242. James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 218 (1996).

243. Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 243 (2004).

244. *Fact Check: Provider Consolidation Drives Up Prices*, AMERICA’S HEALTH INSURANCE PLANS COVERAGE (Feb. 17, 2012), <http://www.ahipcoverage.com/2012/02/17/fact-check-provider-consolidation-drives-up-prices/>. An alternative is to give up on health care anti-

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Legal scholar Kevin Werbach has observed that the Internet is centripetal, “pull[ing] itself together as a coherent whole.”<sup>245</sup> For Werbach, network formation theory explains these centripetal tendencies and some of “the pressures threatening to pull the Internet apart” into balkanized units.<sup>246</sup> Werbach has counseled that governments need to “catalyz[e] network formation, and moderat[e] the forces that push towards excessive concentration of power.”<sup>247</sup> These recommendations should also govern new efforts to create “virtual networks” of care in the wake of PPACA. Like many forms of network power, the ACOs could quickly have negative unintended consequences if regulators fail to anticipate the ways they could be abused.<sup>248</sup> ACOs may work, but only if policymakers can replace classic instruments of health care regulation with calibrated financing decisions that reflect new industry realities.<sup>249</sup> Health information technology will be vital to this transition.<sup>250</sup>

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trust as a largely failed project, and to start regulating dominant ACOs as veritable health care utilities, as critical to regional infrastructure as roads, electricity, or water. See Frank Pasquale, *The Limits of Competition*, CONCURRING OPINIONS (Oct. 26, 2009), <http://www.concurringopinions.com/archives/2009/10/the-limits-of-competition-and-the-rebirth-of-the-public-option.html> (suggesting that antitrust exemptions may be responsible for certain insurer failures). The logic of concentration seems inevitable in the field: Insurers and providers have long been in an arms race for bargaining power, and as soon as one side gets permission to merge or acquire, the other clamors for it. *Id.*

245. Kevin D. Werbach, *The Centripetal Network: How the Internet Holds Itself Together, and the Forces Tearing it Apart*, 42 U.C. DAVIS L. REV. 343, 343 (2009).

246. *Id.* at 345.

247. *Id.* at 346, 410.

248. See Frank Pasquale, *Network Power: Forced and Free*, CONCURRING OPINIONS (May 27, 2008), [http://www.concurringopinions.com/archives/2008/05/network\\_power\\_f.html](http://www.concurringopinions.com/archives/2008/05/network_power_f.html) (analogizing the success at Google to network effects and government intervention that created network power for telephone and cable companies).

249. See Peter Fise, *Prognosis for Synergy Between Accountable Care Organizations and Bundled Payments in Medicare*, 28 J. CONTEMP. HEALTH L. & POL’Y 296, 322–23 (2012) (concluding that programs must be implemented with flexible regulations).

250. Amy K. Fehn, *The Importance of Health Information Technology for Accountable Care Organizations*, ABA HEALTH ESOURCE (June 2, 2011), [http://www.americanbar.org/newsletter/publications/aba\\_health\\_esource\\_home/aba\\_health\\_law\\_esource\\_1106\\_aco\\_fehn.html/](http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1106_aco_fehn.html/) (“The proposed rules for Accountable Care Organizations (ACOs) participating in Medicare Shared Savings Program . . . highlights the important role health information technology will play . . .”).

In the older instances of capitation and gainsharing, critics worried that providers would be incentivized to cut costs by skimping on care.<sup>251</sup> The ACO concept attempts to avoid this problem by fully preserving fee for service payments under Medicare's Diagnosis Related Group System (for hospitals) and the Resource Based Relative Value Scale System (for physicians).<sup>252</sup> It also conditions the distribution of any gains on maintenance of a certain baseline of quality.<sup>253</sup> In the notice of proposed rulemaking on ACOs in early 2011, HHS announced sixty-five quality indicators that ACOs would need to report.<sup>254</sup> After a blizzard of critical comments, the agency backed down in the final rule, only requiring thirty-three measures.<sup>255</sup>

Since care coordination is a large part of the value proposition of ACOs, they can be counted on to deploy advanced health information technology.<sup>256</sup> Moreover, the mandated flexibility of the ACO concept will require nimble systems that allow patients to move in and out of

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251. See, e.g., William H. Thompson, *Aligning Hospital and Physician Incentives in the Era of Pay-for-Performance*, 3 IND. HEALTH L. REV. 327, 341 (2006) ("By their nature, gainsharing programs are focused almost entirely on cost-savings, not quality or efficiencies; although cost, quality and efficiencies are not necessarily mutually exclusive.").

252. Jackson Williams, *The "Shared Accountability" Approach to Physician Payment: Four Options for Developing Accountable Care Organizations*, 7 IND. HEALTH L. REV. 185, 190 (2010) ("The ACO is seen as having the potential to harness some of the positive characteristics of managed care—such as . . . the infrastructure of an integrated delivery system—without the negative characteristics . . . because it remains a fee-for-service system, retaining independent proprietorships, and any financial incentives to stint on care can be counterbalanced, or outweighed, by incentives to improve patient outcomes.").

253. See RTI INT'L, *supra* note 222, at 1 ("[I]f an ACO meets quality standards and achieves savings and also meets or exceeds a Minimum Savings Rate (MSR), the ACO will share in savings, based on the quality score of the ACO.").

254. 76 Fed. Reg. 19,528, 19,571–19,591 (Apr. 7, 2011).

255. 76 Fed. Reg. 67, 802, 67,889–67,890 (Nov. 2, 2011). The thirty-three measures included one based on data provided to CMS and ONC-HIT as part of the HITECH incentive programs for Health IT adoption; seven focused on patient/caregiver experiences, to be reported by conducting patient surveys; three focused on care coordination, to be reported by using medical claims; and several at-risk population measures (for those with diabetes, heart disease, and some other conditions) to be reported under a group practice reporting option system. *Id.*

256. Terry, *Anticipating*, *supra* note 111, at 110 ("[A]s laboratories for future healthcare models, ACOs are expected to innovate through their adoption of HIT ["Health Information Technology]").

particular ACOs.<sup>257</sup> This health IT should also prove valuable in building a quality case for individual ACOs claiming shared savings, and for ACOs as a delivery system of reform generally.<sup>258</sup>

Consultants are already advising on “what IT underpinnings will be necessary” for accountable care models.<sup>259</sup> At a Healthcare Information and Management Systems Society conference, Dave Garets, an executive director at the Advisory Board Company, discussed how ACOs would need IT upgrades for network interconnectivity, clinical knowledge management, patient participation, financial operations, and population risk management.<sup>260</sup> Patients may start with simple email access to scheduling, then “graduate” to full PHRs and passive monitoring of health status.<sup>261</sup> Clinical knowledge management can evolve from EHRs to structured clinical documentation and predictive analytics.<sup>262</sup> Network interconnectivity could plug the ACO into larger health information exchanges designed to monitor regional populations.<sup>263</sup>

Though implementation may be technical and complex, sophisticated informatics can promote uncontroversial goals.<sup>264</sup> For exam-

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257. *See id.* at 108 (“As originally conceptualized ACOs would require. . . robust HIT systems in order to integrate the data flow between the participants and to provide outcomes reporting.”).

258. *Id.* at 109.

259. Jennifer Prestigiacomo, *IT Blueprints for ACOs*, HEALTH CARE INFORMATICS (Feb. 20, 2012), <http://www.healthcare-informatics.com/article/it-blueprint-acos>; *see also* Terry, *Anticipating*, *supra* note 111, at 108 (“HIT requirements and synchronization with MU [meaningful use] pervaded the ACO proposed regulation.”).

260. *See* Mike Milliard, *Garets Is Sanguine About IT Future—with Caveats*, HEALTHCARE IT NEWS (Feb. 18, 2010), <http://www.healthcareitnews.com/print/11946> (discussing conference and Garets’ comments).

261. Nicolas P. Terry, *Personal Health Records: Directing More Costs and Risks to Consumers?*, 1 DREXEL L. REV. 216, 220 (2009).

262. *See e.g.*, SHARON SILOW-CARROLL ET AL., THE COMMONWEALTH FUND, USING ELECTRONIC HEALTH RECORDS TO IMPROVE QUALITY AND EFFICIENCY: THE EXPERIENCES OF LEADING HOSPITALS 4, 17 (2012) (noting that EHRs are increasingly being used by hospitals for clinical documentation and predictive analytics).

263. *Id.* at 21, 32–33 (concluding that hospitals should use EHRs for regional data exchanges for sharing data with other hospitals).

264. Daniel Marino, *Translating Accountable Care Goals into IT Action*, HEALTHCARE INFORMATICS (Aug. 30, 2011), <http://www.healthcare-informatics.com/article/translating-accountable-care-goals-it-action> (“The push for accountable care has created a new vocabulary for healthcare leaders: clinical integration, longitudinal records, ambulatory net-

ple, a “clinical data repository (also called a patient disease registry) . . . allows an organization to report off clinical data, which is needed for calculating actual clinical quality outcomes and comparing them against industry benchmarks.”<sup>265</sup>

#### *D. Data-Driven Drug and Device Optimization*

There are serious deficiencies in America’s system of pharmacovigilance—namely “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”<sup>266</sup> This Section reviews leading reform proposals and explains how some of the tactics and methods developed by leading information industries could be applied to the assessment of drugs and devices.<sup>267</sup>

Digitized health data should enable extraordinary new possibilities for medical research.<sup>268</sup> Observational research (based on actual patients’ experience with drugs and procedures) may turn out to be more useful than clinical trials once a critical mass of outcomes has been recorded and researchers can control for environmental and other variations.<sup>269</sup> Legal scholars have examined the trade-offs between data portability, standardization, privacy, and innovation in EHRs.<sup>270</sup> One key to policy success in the EHR field will be distin-

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works, patient registries, care protocols, and more. Many hospital CIOs are uncertain how to piece it all together, and they are having trouble pinning down the IT requirements for making accountable care a reality.”).

265. *Id.*

266. WORLD HEALTH ORG., THE IMPORTANCE OF PHARMACOVIGILANCE 7 (2002), *available at* <http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf>.

267. *See infra* Part III.D.

268. PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT: REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTH CARE FOR AMERICANS: THE PATH FORWARD 5 (2010), *available at* <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf> (describing potential improvements in care).

269. *Id.* at 66–67.

270. *See* Greg R. Vetter, *Slouching Toward Open Innovation: Free and Open Source Software for Electronic Health Information*, 30 WASH. U. J.L. & POL’Y 179, 179–86 (2009) (arguing that “contemporary FOSS [free and open source software]” approaches to open innovation may not necessarily fit every software market [for electronic health information]” and examining the issues with FOSS in a “business-to-business software market within health care where the U.S. government recently has supported efforts to promote a FOSS product”);

guishing between raw data (which should be both portable and, when properly anonymized, subject to academic research)<sup>271</sup> and its interpretation and organization (which are more justifiably considered intellectual property of a particular firm).<sup>272</sup> Vendors of EHR software can exploit a combination of trade secrecy law and licensing agreements to help providers “lock up” data in proprietary formats.<sup>273</sup> If any particular entity retains excessive control over data, many important forms of research may be unduly limited.<sup>274</sup> Scientists also worry about a trend toward obscurity in the computational modeling of medical interventions.<sup>275</sup>

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Barbara Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 70–77 (2011) (arguing that the “debate should be about appropriate public uses of private data and how best to facilitate these uses while adequately protecting individuals’ interests”); Marc Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 AM. J.L. & MED. 586, 586–89 (2010) (noting that the way in which “the law defines ownership of patient data will shape whether its benefits can be developed and also affects patient confidentiality” and arguing that “treating patient data as private property precludes forming comprehensive databases required for many of its most important public health and safety uses”).

271. Marc A. Rodwin, *The Case for Public Ownership of Patient Data*, 302 J. AM. MED. ASS’N 86, 88 (2009). For a good discussion of laws about anonymization procedures, see Barbara Evans, *Ethical and Privacy Issues in Pharmacogenomic Research*, in PHARMACOGENOMICS: APPLICATIONS TO PATIENT CARE (Howard L. McLeod et al. eds., 2d ed. 2009).

272. For the benefits of such data analysis, see David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 16 (2005); Walter F. Stewart et al., *Bridging the Inferential Gap: The Electronic Health Record and Clinical Evidence*, 26 HEALTH AFF. w181, w181–82 (2007).

273. Pasquale, *Restoring Transparency*, *supra* note 200.

274. See Longman, *supra* note 131, at 23 (alleging that “billions of taxpayers’ dollars are about to be poured into expensive, inadequate proprietary software, thanks to a provision in the stimulus package”). There are indications that the agencies may be responding to concerns like those expressed by Longman. See, e.g., Jordan T. Cohen, *CMS and HHS Release New Proposed Rules Governing Health IT—Part 1: Overview of Proposed Rule on “Meaningful Use,”* HEALTH REFORM WATCH (Jan. 3, 2010), <http://www.healthreformwatch.com/2010/01/03/cms-and-hhs-release-new-proposed-rules-governing-health-it-%E2%80%93part-1-overview-of-proposed-rule-on-%E2%80%9Cmeaningful-use%E2%80%9D/>.

275. Jennifer Kahn, *Modeling Human Drug Trials—Without the Humans*, WIRED, Dec. 2009, at 156, 157, 194 (“In early 2004 . . . the American Diabetes Association asked a physician and mathematician named David Eddy to run his own . . . trial [on atorvastatin]. He would do it, though, without human test subjects, instead using a computer model he had designed called Archimedes. The program was a kind of SimHealth: a vast compendium of medical knowledge drawn from epidemiological data, clinical trials, and physician in-

Efthimios Parasidis's article, *Patients over Politics*, is among the leading legal academic proposals for reform of systems of pharmacovigilance.<sup>276</sup> Parasidis begins by focusing on popular misconceptions about the role of the FDA and the scope of its powers.<sup>277</sup> Many consumers assume that the FDA has carte blanche authority and ample funding to detect adverse effects from drugs once they are marketed.<sup>278</sup> Parasidis shows, however, that even after the Vioxx scandal, an Institute of Medicine report recommending a vast increase in its powers, and the passage of the Food & Drug Administration Amendments Act of 2007, the FDA still lacks the "resources to compel, monitor, and review post-market research" adequately.<sup>279</sup> Parasidis examines in detail the long history of FDA underfunding and the more recent political dynamics that help ensure that this underfunding will continue to be the case.<sup>280</sup> He convincingly argues that post-approval surveillance will only reach its full potential if a wider array of stakeholders begins to take advantage of the emerging health data infrastructure to critically evaluate the effects of various treatments.<sup>281</sup>

If the free flow of data can be elevated to constitutional status to run roughshod over privacy concerns (as in the case of *Sorrell v. IMS Health Inc.*<sup>282</sup>), perhaps it may eventually improve pharmacovigilance by trumping trade secrecy laws.<sup>283</sup> Pharmaceutical firms have some-

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interviews, which Eddy had laboriously translated into differential equations over the past decade. . . . Eddy's secretive habits are . . . troubling, according to David Nathan, director of the Diabetes Center at Massachusetts General Hospital. "If you listen to David, he has 10,000 variables and differential equations describing everything from blood sugar to office furniture . . . . But it's never quite clear what they are or how they interact. All the calculations happen inside a black box. And that's a problem because there's no way to tell whether the model's underlying assumptions are right."").

276. Parasidis, *supra* note 40, at 929, 977 (proposing "reform measures that mitigate risk-enhancing aspects of the regulatory framework for medical products").

277. *Id.* at 931.

278. *Id.* at 931–32.

279. *Id.* at 931. By proposing integration of post-market drug surveillance into an extant health IT infrastructure, Parasidis tries to sidestep bitter political battles about the funding of new FDA initiatives. *Id.* at 984–85.

280. *Id.* at 936–60.

281. *Id.* at 970–74.

282. 131 S. Ct. 2653 (2011).

283. *Id.* at 2670–72 (ruling that drug companies have a constitutional right to access certain types of data without undue state interference). For a critical description of the stakes of *Sorrell*, see David Orentlicher, *Prescription Data Mining and the Protection of Patients'*

times continued to market drugs even after reports emerge that undermine the rationale for taking the drug, let alone paying for it.<sup>284</sup> If Parasidis's policy proposals are enacted, they will seriously undercut that troubling method of attaining short-term profits at the cost of long-term sustainable business models.<sup>285</sup>

Sharona Hoffman and Andy Podgurski have detailed how such advanced programs of research on effectiveness could work.<sup>286</sup> Their proposal for new forms of personalized medicine takes to the individual level what Parasidis envisions for population-wide analysis:

We propose the development of a broadly accessible framework to enable physicians to rapidly perform, through a computerized service, medically sound personalized comparisons of the effectiveness of possible treatments for patients' conditions. A personalized comparison of treatment effectiveness . . . for a given patient (the subject patient) would be based on data from EHRs of a cohort of patients who are similar to the subject patient (clinically, demographically, genetically), who received the treatments previously and whose outcomes were recorded.<sup>287</sup>

According to Hoffman and Podgurski, such a database query could identify "for a given patient, an appropriate reference group (cohort) of similar, previously treated patients whose EHRs would be

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*Interests*, 38 J.L. MED. & ETHICS 74, 81 (2010) ("When people develop relationships with their physicians and pharmacists, they are entitled to the assurance that information about their medical condition will be used for their benefit and not to place their health at risk or to increase their health care costs."); Frank Pasquale, *Privacy as a First Amendment Value*, HEALTH CARE BLOG (Apr. 29, 2011), <http://thehealthcareblog.com/blog/2011/04/29/rethinking-ims-health-v-sorrell-privacy-as-a-first-amendment-value/>.

284. See Pasquale, *Restoring Transparency*, *supra* note 200, at 240 (recognizing that "[p]harmaceutical companies also push to keep exclusive access to their own data—even when serious public health concerns arise about their products").

285. See Parasidis, *supra* note 40, at 934 (explaining that until systems of post-market surveillance are far more sophisticated, tort law will play a critical role in establishing a baseline of evidence to measure the true costs and benefits of drugs). Unfortunately, as Parasidis documents, "[f]ederal statutes grant broad immunities to vaccine and medical device sponsors, and generic drug sponsors are immune from all state law failure-to-warn claims." *Id.* This makes responsive regulation all the more essential.

286. Hoffman & Podgurski, *Improving Health Care Outcomes Through Personalized Comparisons of Treatment Effectiveness Based on Electronic Health Records*, 39 J.L. MED. & ETHICS 425, 425 (2011) [hereinafter Hoffman & Podgurski, *Improving Health Care Outcomes*].

287. *Id.*

analyzed to choose the optimal treatment for the patient at issue.”<sup>288</sup> Their proposal is a logical extension of an idea promoted in an Institute of Medicine report known as the “Wilensky Proposal,” which called for more targeted comparative effectiveness research.<sup>289</sup> Research has already demonstrated that pharmacogenetic algorithms can outperform algorithms that consider only clinical factors.<sup>290</sup>

The PCAST also endorsed aggressive use of health data to ensure new research opportunities.<sup>291</sup> The PCAST authors concluded that many clinical research studies today are “out of date before they are even finished,” “burdensome and costly,” and too narrowly focused.<sup>292</sup> They endorsed health information technology that is enabled for “syndromic surveillance,” “public health monitoring,” and “adverse event monitoring” by aggregating observational data.<sup>293</sup>

Of course, there are challenges to this type of research. Systems must move beyond mere transparency to data entry standards that allow for the intelligibility required by personalized medicine.<sup>294</sup> As Hoffman and Podgurski recognize, “the need to code all presenting comorbidities” and to identify “patients who have the specific condition to be studied” is crucial to data quality.<sup>295</sup> There is a tension between untrammelled innovation by vendors at any given time and later, predictable needs of patients, doctors, insurers, and hospitals to compare their records and to transport information from one filing system to another.<sup>296</sup>

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288. *Id.* at 426.

289. *See* INST. OF MED., CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 52 (2007) (addressing comparative effectiveness).

290. J. Woodcock and L. J. Lesko, *Pharmacogenetics—Tailoring Treatment for the Outliers*, 360 NEW ENG. J. MED. 811, 811 (2009).

291. PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., *supra* note 268, at 64 (recommending use of “large datasets” to address numerous issues in clinical research).

292. *Id.* at 63.

293. *Id.* at 64.

294. *See* Hoffman & Podgurski, *Improving Health Care Outcomes*, *supra* note 286, at 429 (explaining the benefits of personalized comparisons of treatment effectiveness (PCTEs), a form of personalized medicine, that uses information obtained through a large database search to “find a cohort for a patient needing treatment”).

295. Hoffman & Podgurski, *Improving Health Care Outcomes*, *supra* note 286, at 433.

296. Sharona Hoffman & Andy Podgurski, *Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 Harv. J.L. & Tech. 103, 151 (2008) [hereinafter Hoffman & Podgurski, *Finding A Cure*] (describing the tension and recommending

For example, one system may be able to understand “C,” “cgh,” or “koff” as “cough,” and may well code it in any way it chooses.<sup>297</sup> But to integrate and to port data, all systems need to be able to translate symptoms, diagnoses, interventions, and outcomes into commonly recognized coding.<sup>298</sup> Competition also depends on data portability: Health care providers can only credibly threaten to move their business away from an unsatisfactory vendor if they can transport those records.<sup>299</sup> Patients want their providers to seamlessly integrate records.<sup>300</sup> Stage II of meaningful use regulation can promote a common language of medical recordkeeping.<sup>301</sup> As Hoffman and Podgurski recommended in 2008:

[I]t is necessary for all vendors to support what we will call a “common exchange representation” (“CER”) for EHRs. A CER is an artificial language for representing the information in EHRs, which has well defined syntax and semantics and is capable of unambiguously representing the information in any EHR from a typical EHR system. EHRs using the CER should be readily transmittable between EHR systems of different vendors. The CER should make it easy for vendors of EHR systems to implement a mechanism for translating accurately and efficiently between the CER and the system’s internal EHR format.<sup>302</sup>

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regulations that “require EHR system vendors and health care providers to make reasonable efforts to identify and employ best practices relating to all of the following: hazard and risk analysis and mitigation; software development, validation, and maintenance; security measures; and system integration and operation”).

297. *Id.* at 152 (noting that “medical terminology is complex, variable, and evolving”).

298. *Id.* at 153 (promoting a “common exchange representation” (CER), an artificial language that represents information).

299. Niva Elkin-Koren, *User-Generated Platforms*, in *WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY* 111, 121–22 (Rochelle C. Dreyfus, Harry First & Diane L. Zimmerman eds., 2010) (describing the importance of data portability).

300. David Lagesse, *Deloitte: Patients Want Electronic Health Records*, U.S. NEWS AND WORLD REPORT (Mar. 4, 2008), [http://money.usnews.com/money/blogs/daves-download/2008/03/04/deloitte-patients-want-electronic-health-records\\_print.html](http://money.usnews.com/money/blogs/daves-download/2008/03/04/deloitte-patients-want-electronic-health-records_print.html) (noting that a survey by the Deloitte Center for Health Solutions reported that “3 of 4 consumers want their doctors to provide online access to an integrated medical record and that 1 in 4 would pay more for the service”).

301. Hoffman & Podgurski, *Finding a Cure*, *supra* note 286, at 151–53 (citing the difficulties that medical terminology presents in EHR system record keeping).

302. *Id.* at 153.

There are also important opportunities for standardization in the security field.<sup>303</sup> The discussion can quickly become technical, but the underlying purpose is clear: to develop some standard forms of interacting in a realm where “spontaneous order” is unlikely to arise, and where network effects (as well as what David Grewal describes as network power) could lead to the lock-in of suboptimal patterns of data storage and transfer.<sup>304</sup>

Parasidis also describes how the development of health IT infrastructures in the United States can enable forms of surveillance that are more rigorous, comprehensive, and actionable in the world of policy and more user-friendly for patients.<sup>305</sup> As he observes, “EHR systems now permit advanced data-entry options such as ‘free text [entry], templated data entry, dictation, speech recognition, and freehand graphic input.’”<sup>306</sup> Rather than getting between doctor and patient, advanced EHR stands poised to silently monitor and improve their relationship.<sup>307</sup> The same record systems that are designed to digitize health diagnoses and interventions can also generate outcome data if they are configured appropriately. Such data would help ensure that patients and authorities are truly informed about the risks and benefits of drugs.<sup>308</sup> A complete record of “demographics, progress notes, vital signs, medical history, immunization history, and laboratory and radiological reports” can contribute greatly to “evidence-

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303. *Id.* at 156 (“As is true for a common exchange format, standardized security policies and mechanisms are unlikely to be adopted by vendors and providers without a regulatory mandate. In order to facilitate compliance and provide vendors with clear guidance, the regulatory mandate might incorporate, by explicit reference, some established and emerging security standards, such as the Internet Engineering Task Force’s Transport Layer Security (“TLS”) standard or its Public-Key Infrastructure (X.509) standard.”).

304. DAVID GREWAL, NETWORK POWER: THE SOCIAL DYNAMICS OF GLOBALIZATION 21–22 (2009) (advancing an argument that “focus[es] on the power that standards have in bringing in to being new global networks”). One of the greatest challenges for health care providers as they adopt this type of technology is balancing proprietary interests in innovative data entry options and modes of representation with the public need for interoperability and portability of data. *Id.* at 23. The second two stages of “meaningful use” requirements established by HHS will need to balance these two goals. *Id.* Standards play a crucial role in networks—they determine how people and entities are connected. *Id.*

305. Parasidis, *supra* note 40, at 966–67.

306. *Id.* at 965.

307. *Id.*

308. *Id.* at 967–68.

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based decision support, quality management, and health-outcomes reporting at both the individual and population levels.”<sup>309</sup>

In the realm of health IT, Parasidis, Terry, Hoffman, and Podgurski are among the first legal academics to convincingly merge literatures of health system transformation, practical implementation, and legal guidance. They suggest that the practical feasibility of transforming healthcare generally, and post-market pharmaceutical surveillance in particular, into an information industry with the types of productivity gains we usually associate only with Silicon Valley.<sup>310</sup> As Parasidis notes of the FDA’s deployment of “Mini-Sentinel:”

Rather than creating a centralized database, Mini-Sentinel uses a distributed data network that is linked by a coordinating center. The Mini-Sentinel data network incorporates EHRs from diverse data sets that are maintained by public and private stakeholders. Each data partner retains control over its own patient-level data and permits others to access its aggregated and de-identified medical data.<sup>311</sup>

Just as the Department of Homeland Security (“DHS”) and National Security Agency (“NSA”) have advanced domestic intelligence capabilities by querying distributed databases from diverse public and private sector partners, the FDA can now apply such technology toward improving population health.<sup>312</sup> As the next Part shows, creative partnerships with private sector contractors can build institutional capacity to promote public health.

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309. *Id.* at 964.

310. See Parasidis, *supra* note 40, at 984–86 (proposing integration of post-market drug surveillance into an extant health IT infrastructure); Hoffman & Podgurski, *Improving Health Care Outcomes*, *supra* note 286, at 425 (proposing the development of a “broadly accessible framework” that enables doctors to quickly perform comparisons of treatments); Hoffman & Podgurski, *Finding a Cure*, *supra* note 296, at 151 (recommending regulations that require doctors to use IT to improve practices).

311. Parasidis, *supra* note 40, at 971.

312. For an account of the DHS approach, see Danielle Keats Citron and Frank Pasquale, *Network Accountability for the Domestic Intelligence Apparatus*, 62 HASTINGS L.J. 1441, 1449 (2011) (discussing the close ties of private entities to state and federal “fusion centers,” which collect and share information and intelligence).

#### IV. WATCHING THE WATCHERS: PROTECTING PRIVACY AND PROPRIETARY DATA

Comparing homeland security and health surveillance may strike some readers as either facile or menacing. To be sure, the quest for intelligibility described above has some resonance with the concept of “legibility” explored and critiqued in works like James A. Scott’s *Seeing Like a State*.<sup>313</sup> We can all imagine troubling misuses of data.<sup>314</sup> But there are important differences between the models of data collection and analysis proposed by entities like PCAST and the clumsier, more manipulative models of population management criticized in the surveillance studies literature.<sup>315</sup>

First, medical researchers have already developed elaborate methods of de-identifying and protecting data in research settings.<sup>316</sup> Scholars like Parasidis, Hoffman, and Podgurski propose an extension of the research enterprise into the vast stores of data that will be enabled by advanced health information technology.<sup>317</sup> In the case of incidental findings, Susan Wolf has already identified a fading boundary between research and treatment, which might occasion an intervention in the midst of an experimental inquiry devoted to entirely different aims.<sup>318</sup> If carefully applied to the realm of personalized comparisons of treatment effectiveness and comparative effectiveness

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313. See generally JAMES A. SCOTT, *SEEING LIKE A STATE: HOW CERTAIN SCHEMES TO IMPROVE THE HUMAN CONDITION HAVE FAILED* (1998) (critiquing “schematic visions” that fail to respect local knowledge and variation).

314. Several laws address such misuses. See, e.g., Breach Notification for Unsecured Protected Health Information Interim Final Rule, 45 C.F.R. § 164 (2011); FTC Health Data Breach Notification Final Rule, 16 C.F.R. § 318 (2012).

315. THE SURVEILLANCE STUDIES READER 13 (Sean P. Hier & Josh Greenberg eds., 2007) (surveying critiques of panoptic, cryptopic, and other forms of oppressive monitoring).

316. Properly deployed, de-identification can protect patients’ privacy while enabling research. See Evans, *supra* note 271 (describing “several important categories of tissue specimens and health data commonly used in pharmacogenetic research (for example, anonymized, coded, and identified tissue specimens and health data)” and distinguishing “privacy authorization requirements under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule from informed consent requirements”).

317. See *supra* Part III.D.

318. See generally, Susan M. Wolf, *Incidental Findings in Neuroscience Research: A Fundamental Challenge to the Structure of Bioethics and Health Law*, in OXFORD HANDBOOK OF NEUROETHICS (Judy Illes & Barbara Sahakian eds., 2011).

research, researchers' extant standards of anonymization and de-identification could allay many privacy concerns.<sup>319</sup> Combined with audit trails, which document access to records, and real penalties for breaches, these practices could promote a health data infrastructure that addresses concerns about misuse of data.<sup>320</sup>

Second, both HHS and DOJ have developed an extraordinary apparatus for combating fraud and abuse.<sup>321</sup> The public-private surveillance partnerships pioneered in their fraud-fighting efforts are a model for both the first-order problem of collecting and analyzing data and the second-order problem of "watching the watchers" to ensure that data is used properly.<sup>322</sup> Having honed these techniques in the context of law enforcement to protect the public purse, HHS now needs to turn them to assuring the integrity and effectiveness of a developing health information network.<sup>323</sup> The first step will be another "grand bargain" for big data: more access to patient records in exchange for greater accountability for their use.<sup>324</sup>

A. *Privacy, De-Identification, and Research*

Two of the most important issues affecting health technology policy are transparency and access. Regulators must decide whether to permit innovators to control data flows to give them incentives, and where such control must end to respect broader social concerns about privacy.<sup>325</sup> Individuals justly are concerned that data or specimens related to them can be used in ways that compromise future opportunities. As William Pewen has noted, "Americans' support for the use of their [EHRs]—even to facilitate treatment and payment—is limited; 78 percent supported giving physicians access to their EHR, while only 30 percent favored health plan access."<sup>326</sup> Research data

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319. *See infra* Part IV.A.

320. *See infra* Part IV.A.

321. *See infra* Part IV.B.

322. *See infra* Part IV.B.1.

323. *See infra* Part IV.B.2.

324. *See infra* Part IV.B.2.

325. *See* Pasquale, *Restoring Transparency*, *supra* note 200, at 242–43 (discussing the privacy concerns of patients and secrecy protections of companies).

326. William Pewen, *Breach Notice: The Struggle for Medical Records Security Continues* ("[P]atients have been outraged to receive solicitations for purchases ranging from drugs to burial plots, while at the same time receiving care which is too often uncoordinated and unsafe. It is no wonder that many Americans take a circumspect view of health IT.").

may be even more sensitive than entries about a patient's existing conditions and complaints, since it can include direct and incidental findings whose implications have not been fully considered and explored by the patient.<sup>327</sup>

These concerns are reflected in health privacy law. Entities covered by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") are restricted in their uses of health information in many settings.<sup>328</sup> Compliance professionals must navigate a complex legal landscape as they conduct medical research.<sup>329</sup> The Federal Policy for the Protection of Human Subjects (the "Common Rule"), the FDA framework of human-subject protections, HIPAA, and related regulations create many obligations.<sup>330</sup> Breach notification laws encourage encryption.<sup>331</sup> As Barbara Evans has noted, "[t]he Federal regulations allow individual states to impose additional, higher privacy and human-subject protections on research that is within each state's jurisdiction," creating another layer of complexity in the compliance process.<sup>332</sup> State laws requiring affirmative consent can upend the expectations of researchers who have meticulously complied with federal rules and guidelines.<sup>333</sup>

One way to reassure patients that their data will not be misused is to reduce or encrypt the linkage between data and its source.<sup>334</sup> Various legal regimes have created a complex set of terminologies for in-

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327. See, e.g., Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 241 (2008) (noting that an incidental finding may reveal sensitive data the person may not want shared).

328. 45 C.F.R. § 164.502(b)(1) (2011).

329. See *Regulations*, HHS.GOV, <http://www.hhs.gov/ohrp/humansubjects/index.html> (last visited Nov. 18, 2012) (highlighting federal regulations).

330. CARL COLEMAN ET AL., *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* (2005).

331. They encourage, but do not require, encryption, by reducing penalties for the loss of encrypted data. Harley Geiger, *HHS Should Require the Encryption of Portable Devices to Curb Health Data Breaches*, CTR. FOR DEMOCRACY & TECH. (Mar. 16, 2011), <https://www.cdt.org/blogs/harley-geiger/hhs-should-require-encryption-portable-devices-curb-health-data-breaches>.

332. Evans, *supra* note 271, at 330.

333. *Id.* at 331.

334. Geiger, *supra* note 331.

dicating how well-linked given data is to its source.<sup>335</sup> Evans's account of the "networked" nature of pharmacogenomic discovery would help health IT policymakers grasp the potential of information flows, and understand how unharmonized legal requirements can impede innovation.<sup>336</sup> The National Bioethics Advisory Commission, the International Conference on Harmonization, and the HIPAA Privacy Rule have created diverse and sometimes overlapping categories of information.<sup>337</sup> A thriving research sector must have some mechanisms in place for monitoring and controlling data flows.<sup>338</sup>

Evans does not propose a sweeping solution to the problems raised by complex and conflicting data flow rules.<sup>339</sup> Limits on access and reuse reflect valid concerns: As endless stories of breaches and new data uses proliferate, data subjects need more robust assurances about controlled data dissemination.<sup>340</sup> Evans also powerfully critiques the opacity and possible conflicts of interests in the Institutional Review Boards ("IRBs") and Privacy Boards that make many critical decisions about data and specimen flow.<sup>341</sup> Her work suggests that whatever rules govern the emerging infrastructure of health data sur-

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335. See Joseph Conn, *Data Encryption Just One Option Under Security Law*, MODERN HEALTHCARE (May 12, 2009, 11:00 AM), <http://www.modernhealthcare.com/article/20090512/NEWS/305129979> (explaining some of the different levels of encryption in HIPAA, such as de-identified records compared to records with limited data sets).

336. Evans, *supra* note 271, at 325.

337. *Id.* For example, there are three distinctive levels of information linkage recognized by HIPAA. See U.S. DEP'T. OF HEALTH & HUMAN SERVS., SUMMARY OF THE HIPAA PRIVACY RULE 1, 3-4 (2003), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf> (explaining what information is protected by HIPAA).

338. ALLAN FRIEDMAN & DAVID LAZAR, KENNEDY SCH. OF GOV'T, INFORMATION SHARING AND PRIVACY WITH PERSONAL MEDICAL RECORDS 1 (2006), available at <http://allan.friedmans.org/papers/medical-records-mitre.pdf> (explaining the importance of controlling patient data flow).

339. Evans, *supra* note 271, at 325-28.

340. OFFICE FOR CIVIL RIGHTS, DEP'T. OF HEALTH & HUMAN SERVS., ANNUAL REPORT TO CONGRESS ON BREACHES OF UNSECURED PROTECTED HEALTH INFORMATION 1, 9-10 (2009-2010), available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachrept.pdf>.

341. Evans, *supra* note 271, at 328.

veillance, they will need to be complemented by monitoring that seeks to detect and deter inappropriate uses of information.<sup>342</sup>

If patients are to fully “buy in” to digitization of health records (and the full array of opportunities for use of them), they will need to be able to understand exactly how their digital records exist (and are used) in an increasingly complex virtual landscape. Patients need to engage in the “right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested,” and to have the information in formats that allow their own trusted interpreters to make sense of it.<sup>343</sup> Before HITECH, the HIPAA Privacy Rule limited patients’ ability to understand the nature and range of disclosures of their records because disclosures for “treatment, payment and health care operations” did not need to be accounted for.<sup>344</sup> After HITECH, such disclosures need to be in accountings of electronic records.<sup>345</sup>

Technical standards can play a crucial role in securing network accountability. In a notice of proposed rulemaking, HHS recognized that “use of audit trails and the right to an accounting of disclosures improves the detection of breaches and assists with the identification of weaknesses in privacy and security practices.”<sup>346</sup> Audit logs record

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342. See generally Evans, *supra* note 271, at 313–38 (discussing the concerns and solutions regarding data flow).

343. 45 C.F.R. § 164.528 (2011).

344. *Id.*

345. Before HITECH, 45 C.F.R. § 164.528 restricted the right to an accounting of disclosures by exempting disclosures that were “[t]o carry out treatment, payment and health care operations.” 45 C.F.R. § 164.528(a)(1)(i) (2009). HITECH removed that exception. 42 U.S.C. § 17935(c) (West 2010) (“In applying section 164.528 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information . . . the exception under paragraph (a)(1)(i) of such section shall not apply to disclosures through an electronic health record made by such entity of such information . . .”).

346. HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act, 76 Fed. Reg. 31,426, 31,427 (proposed May 31, 2011) (to be codified at 45 C.F.R. pt. 164) [hereinafter HIPAA Privacy Rule], available at <https://www.federalregister.gov/articles/2011/05/31/2011-13297/hipaa-privacy-rule-accounting-of-disclosures-under-the-health-information-technology-for-economic#p-34>; see also 45 C.F.R. § 170.302 (2011) (“[R]ecord actions related to electronic health information in accordance with the standard specified in § 170.210(b) [and] [g]enerate audit log [by] [e]nabl[ing] a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the

the activity taking place in an information-sharing network,<sup>347</sup> including “queries made by users, the information accessed, information flows between systems, and date- and time-markers for those activities.”<sup>348</sup> If audit logs are immutable and pervasively attributable, they should seriously deter misuse of data.<sup>349</sup>

Some industry comments on the rulemaking vigorously opposed aggressive implementation of consumer rights.<sup>350</sup> Nevertheless, in the Omnibus HIPAA Rule released in January 2013, HHS confirmed the

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standard at 170.210(b).”); Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,591 (July 28, 2010) (to be codified at 45 C.F.R. pt. 170)) (requiring that certified EHR technology have the following capabilities “to, at a minimum, support eligible professionals’ and eligible hospitals’ efforts to achieve what had been proposed for meaningful use Stage 1 under the Medicare and Medicaid EHR Incentive Programs proposed rule”); 45 C.F.R. § 170.210 (2011) (explaining “[t]he date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed or deleted; and an indication of which action(s) occurred and by whom must also be recorded”).

347. 28 C.F.R. § 23 (2012) (discussing criminal intelligence systems operating policies).

348. MARKLE TASK FORCE ON NAT’L SEC. IN THE INFO. AGE, MARKLE FOUND., IMPLEMENTING A TRUSTED INFORMATION SHARING ENVIRONMENT: USING IMMUTABLE AUDIT LOGS TO INCREASE SECURITY, TRUST, AND ACCOUNTABILITY I (2006). The Markle Foundation has worked on several important reports on deploying cutting edge IT in agencies, including HHS. *Id.* at 4.

349. For a discussion of the importance of immutable audit logs, see Pasquale and Citron, *supra* note 312, at 1473 (explaining that “[i]mmutable audit logs [promote] data integrity and relevance. [by] watermark[ing data] with its provenance, assuring attributions and verifiability of observations (much as citations help assure the validity of an assertion in an academic work)[and promoting] tethering and full attribution of data to allow corrections to propagate through the system” (internal citations omitted)).

350. MCDERMOTT WILL & EMERY, LLP, OCR’S PROPOSED REVISIONS TO ACCOUNTING FOR DISCLOSURES STANDARD PRODUCES STRONG OPPOSITION FROM MANY COVERED ENTITIES, 1–2 (2011), *available at* <http://www.mwe.com/info/news/wp1011b.pdf>; Jennifer L. Edlind, HIPAA Privacy Rule Accounting of Disclosures (RIN 0991-AB62); Notice of Proposed Rulemaking, 76 Fed. Reg. 31426 (May 31, 2011), Aug. 1, 2011, at 1 (responding to request for comment on HIPAA Privacy Rule and Accounting of Disclosures in capacity as University Hospital Privacy Officer); Larry Davis, Attention: HIPAA Privacy Rule Accounting of Disclosures (RIN 0991-AB62); Notice of Proposed Rulemaking, 76 Fed. Reg. 31426 (May 31, 2011), July 21, 2011, at 3 (responding to request for comment on HIPAA Privacy Rule and Accounting of Disclosures in capacity as St. Bernards Healthcare Corporate Compliance Officer).

importance of promoting patients' access to their records. According to this final rule, covered entities must provide individuals "with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format."<sup>351</sup> In any twelve-month period, the first accounting requested by an individual from a covered entity must be provided for free, within sixty days of the request (with some narrow exceptions).<sup>352</sup>

Expanding access to personal information is part of a larger movement to hold corporate actors accountable in an era of rapidly declining data storage costs.<sup>353</sup> Asked about privacy practices, Google's former CEO Eric Schmidt once said, "[w]e like to get right up to the creepy line, but not cross it."<sup>354</sup> But it would probably be more accurate to say that he and other corporate leaders do not want to be *caught* crossing the creepy line. Law and technology provide a rich variety of tactics to avoid that possibility.<sup>355</sup> Accountings of disclo-

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351. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act, 78 Fed. Reg. 5,566 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts 160, 164) (expanding individuals' rights to access protected health information). Such accountings must include:

- (i) The date of the disclosure;
- (ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
- (iii) A brief description of the protected health information disclosed; and
- (iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

45 C.F.R. § 164.528(b)(2).

352. 45 C.F.R. § 164.528(c)(2) ("The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.").

353. Pasquale, *Restoring Transparency*, *supra* note 200, at 237–39.

354. Derek Thompson, *Google's CEO: 'The Laws Are Written by Lobbyists'*, ATLANTIC ONLINE (Oct. 1, 2010, 11:58 AM), <http://www.theatlantic.com/technology/archive/2010/10/googles-ceo-the-laws-are-written-by-lobbyists/63908/>.

355. Pasquale, *Restoring Transparency*, *supra* note 200, at 235–39.

asures should provide a persistent record of data use that should deter at least some privacy violations.<sup>356</sup>

*B. Public-Private Surveillance Partnerships*

Fortunately, technologically sophisticated models for persistent monitoring of health care enterprises have developed over the past decade.<sup>357</sup> Private and public payers have developed elaborate methods of deterring overbilling.<sup>358</sup> Though private insurers' methods are largely proprietary, public programs like Medicaid and Medicare have released details about their sources, tactics, and methods.<sup>359</sup> HHS has also demonstrated a heartening track record of learning from failed enforcement methods and trying new approaches.<sup>360</sup> Its public-private partnerships in the fraud area could prove a model of modulated and responsive regulation in response to expanded opportunities for abuse in the realm of health data.<sup>361</sup>

The U.S. government has been improving its surveillance capabilities and developing templates for public-private partnerships in monitoring and analyzing large quantities of data.<sup>362</sup> DHS and CMS have implemented ambitious methods of gathering intelligence to allow early detection and deterrence of troubling patterns.<sup>363</sup> For example, DOJ and HHS greatly increased fraud and abuse recoveries by more aggressively deploying data mining technology.<sup>364</sup> By contracting with expert companies, public authorities leveraged corporate expertise for public purposes.<sup>365</sup>

Fraud may be the most grotesque example of wasted health care expenditure. Fortunately, fraud recovery efforts are illuminating the way toward a more comprehensive system of monitoring health care professionals, patients, and support providers.<sup>366</sup> Those who follow

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356. See HIPAA Privacy Rule, *supra* note 346 (pointing out that audit trails "discourage inappropriate behavior").

357. See *infra* Part IV.B.1.

358. See *infra* Part IV.B.1.

359. See *infra* Part IV.B.1.

360. See *infra* Part IV.B.1.

361. See *infra* Part IV.B.1.

362. See *infra* Part IV.B.2.

363. See *infra* Part IV.B.2.

364. See *infra* Part IV.B.2.

365. See *infra* Part IV.B.2.

366. See *infra* Part IV.B.2.

health care fraud and abuse know that data mining in that field has improved enforcement practices in ways that are helpful to agencies and even potential defendants, who are encouraged to develop more efficient business processes to avoid audits.<sup>367</sup> Moreover, even in a health policy landscape that is often riven by partisan divisions, the utilization of health information technology to combat fraud and abuse has been a top priority of both Republican and Democratic administrations.<sup>368</sup> After describing the problems with fraud and abuse enforcement of the 1980s and 1990s,<sup>369</sup> this Section explains the role of technology and public-private partnerships in detecting and punishing problematic provider behavior.<sup>370</sup>

### 1. *Rocky Beginnings for Fraud & Abuse Enforcement*

Fraud and abuse have long been a scourge of the U.S. health care system.<sup>371</sup> Stories abound of diluted medications, unlicensed providers, cosmetic surgery misrepresented as ‘medically necessary,’ and kickbacks designed to bilk CMS.<sup>372</sup> Congress has passed several laws to bar certain transactions and to impose serious penalties for abusive practices.<sup>373</sup> It has also empowered agencies to enforce old statutes with renewed vigor.<sup>374</sup> Enforcers heavily rely on civil false

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367. *See infra* Part IV.B.2.

368. *See infra* Part IV.B.2.

369. *See infra* Part IV.B.1.

370. *See infra* Part IV.B.2.

371. *See infra* Part IV.B.1; MALCOLM K. SPARROW, LICENSE TO STEAL: HOW FRAUD BLEEDS AMERICA’S HEALTH CARE SYSTEM 40 (2000); Leemore Dafny and David Dranove, *Regulatory Extrapolation and Management Changes: Upcoding in the Hospital Industry*, 52 J.L. & ECON. 223 (2009); Daniel R. Levinson, *A New Era of Medicare Oversight*, 15 J. HEALTH CARE L. & POL’Y, 249, 252 (2012) (describing the history and inadequacies of a pay-and-chase model).

372. FED. BUREAU OF INVESTIGATION, FINANCIAL CRIMES REPORT TO THE PUBLIC: 2010–2011, available at <http://www.fbi.gov/stats-services/publications/financial-crimes-report-2010-2011>.

373. *See, e.g.*, 18 U.S.C. § 1347 (2006) (addressing health care fraud); 18 U.S.C. § 24 (2006) (providing definitions relating to federal health care offense); Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142 (1977).

374. For example, the False Claims Act had been on the books for over a century to deter those who would cheat the government by billing it for unnecessary services. The Civil False Claims Act prohibits the knowing filing of a false or fraudulent claim for payment to the United States, and the knowing use of a false record or statement material to

claims actions to stop fraud and abuse by providers who rely on payments from government-funded insurance programs.<sup>375</sup> Congress also passed a number of more specific laws that directly address the propriety of particular transactions; for example, whether a doctor could refer a patient to an imaging center or hospital in which the doctor held an ownership interest.<sup>376</sup> Entire health law courses focus on the prohibitions, safe harbors, and related legal guidances arising out of laws like Stark I and II and the Anti-Kickback Statute.<sup>377</sup>

Unfortunately, the statutes are so complex and multifaceted that it is difficult for many providers to understand where aggressive business practices end and illegal acts begin. By the mid-1990s, Professor James Blumstein concluded that the medical marketplace had begun to resemble Prohibition-era bars, where authorities largely tolerated nominally illegal behavior.<sup>378</sup>

The Office of the Inspector General of HHS attempted to clarify matters with “fraud alerts,” guidance practices, and advisory opinions.<sup>379</sup> Critics were not impressed. David Frankford concluded that “laws like [these] . . . are absolutely incapable of logically defining, much less policing against, inflated prices . . . . [T]hey fail even to

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get a false or fraudulent claim paid, among other conduct. 31 U.S.C. § 3729(a)(1)–(2) (2006). HIPAA also contributed to fraud enforcement by establishing the Health Care Fraud and Abuse Control Program. 42 U.S.C. § 1395i(k)(2)(C) (2006).

375. Civil actions have a less strict scienter requirement than criminal law or the Medicare/Medicaid civil false claims statute. *Compare* 31 U.S.C. § 3729 (civil false claims, expressly stating “no proof of specific intent to defraud is required.”) *with* 18 U.S.C. § 287 (criminal false claims); *see also* *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) (addressing the “ostrich-with-his-head-in-the-sand problem” of contractors who are not personally aware of overcharges”).

376. *See* Rebecca Bethard, *Physician Self-Referral: Beyond Stark II*, 43 BRANDEIS L.J. 465, 478–479 (2005) (promoting “the prohibition of physician referral of patients to any entity in which they have a financial interest for both public funds and private pay sources”); Medicare and State Health Care Programs: Fraud and Abuse: Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 223 (Nov. 19, 1999).

377. *See, e.g.*, Isaac Buck, *Health Care Fraud and Abuse Syllabus*, Seton Hall Law School, Spring, 2012 (on file with author).

378. *See supra* text accompanying note 242. This is still a problem. *See, e.g.*, Jean M. Mitchell, *The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*, 26 HEALTH AFF. w415 (2007).

379. *See* OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH AND HUMAN SERVS., <https://oig.hhs.gov/>.

create a language for comprehensible debate.”<sup>380</sup> Policy analysts found much to be desired in the laws’ treatment of financial incentives and billing practices.<sup>381</sup>

In one of the leading health care fraud cases, *United States v. Krizek*,<sup>382</sup> heavy-handed enforcement tactics became a cause célèbre for Congress.<sup>383</sup> In the case, a small psychiatric practice was sued for over \$80 million because of its billing and coding practices.<sup>384</sup> The two clerical workers at the practice (one of whom, Mrs. Krizek, was the wife of the psychiatrist) would often assume that the most expensive category of care was provided, without confirming details with the

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380. David Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1937 (1989). *But see* Arnold S. Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749, 750 (1985) (claiming that, “when physicians seek income beyond fee for service and make business arrangements with other providers of services to their patients . . . [s]uch arrangements introduce a new and unnecessary conflict, which strains the physician’s fiduciary commitment to the patient”).

381. Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 355–56 (2010) (describing critiques of the program).

382. 111 F.3d 934 (D.C. Cir. 1997).

383. For a leading account of the case, see Thomas L. Greaney & Joan H. Krause, *United States v. Krizek: Rough Justice Under the Civil False Claims Act*, in HEALTH LAW AND BIOETHICS: CASES IN CONTEXT 187, 199–200 (Sandra H. Johnson et al. eds., 2009). Relating her experience to the traumas of authoritarian rule in Czechoslovakia, Mrs. Krizek testified before a sympathetic congressional committee on the “Kafkaesque” features of the fraud prosecution. *Administrative Crimes and Quasi-Crimes: Hearing Before the Subcomm. on Commercial and Admin. Law of the H. Comm. on the Judiciary*, 105th Cong. 42 (1998), available at [http://commdocs.house.gov/committees/judiciary/hju59925.000/hju59925\\_0.htm](http://commdocs.house.gov/committees/judiciary/hju59925.000/hju59925_0.htm) (“We have been fighting to establish the truth about my husband’s medical practice for almost 6 years. It has been a very difficult thing to do in this era where Kafkaesque administrative rules can and do result in the criminalization of medicine. Based on Health Care Financing Administration, HCFA, regulations, the Government filed an \$81 million lawsuit under the False Claims Act against my husband and me. The suit has been our worst nightmare.”).

384. *United States v. Krizek*, 859 F. Supp. 5, 7 (D.D.C. 1994); *Krizek*, 111 F.3d at 935–36. Liability can quickly add up because of potential penalties of several thousand dollars per false claim. *See* 31 U.S.C. § 3729(a) (stating that liability carries a civil penalty between \$5,000 and \$10,000 “plus 3 times the amount of damages which the Government sustains because of the act of that person”).

provider, Dr. Krizek.<sup>385</sup> They would also upcode appointments by billing for all the time related to the patient, rather than direct consultation time.<sup>386</sup>

Defendants like the Krizeks complained that they had honest misunderstandings of the billing codes.<sup>387</sup> For example, while Dr. Krizek may not have spent fifty minutes in person with a given patient for whom he billed for a fifty-minute visit, he could have spent more than fifty minutes on follow-up phone calls and administrative responsibilities relating to the patients' medication, insurance, and institutionalization.<sup>388</sup> The Krizeks claimed that they had neither the time nor money to consult attorneys on such interpretations.<sup>389</sup>

Since 1998, the health care fraud landscape had changed markedly, in ways that would make the plight of the Krizeks far less likely in the future. Fraud has continued, but enforcers have found more granular methods of addressing it. Both HHS and DOJ, the agencies primarily responsible for combating health care fraud in the Medicare program, have developed sophisticated methods to assure early detection of potentially fraudulent activity. Increased interagency cooperation and enhanced technical capabilities have greatly improved enforcement methods.<sup>390</sup> By intensively analyzing data, contractors can spot warning signs and deploy interventions less disruptive and stigmatizing than prosecution.<sup>391</sup> Spectacular "busts" still occur, but the standard case involves more measured and calibrated interventions.<sup>392</sup> The story of growing use of health information technology in fraud and abuse detection and enforcement is an example of government leading the health sector toward becoming a full-fledged information industry, with all the implied gains in efficiency and standardization.

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385. *Krizek*, 859 F. Supp. at 9.

386. *Id.*

387. *Id.* at 10.

388. *Id.* at 9–10.

389. *Id.* at 12–13 (“[D]efendants emphasize[d] the ‘Ma and Pa’ nature of [the practice].”).

390. ALICE G. GOSFIELD, *MEDICARE AND MEDICAID FRAUD & ABUSE* § 1:4 (2012).

391. *See id.*

392. For the “bust” model, see News Release, Department of Justice Office of Public Affairs, Dallas Doctor Arrested for Alleged Role in Nearly \$375 Million Health Care Fraud Scheme (Feb. 28, 2012), *available at* <http://www.justice.gov/opa/pr/2012/February/12-crm-260.html>.

## 2. Data Mining as a Fraud Enforcement Priority

The Deficit Reduction Act of 2005 allocated about \$480 million in funding (over a ten-year period) to enable states to perform sophisticated fraud analysis as well.<sup>393</sup> Each state must have a Medicaid Management Information System (“MMIS”).<sup>394</sup> The Medicaid Integrity Program obligates states to mirror processes established by the Medicare Integrity Program.<sup>395</sup> Each state that establishes a Medicaid Management Information System by creating centralized repositories for data can more easily detect “fraudulent, abusive, unnecessary, or inappropriate utilization.”<sup>396</sup> For example, the records may reveal “patterns identified with respect to service, time, or patient that appear to be suspect or otherwise implausible.”<sup>397</sup>

To permit more extensive data mining and collaboration with other enforcement agencies, CMS began developing the Medicaid Integrity Group (“MIG”) data engine in 2008, potentially combining data from MMIS and each states’ Medicaid Statistical Information Systems.<sup>398</sup> Both the MIG data engine and an Integrated Data Repository (“IDR”) are designed to support enforcement efforts.<sup>399</sup> When completed, the IDR will include claims and payment data from various health care programs.<sup>400</sup> The IDR is slated to include “state-of-the-art health informatics.”<sup>401</sup> The integration of Medicare and Medicaid

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393. GOSFIELD, *supra* note 390, at § 1:4 (citing Deficit Reduction Act of 2005 § 603; 42 U.S.C. § 1396(a) (2012)).

394. Pub. L. 92-603, Sec. 235; 45 C.F.R. § 250.90 (1974), amended as 42 C.F.R. § 433(c) (2011).

395. 42 C.F.R. § 455(C) (2011).

396. Kathy Giannangelo, *Mining Medicare and Medicaid Data to Detect Fraud*, 78 J. AM. HEALTH INFO. MGMT. ASS’N. 66, 68 (2007).

397. GOSFIELD, *supra* note 390, at § 6:13.

398. CTR. FOR MEDICARE AND MEDICAID SERVS., COMPREHENSIVE MEDICAID INTEGRITY PLAN OF THE MEDICAID INTEGRITY PROGRAM 3 (2009), *available at* <http://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/CMIP2009-2013.pdf>.

399. *Id.*; *Exhibit 300 (BY2010) for CMS Integrated Data Repository*, HHS.GOV, <http://www.hhs.gov/ocio/capitalplanning/exhibit300/FY10Exhibit300/cmsintegrateddatarepository.html> (last visited Oct. 28, 2012).

400. *Exhibit 300 (BY2010) for CMS Integrated Data Repository*, *supra* note 399.

401. *CMS Integrated Data Repository (IDR)*, CMS.GOV, <http://www4a.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html?redirect=/IDR/> (last visited Oct. 28, 2012).

claims, beneficiary data, provider data, and plan data into one system suggests the ambition of Google or other tech giants, which have harnessed cross-database search capacities for a variety of innovative ends.<sup>402</sup>

Critics of Medicaid have complained about the fragmented nature of its administration.<sup>403</sup> Anti-fraud programs, however, appear to be unifying sources of data that were once disparate. The data miners are comparing findings from the Medicare program across states.<sup>404</sup> Just as a network of fusion centers can readily transmit troubling or suspicious patterns of criminal intelligence horizontally (to other state or local level agencies) or vertically (to national agencies), state Medicaid Integrity Programs both empower and are empowered by rapid data flows.<sup>405</sup> The Medicare-Medicaid Data Match Program, or Medi-Medi project, breaks down barriers between the surveillance and analysis done by different entities.<sup>406</sup>

The CMS processes billions of dollars in payments each year, at a fraction of the administrative cost of most private insurers.<sup>407</sup> This is not, strictly speaking, a triumph of government over business. Rather, CMS buys its administrative expertise the old-fashioned way: in the marketplace.<sup>408</sup> By deploying a team of private sector contractors at the cutting edge of information industries, the agency has significantly increased fraud recoveries and promoted responsible billing practices. According to the Office of the Inspector General of HHS, CMS

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402. GOSFIELD, *supra* note 390, at § 6:13.

403. *See supra* notes 312, 380.

404. *See supra* note 312.

405. *Id.*

406. *See The Medicare-Medicaid (Medi-Medi) Data Match Program*, OFFICE OF INSPECTOR GEN., <https://oig.hhs.gov/oei/reports/oei-09-08-00370.asp> (last visited Oct. 28, 2012).

407. *See* CTRS. FOR MEDICARE AND MEDICAID FRAUD, CMS FRAUD PREVENTION INITIATIVE 1 (2012), *available at* <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/BackgrounderFraudPreventionInitiative.pdf> (“Health care fraud perpetrators steal billions of dollars each year from Federal and State governments . . . . Through the Fraud Prevention Initiative, the Centers for Medicare & Medicaid Services (CMS) is working to ensure that correct payments are made to legitimate providers . . . .”).

408. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-592, MEDICARE INTEGRITY PROGRAM: MEDICARE INTEGRITY PROGRAM: CMS USED INCREASED FUNDING FOR NEW ACTIVITIES BUT COULD IMPROVE MEASURES OF PROGRAM EFFECTIVENESS 7 (2011), *available at* <http://www.gao.gov/assets/330/322183.pdf> (describing contractors' roles and legal authority).

recovered seventeen dollars for every dollar it spent on health care fraud enforcement in 2008.<sup>409</sup>

As classic deterrence theory would predict, part of the response to the persistence of fraud has been increasing the penalties so that those caught would face jail time, large fines, or permanent exclusion from federal programs.<sup>410</sup> But this strategy can be risky and expensive. Proving criminal intent in a highly technical field is daunting, as DOJ teams have discovered anew in the wake of an epidemic of mortgage malfeasance and foreclosure fraud.<sup>411</sup>

A complementary approach is to broaden the scope of surveillance to enable a series of less intense interventions designed to immediately catch grotesque frauds and to educate and nudge errant, sloppy, or suspicious providers toward better behavior. That has been the approach of the Medicare Integrity Program and follow-up projects aimed at Medicaid providers.<sup>412</sup>

The CMS has pioneered innovative deployments of private sector contractors in social welfare programs. It has used “fiscal intermediaries (FIs), carriers, and durable medical equipment regional carriers (DMERCs) to process Part A, Part B, and durable medical equipment (DME) claims for reimbursement” for decades, and it has used Quality Improvement Organizations (“QIOs”) to assess the value and effectiveness of care offered.<sup>413</sup> The agency has also employed a wide array of contractors to detect and deter improper payments.<sup>414</sup>

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409. OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2008 ANNUAL PERFORMANCE REPORT 2 (2008), available at [http://oig.hhs.gov/publications/docs/budget/FY2008\\_APR.pdf](http://oig.hhs.gov/publications/docs/budget/FY2008_APR.pdf). As Krause has observed, “[t]he ratio was calculated as the agency’s ‘expected recoveries’ from audit disallowances, investigative returns, and administrative enforcement divided by its annual budget authority.” Krause, *supra* note 381, at 356 n.62.

410. See *infra* notes 375, 384.

411. See, e.g., John Eaglesham, *Financial Crimes Bedevil Prosecutors*, WALL ST. J., Dec. 6, 2011, at C1 (“[A]n initial burst of optimism by federal officials when they began examining [financial fraud] . . . slowly gave way to frustration over how to prove criminal intent.”).

412. State Medicaid Fraud Control Units: Data Mining, 76 Fed. Reg. 14,637 (proposed Mar. 17, 2011) (to be codified at 42 C.F.R. pt. 1007). Divisions within OIG (such as the Office of Audit Services, Office of Investigations, and Office of Evaluation and Inspections) can also undertake data analysis. 5 U.S.C. App. 3 § 2(2)(B); see also U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 408 (analyzing CMS use of its funding).

413. Sara Kay Wheeler et al., *Meet the Fraud Busters: Program Safeguard Contractors and Zone Program Integrity Contractors*, 4 J. HEALTH & LIFE SCI. L. 1 (2011) (citing 42 C.F.R. §§ 421.100 (FIs), 421.200 (carriers), 421.210 (DMERCs) and describing the functions of

The CMS is committed to “developing new methods and technologies to stay ahead of criminals and identify their patterns of behavior early” and “data analysis to identify cases of suspected fraud, waste and abuse.”<sup>415</sup> The Medicare Program Integrity Manual governs Medicare fraud-detection contractors, along with applicable Statements of Work.<sup>416</sup> According to the manual, comprehensive error rate testing (“CERT”) contractors “establish[] error rates and estimates of improper payments.”<sup>417</sup> The Recovery Audit Contractors (“RACs”) “detect and correct improper payments in the Medicare FFS [fee for service] program and provide information to CMS, ACs [affiliated contractors] and MACs [Medicare administrative contractors].”<sup>418</sup>

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each); *see also* CTRS. FOR MEDICARE AND MEDICAID SERVS., MEDICARE PROGRAM INTEGRITY MANUAL § 1.3.6 (last updated Nov. 20, 2009) [hereinafter MEDICARE PROGRAM INTEGRITY MANUAL]; 42 C.F.R. § 421.304 (describing the function of Medicare Integrity Program Contractors).

414. Timothy Martin, *Revenue-Cycle Management and Reimbursement: The Impact of Health Law and Health Reform on Providers*, 4 J. HEALTH & LIFE SCI. L. 159 (2011) (discussing the creation and authorization of contractors and the methods utilized in analyzing claims); *see also* Mark E. Reagan and Mark A. Johnson, *Taming the Medicaid Beast: The Federal Government's Ambitious Attempt to Combat Medicaid Fraud, Waste, and Abuse*, 3 J. HEALTH & LIFE SCI. L. 1 (2010) (explaining “the role and duties of Medicaid Integrity Contractors”).

415. *Anatomy of a Fraud Bust: From Investigation to Conviction: Hearing Before the S. Comm. on Finance*, 112th Cong. (2012) (statement of Peter Budetti, Director, Ctr. for Program Integrity, Health & Human Servs.), *available at* <http://www.hhs.gov/asl/testify/2012/04/t20120424a.html>.

416. MEDICARE PROGRAM INTEGRITY MANUAL, *supra* note 413, § 1.1 (“Medicare administrative contractors (MACs), comprehensive error rate testing (CERT) contractors, recovery audit contractors (RACs), program safeguard contractor (PSCs) and zone program integrity contractors (ZPICs) shall follow the PIM [Program Integrity Manual] as required by their applicable Statement of Work (SOW).”).

417. *Id.* § 1.3.1. (“Error rates produced by the CERT program” are used to “identify where to target [] improper payment prevention efforts.”). A Fraud Prevention System (FPS) runs “predictive algorithms and other sophisticated analytics nationwide against all Medicare fee-for-service claims . . . prior to payment.” *Assessing Medicare and Medicaid Program Integrity: Hearing Before the Subcomm. on Gov't Org., Efficiency, & Fin. Mgmt. of the H. Comm. on Oversight & Gov't Reform*, 112th Cong. (2012) (statement of Peter Budetti, Director, Center for Program Integrity, Health & Human Services), *available at* <http://www.hhs.gov/asl/testify/2012/06/t20120607a.html>.

418. MEDICARE PROGRAM INTEGRITY MANUAL, *supra* note 413, § 1.3.1(C). It is difficult to prevent all improper payments, considering that more than 1 billion claims are processed each year. *Id.* To address this issue, CMS uses specialized programs to detect and

Once these surveillance entities produce data, Medicare Administrative Contractors [“MACs”] can identify program vulnerabilities and develop approaches to respond to wayward providers.<sup>419</sup> Their medical reviews do not have to culminate in charges or prosecutions; rather, “prepayment edits” and provider education are preferred in many situations.<sup>420</sup> In severe cases, MACs can refer problem providers to Program Safeguard Contractors (“PSCs”) and Zone Program Integrity Contractors (“ZPICs”), which conduct data analysis focused on potentially fraudulent activity, as well as “benefit integrity investigations.”<sup>421</sup>

ZPICs are emerging as sophisticated analysts of data. They engage not only in reactive but proactive efforts to identify fraud, combing records for outliers. They can access a wide array of information sources.<sup>422</sup> Conditions of participation for providers in CMS programs may enable further surveillance.<sup>423</sup>

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correct improper payments and “provide information to CMS, ACs and MACs that could help protect the Medicare Trust Funds by preventing future improper payments.” *Id.*

419. *Id.* at § 1.3.1.B (Medicare contractors “primarily use error rates produced by the CERT program and vulnerabilities identified through the RAC program to identify where to target their improper payment prevention efforts.”).

420. Medical Appeals Council reviews are designed to spot errors. The Medicare Program Integrity Manual advises contractors that “most errors do not represent fraud. Most errors are not acts that were committed knowingly, willfully, and intentionally.” *Id.* § 1.3.9.

421. 42 U.S.C. § 1395ddd (PSCs); 42 U.S.C. 1395kk (ZPICs); *see also* Wheeler et al., *supra* note 413, at 14 (“ZPICs have been charged with tasks similar to those assigned to PSCs, but covering larger geographic areas and additional claim categories, including Medicare Parts A, B, C, and D; durable medical equipment; home health and hospice; and the Medicare Medicaid Data Match Project.”).

422. Wheeler et al., *supra* note 413, at 23. ZPICs can access referrals from MACs, QIOs, states’ Medicaid fraud control units, state licensing boards, and U.S. Attorney offices; OIG reports; beneficiary complaints; fraud alerts; national claims data from the Health Care Customer Information System; National Claims Data from the CMS Data Center’s Part B Analytics. *Id.* Complaints can be fielded from virtually any person with “direct and independent information of the fraud,” including compliance officers, employees (both current and former), technologists, auditors, accountants, consultants, and salespersons. *Id.*

423. 42 C.F.R. § 405.370; 42 C.F.R. § 455.2 (authorizes government use of claims data mining to detect alleged fraud in Medicare and Medicaid, respectively); 42 U.S.C. § 1395ddd (authorizes HHS to enter into contracts with eligible entities to conduct fraud detecting activities); *United States v. Miller*, 425 U.S. 435, 440 (1976); Christopher Slobogin, *Government Data Mining and the Fourth Amendment*, 75 U. CHI. L. REV. 317, 330 (2008).

Sampling methods are likely to improve and become less controversial as data capture and the science of data analysis advance.<sup>424</sup> Anti-fraud contractors engage in intense and fine-grained surveillance. Just as David Ticoll & Don Tapscott predicted in 2003 that “radical transparency” would shake up the business world,<sup>425</sup> CMS’s myriad contractors are motivating health care providers to modernize their practices.<sup>426</sup> Moreover, because the Medicare Program Integrity Manual does not define how sustained or how high a provider’s error rate must be for a PSC or ZPIC to engage in statistical sampling and extrapolation,<sup>427</sup> there is pressure for continuous quality improvement.

If the consequences of errant billing were as generally grievous as they were for the Krizeks, this mode of panoptic enforcement would be deeply troubling. The range of remedies available to MACs and ZPICs, however, lowers the stakes of surveillance. For example, Medicare Administrative Contractors can engage in prepayment review that keeps an overpayment (and thus a particular episode of fraud) from ever reaching a provider.<sup>428</sup> In the Krizeks’ case, a computer system could have recognized and rejected the claims filed on days when Dr. Krizek was alleged to have worked more than twenty-four hours.

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424. MEDICARE PROGRAM INTEGRITY MANUAL, *supra* note 413, § 2.2, 2.4. Medicare Claims Flow indicates that providers information goes to claims payers (twenty-two CMS MAC contractors), then to Claims Processing Systems. ZPICs may eventually coordinate efforts with domestic intelligence agencies known as fusion centers, which freely mine data from citizens’ financial records, data brokers’ digital dossiers, and cell phones. *Cf.* Citron & Pasquale, *supra* note 312, at 1449 (describing deployment of California fusion center resources to combat insurance fraud).

425. DAVID TICOLL & DON TAPSCOTT, *THE NAKED CORPORATION: HOW THE AGE OF TRANSPARENCY WILL REVOLUTIONIZE BUSINESS* 5 (2003) (describing openness as a business imperative).

426. The Recovery Audit Contractor Program was created by the Medicare Modernization Act of 2003 to recover Medicare overpayments under Fee-For-Service Medicare Plans. The Tax Relief and Health Care Act of 2006 made the program permanent, and required implementation in all states by 2010. During the demonstration program that ran from 2005 to 2008, the RAC program had identified approximately \$992.7 million of improper overpayments for CMS. As the authority, functions, and objectives of contractors differ, providers are advised to “develop unique plans for communicating and interacting with each contractor to minimize the risk of sanctions for alleged noncompliance.” Wheeler et al., *supra* note 413, at 7.

427. Wheeler et al., *supra* note 413, at 20.

428. MEDICARE PROGRAM INTEGRITY MANUAL, *supra* note 413, § 3.3.4.

Intervention would have come much sooner and been less disruptive to all parties involved.

The level of surveillance engaged in by CMS's contractors may be disturbing to some observers. Nonetheless, authorities in the area are trying to match the technological advantages accrued by providers as they utilize powerful new programs to optimize billing opportunities.<sup>429</sup> For example, physicians can simply "copy and paste" an examination performed on a complex case to a record for a less complex case, or "clone" records.<sup>430</sup> Dr. Donald Simborg has worried that, "[w]ithout proactive fraud management functions built in, fraud will increase in an electronic environment."<sup>431</sup> Simborg goes so far as to recommend a process of fraud detection built into EHRs themselves, reminiscent of FTC's push for "privacy by design" to be included in hardware and software used by consumers.<sup>432</sup> Though the enforcement tactics of CMS, OIG, and DOJ have not yet included fraud detection "baked in" to software, the past decade's developments in the digitization of CMS's program integrity tactics need to be situated in a broader political economy of law enforcement. Administrators must weigh the benefits of accuracy against the costs of observation, monitoring, and the panoply of rights and investigations necessarily granted in a given proceeding. Cheaper monitoring generally reduces the

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429. Fred Schulte, *Billing Software Helps Medical Professionals Document Higher Fees*, CTR. FOR PUB. INTEGRITY (Sept. 19, 2012), <http://www.publicintegrity.org/2012/09/19/10812/growth-electronic-medical-records-eases-path-inflated-bills> ("Medicare regulators . . . acknowledge they are struggling to rein in a surge of aggressive—and potentially expensive—billing by doctors and hospitals that they have linked, at least anecdotally, to the rapid proliferation of the billing software and electronic medical records. A variety of federal reports and whistleblower suits reflect these concerns."); Reed Abelson, *Medicare Bills Rise as Records Turn Electronic*, N.Y. TIMES, Sept. 21, 2012, at A1; Jeffrey Helton, *Avoiding Fraud Risks Associated with EHRs*, HEALTH FIN. MGMT. ASS'N (2010), available at <http://www.mfrpc.com/Default.aspx?DN=f927c939-4f17-44ae-870d-dcbaa978d59c>.

430. Daniel Essin, *The Ethical Dilemma Created by EHRs*, PHYSICIANS PRACTICE, June 18, 2012, available at <http://www.physicianspractice.com/blog/content/article/1462168/2083374>; Robert E. Hirschtick, *Copy-and-Paste*, 295 J. Am. Med. Ass'n 2335 (2006) ("By the power of repetition, everything in EMR becomes true.").

431. Donald Simborg, *There Is No Neutral Position on Fraud*, J. AM. MED. INFORMATICS ASS'N (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3168321/>.

432. FED. TRADE COMM'N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE v (2012), available at <http://www.ftc.gov/os/2010/12/101201privacyreport.pdf> ("Companies should adopt a 'privacy by design' approach by building privacy protections into their everyday business practices.").

costs of enforcement. It diminishes the attractiveness of severe prosecutions, focusing instead on a series of calibrated interventions.<sup>433</sup>

This is, perhaps, yet another example of the evolution of processes of punishment that Foucault observed: from well-publicized and dramatic imprisonments of wrongdoers to a softer yet more pervasive power. Legal scholars are mainly familiar with Foucault as a cutting critic of this evolution, someone who reminds us of the constraining and enervating aspects of disciplinary procedures that succeed insofar as they embed themselves seamlessly into technology, architecture, and social assumptions.<sup>434</sup> Yet there are more or less appropriate places for surveillance, and if there is any realm where the biopolitics of persistent monitoring is appropriate, it may well be that of health care.<sup>435</sup> As the 1999 Institute of Medicine report<sup>436</sup> reminds us, tens of thousands of individuals die each year due to preventable medical error.<sup>437</sup> To the extent that data mining helps us

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433. . For example, Medicaid Integrity Contractors (MICs) do not just punish fraud; they can also engage in education to assure that providers know how the law applies to them. Mark E. Reagan and Mark A. Johnson, *Taming the Medicaid Beast: The Federal Government's Ambitious Attempt to Combat Medicaid Fraud, Waste, and Abuse*, 3 J. HEALTH & LIFE SCI. L. 13 (2010) (“Based on the information learned by the Review and Audit MICs, Education MICs educate healthcare providers, state Medicaid officials, and others about a variety of Medicaid program integrity issues via web-based and traditional methods. As opposed to Review and Audit MICs, Education MICs are not necessarily assigned geographic responsibilities.”).

434. See MICHEL FOUCAULT, *DISCIPLINE AND PUNISH: THE BIRTH OF THE PRISON 195–217* (1977) (surveying evolving modes of social control, from “spectacularly” cruel and painful violence to more subtle modes of monitoring, reward, and deterrence).

435. Larry Catá Backer, *Surveillance and Control: Privatizing and Nationalizing Corporate Monitoring After Sarbanes-Oxley*, 2004 MICH. ST. L. REV. 327, 328 (2004) (examining the “consequences flowing from the imposition of increasingly significant governmentally directed and enforced surveillance . . . on private actors within the economic sphere”).

436. INST. OF MED., *TO ERR IS HUMAN I* (1999), available at <http://www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf>.

437. See generally PETER PRONOVOST & ERIC VOHR, *SAFE PATIENTS, SMART HOSPITALS: HOW ONE DOCTOR'S CHECKLIST CAN HELP US CHANGE HEALTH CARE FROM THE INSIDE OUT* (2010); ATUL GAWANDE, *THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT* (2009); Michael Millenson, *How Many More Dead Patients?*, HEALTH CARE BLOG (Mar. 10, 2012), <http://thehealthcareblog.com/blog/2012/03/10/how-many-more-dead-patients/> (reviewing estimates).

identify obviously problematic patterns of treatment, it can reduce morbidity and mortality.

A bipartisan consensus focusing resources on the fraud and abuse problem reflects larger social trends. As Bernard Harcourt and Loïc Wacquant have shown, neoliberal penalty has been a hallmark of U.S. politics since the 1970s.<sup>438</sup> Overly aggressive fraud and abuse enforcement can achieve both of the aims of neoliberal penalty: a reduction in state support for social welfare spending and the reallocation of governmental energies to “guard labor.”<sup>439</sup> Yet a creative repurposing of the tools of contractors could redirect surveillance from a primarily punitive role to a more constructive one.

Larry Cata Backer has developed a general theory of the role of surveillance in corporate settings. As he has argued, surveillance “serves as a means, made possible by increasingly effective technologies of recording and preservation, to allow the replaying of the past in the future.”<sup>440</sup> Moreover, monitoring and assessment critically involve “assertions of power over what can be seen/recorded/reduced.”<sup>441</sup> The mere threat of intense assessment of interventions can increase productivity.<sup>442</sup> Work can be performed more efficiently as it is recorded and studied.<sup>443</sup> New forms of “high-speed science” and regulation depend on rapid accumulation of data.<sup>444</sup>

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438. BERNARD HARCOURT, *THE ILLUSION OF FREE MARKETS: PUNISHMENT AND THE MYTH OF NATURAL ORDER* 196 (2011) (explaining that “archeology of regulation” shows that when “layers of legal entitlements, technical rules, and criminal prohibitions are exposed, it is clear that the notion of natural order or market efficiency is pure fiction”); Loïc Wacquant, *Class, Race, and Hyperincarceration in Revanchist America*, *DÆDALUS*, Summer 2010, at 74 (describing the “concomitant downsizing of the welfare wing and upsizing of the criminal justice wing of the American state”).

439. Arjun Jayadev and Samuel Bowles, *Guard Labor*, 79 *J. DEV. ECON.* 328, 331 (2006).

440. Larry Cata Backer, *Global Panopticism: States, Corporations and the Governance Effects of Monitoring Regimes*, 15 *IND. J. GLOBAL LEGAL STUD.* 101, 110 (2008).

441. *Id.* at 111.

442. *Id.* at 112.

443. *Id.*

444. Kenneth A. Bamberger, *Technologies of Compliance: Risk and Regulation in a Digital Age*, 88 *TEX. L. REV.* 669, 670 (2012).

To be sure, data mining will not be a panacea.<sup>445</sup> There is still much work to be done to “prevent fraud from occurring, as well as detect fraud both prospectively and retrospectively.”<sup>446</sup> Senator Charles Grassley has alleged that CMS’s modes of funding the contractors are opaque, and that CMS may have ulterior motives that distract or deter it from aggressive enforcement of law.<sup>447</sup> Certain contractors may not be pulling their weight; for example, “in June 2012, the Government Accountability Office (“GAO”) reported that over a five year period, the MIC contractors cost \$102 million and returned less than \$20 million, resulting in an overall loss to the federal government of \$82 million.”<sup>448</sup> While doctors believe that the contractors have also been too harsh and arbitrary in their treatment of health

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445. For example, those committing fraud can change behavior in response to the increased possibility of getting caught. Clifton Phua, *A Comprehensive Survey of Data-Mining Fraud Detection Research*, ARTIFICIAL INTELLIGENCE REV. (2005), available at <http://arxiv.org/ftp/arxiv/papers/1009/1009.6119.pdf>.

446. RTI INT’L (REPORT FOR THE ONCHIT), RECOMMENDED REQUIREMENTS FOR ENHANCING DATA QUALITY IN ELECTRONIC HEALTH RECORDS, ES-2 (2007), [http://www.rti.org/pubs/enhancing\\_data\\_quality\\_in\\_ehrs.pdf](http://www.rti.org/pubs/enhancing_data_quality_in_ehrs.pdf) (discussing needed technical changes in electronic health records; many have not yet been implemented).

447. Letter from Sen. Charles Grassley to CMS Administrator Donald Berwick, M.D. (Oct. 29, 2010), available at <http://finance.senate.gov/newsroom/ranking/download/?id=75ab598e-fc6d-4eb2-9277-de216f13afc6> (“[T]he potential financial conflicts of interest created by the organizational relationships between certain CMS contractors raise questions about whether or not some ZPICS and PSCs can effectively carry out their contractual responsibilities . . . .”); Letter from Sen. Charles Grassley to CMS Administrator Donald Berwick, M.D. (Oct. 15, 2010), available at <http://grassley.senate.gov/about/upload/2010-10-15-Letter-to-CMS.pdf>; OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., WORK PLAN FISCAL YEAR 2011 (2011), available at [http://oig.hhs.gov/publications/workplan/2011/FY11\\_WorkPlan-All.pdf](http://oig.hhs.gov/publications/workplan/2011/FY11_WorkPlan-All.pdf); OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., MEDICARE’S PROGRAM SAFEGUARD CONTRACTORS: PERFORMANCE EVALUATION REPORTS (2006), available at <http://oig.hhs.gov/oei/reports/oei-03-04-00050.pdf>.

448. AM. MED. ASS’N, MEDICARE AND MEDICAID PROGRAM INTEGRITY: RECOMMENDATIONS FOR GREATER VALUE AND EFFICIENCY 3, available at <http://www.ama-assn.org/resources/doc/washington/medicare-medicaid-program-integrity.pdf> (online pamphlet) (citing U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-627, NATIONAL MEDICAID AUDIT PROGRAM: CMS SHOULD IMPROVE REPORTING AND FOCUS ON AUDIT COLLABORATION WITH STATES (2012)).

professionals,<sup>449</sup> other critics want more referrals to DOJ to pursue criminal charges.<sup>450</sup> As of 2010, the American Health Information Management Association (“AHIMA”) estimated that only three to ten percent of health care fraud is being caught.<sup>451</sup> Even more disturbingly, there are some allegations that automation is giving rise not only to new forms of abuse detection but also to new forms of abuse.<sup>452</sup> Bad data may also reduce the possibility of detection.<sup>453</sup>

Despite such problems, it is important to recognize the successes of contractors in utilizing sophisticated data mining to fight fraud.<sup>454</sup> While HHS and DOJ recovered \$2.5 billion in fiscal year 2009,<sup>455</sup> they

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449. Dani Grigg, *Medical Suppliers in Idaho and Nationwide Scramble to Keep Up With Surging Medicare Audits*, IDAHO BUS. REV., June 29, 2012.

450. Letter from Sen. Orrin Hatch and Sen. Charles Grassley to Kathleen Sebelius, Sec’y Dep’t Health & Human Servs. (Oct. 25 2011), *available at* <http://www.finance.senate.gov/newsroom/ranking/release/?id=f4d925eb-a042-42bc-aff9-9d60b1157f8d> (urging HHS to issue a moratoria on the enrollment of new providers and suppliers to support DOJ and HHS-OIG enforcement efforts).

451. AHIMA, A STUDY OF HEALTH CARE FRAUD AND ABUSE: IMPLICATIONS FOR PROFESSIONALS MANAGING HEALTH INFORMATION 2 (2010), *available at* <http://ahimafoundation.org/downloads/pdfs/Fraud%20and%20Abuse%20-%20final%2011-4-10.pdf>.

452. *See* Reed Abelson, *Medicare Is Faulted on Shift to Electronic Records*, N.Y. TIMES, Nov. 29, 2012, at A1 (“Medicare, which is charged with managing the incentive program that encourages the adoption of electronic records, has failed to put in place adequate safeguards to ensure that information being provided by hospitals and doctors about their electronic records systems is accurate.”); Rebekah A.Z. Monson & Elizabeth M. Hein, *Two Steps Forward, One Step Back: HHS Invests in Health IT Infrastructure, But Admits to Failures in Security Enforcement*, 24 HEALTH LAWYER 34 (2011).

453. *Assessing Medicare and Medicaid Program Integrity: Hearing Before the H. Comm. on Oversight and Government Reform*, 112th Cong. (2012) (statement of Ann Maxwell, Regional Inspector Gen., Health & Human Services), *available at* [https://oig.hhs.gov/testimony/docs/2012/Maxwell\\_testimony\\_06072012%20.pdf](https://oig.hhs.gov/testimony/docs/2012/Maxwell_testimony_06072012%20.pdf) (“OIG has found that . . . MSIS data [utilized by MICs] are not current, available, complete, and accurate.”).

454. Pete Yost, *Government: Nearly \$8 Recovered for Every Dollar Spent Investigating Health Care Fraud*, STAR TRIB., Feb. 11, 2013, *available at* <http://www.startribune.com/nation/190690901.html> (“The \$7.90 average return on investment is the highest in the 16-year history of the Health Care Fraud and Abuse Program. Since 1997, the program—a joint effort of the departments of Justice and Health and Human Services—has returned more than \$23 billion to the Medicare trust funds.”).

455. Pete Yost, *Medicare Fraud Enforcement Efforts Recovered \$2.5 Billion In 2009*, HUFFINGTON POST (May 13, 2010, 06:36 PM), [http://www.huffingtonpost.com/2010/05/13/medicare-fraud-enforcement\\_n\\_574553.html](http://www.huffingtonpost.com/2010/05/13/medicare-fraud-enforcement_n_574553.html).

recovered more than \$4 billion in fiscal year 2010.<sup>456</sup> The high-tech Health Care Fraud Prevention & Enforcement Action Team (“HEAT”) established by the agencies has also enhanced monitoring capacity.<sup>457</sup> HHS Secretary Kathleen Sebelius announced that her department was analyzing “claims in real time to flag potential scams . . . [doing] what credit card companies have been doing for decades.”<sup>458</sup> HHS is finally embracing the analytics and search capacity of information industries.

A leading commentator on fraud and abuse enforcement, Joan H. Krause, has praised the HEAT initiative for utilizing “state-of-the-art technology to analyze electronic claims data for patterns that might indicate fraud, in as close to real-time as possible—a practice the health care reform legislation seeks to expand.”<sup>459</sup> She has observed that it is “taking advantage of advances in claims-review technology” to “prevent fraud *before* questionable claims are paid, rather than chasing down the perpetrators (and funds) after the fact.”<sup>460</sup> This technologically enabled enforcement produced immediate results: within months of being announced, it led to several crack-downs.<sup>461</sup>

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456. News Release, Dep’t. Health & Human Servs., Health Care Fraud Prevention and Enforcement Efforts Recover Record \$4 Billion; New Affordable Care Act Tools Will Help Fight Fraud (Jan. 24, 2011), *available at* <http://www.hhs.gov/news/press/2011pres/01/20110124a.html>.

457. *HEAT Task Force*, STOP MEDICARE FRAUD, <http://www.stopmedicarefraud.gov/heattaskforce/index.html> (last visited Oct. 29, 2012) (describing the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”) mission).

458. Kathleen Sebelius, Sec’y Dep’t Health & Human Servs., Address at the Stop Medicare Fraud Summit (Aug. 26, 2010), *available at* <http://www.hhs.gov/secretary/about/speeches/smfsummit.html> (“Under the new law, we’re also making it easier for law enforcement officials to see health care claims data from around the country in one place, combining all Medicare-paid claims into a single, searchable database.”). Data-mining applications are successful in predicting consumer behavior for credit card companies because they can compare a consumer’s credit history with the credit histories of millions of other consumers to predict the likelihood of delinquency. Fred H. Cate, *Government Data Mining: The Need for a Legal Framework*, 43 HARV. C.R.-C.L. L. REV. 435, 473 (2008) (“Most marketers have thousands or even millions of customers upon whose actual behavior they can base patterns for data mining.”).

459. Krause, *supra* note 381, at 368.

460. *Id.*

461. *Id.* (“[B]arely a month after it was announced, more than fifty individuals in Detroit and Miami were indicted for Medicare fraud . . .”); *Anatomy of a Fraud Bust: From In-*

It is easy to get lost in the “alphabet soup” of agencies, contractors, and task forces now addressing health care fraud. Their various methods, however, usually track the modes of search, personalization, and analytics discussed earlier in this Article.<sup>462</sup> They are detecting more misuses of CMS funds. It is now time to turn the significant power and influence of these analytics networks to the twin conundrums of cost containment and quality improvement in medicine.

## V. CONCLUSION

In the film *Sleep Dealer*, a laborer encounters a woman who operates a “memory recorder.”<sup>463</sup> This computerized transcription machine translates past experiences into video re-enactments.<sup>464</sup> The machine occasionally sputters as the laborer narrates his story, and its operator chides him to “be more truthful”—to hew closer to the actual facts.<sup>465</sup> The film is ambiguous as to whether the machine, its operator, or the laborer really knows what actually happened in any given scenario.<sup>466</sup> The video transcriber kindles and mocks the laborer’s desire for an authoritative representation of the past.<sup>467</sup>

For too long, health data systems have been like *Sleep Dealer*’s memory machine, provoking a messy struggle to determine the true value of various treatments. Digitized and networked health IT could streamline the process, bringing some of the productivity gains of in-

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*investigation to Conviction: Hearing Before the S. Comm. on Finance*, 112th Cong. (2012) (statement of Daniel R. Levinson, Inspector Gen., Health & Human Services), *available at* <http://www.finance.senate.gov/imo/media/doc/OIG%20Written%20Test%20SFC%20Anatomy%20FINAL.PDF> (announcing the indictment of ninety-one defendants for Medicare fraud schemes); News Release, U.S. Dep’t. Health & Human Servs., Health Care Fraud Prevention and Enforcement Efforts Recover Record \$4 Billion; New Affordable Care Act Tools Will Help Fight Fraud (Jan. 24, 2011), *available at* <http://www.hhs.gov/news/press/2011pres/01/20110124a.html>; News Release, Dep’t of Justice Office of Pub. Affairs, Dallas Doctor Arrested for Alleged Role in Nearly \$375 Million Health Care Fraud Scheme (Feb. 28, 2012), *available at* <http://www.justice.gov/opa/pr/2012/February/12-crm-260.html>.

462. *See supra* Parts III.D, IV.

463. SLEEP DEALER (Maya Entertainment, 2008).

464. *Id.*

465. *Id.*

466. *Id.*

467. *Id.*

formation industries to medicine.<sup>468</sup> But it can only do so if policy-makers can broker a “grand bargain” between providers, patients, and funders: more access to data for researchers, in exchange for dedicated systems designed to protect the integrity of intellectual property and the security of personally identifiable information.

Naysayers doubt CMS’s institutional capacity to accomplish such reforms. But the agency’s successful deployment of private sector contractors in the context of fraud and abuse enforcement turns the tables on these anti-government critics.<sup>469</sup> Given their own enthusiasm for contracting out government work, they can scarcely allege that the agency is inherently incapable of finding businesses to perform sophisticated data collection and analysis. Public-private surveillance partnerships already subject providers’ bills to rigorous audits;<sup>470</sup> health privacy law will soon require audit-capability for digital medical records.<sup>471</sup> The key question now is whether we will limit these capacities to a law enforcement context or broaden them to affirmatively improve public health and reduce costs.

The laws governing the management of health care information are extremely complex. Some of this complexity is necessary to the subject matter. Yet, it should not obscure the larger goals of health information law. Surveillance of health data has many ends, some public-spirited and others narrowly commercial. Law should incentivize productive surveillance, while being far more cognizant of stakeholders’ rights to block data flows (and annotate or challenge resulting analyses) when such forms of surveillance merely evince an exercise of power, serving only as an effort to redistribute benefits and burdens rather than (respectively) increasing or decreasing them.<sup>472</sup>

The divide between surveillance as an exercise of power and surveillance for public goals can sometimes be blurry.<sup>473</sup> This does not mean, however, that it is futile to develop an industrial policy for the acquisition and use of health information. Rather, we need to promote the types of analysis that are most likely to reduce the disease burden and promote wellness.<sup>474</sup> Once citizens are confident that the health information infrastructure is primarily devoted to promoting

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468. *See supra* Part III.D.

469. *See supra* Part IV.B.

470. *See supra* Part IV.B.

471. *See supra* note 346.

472. *See supra* notes 440–441.

473. *See supra* Part IV.B.2.

474. *See supra* Parts III.D., IV.B.2.

their health, rather than sorting or stigmatizing them, we should witness the kind of broad-scale buy-in that is a sine qua non for a population actively engaged in maintaining its health.<sup>475</sup>

Government alone cannot accomplish this process.<sup>476</sup> It will depend on a constellation of private contractors to react to the new health care landscape with the flexibility and nimbleness that public bureaucracies tend to lack.<sup>477</sup> Even so, we should not expect great results from the private sector alone. Government will need to catalyze comprehensive, interoperable, and auditable data collection systems.<sup>478</sup> Public-private surveillance partnerships can help providers fully realize the value of new health information technology.<sup>479</sup> If they succeed, public health imperatives will often trump standard rights to control data, creating a health information law distinct from traditional doctrines of intellectual property and privacy law.<sup>480</sup>

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475. *See supra* Part III.B.

476. *See supra* Part IV.B.

477. Government is not inherently inefficient, but there are now so many reflexively anti-government factions influencing legislation and its enforcement that public servants' work is often partially sabotaged before it even starts. *See* THOMAS FRANK, *THE WRECKING CREW* 9 (2009) (describing a "vast machinery built for our protection reengineered into a device for our exploitation").

478. *See supra* Part IV.B.

479. *See supra* Part IV.B.

480. *See supra* Part IV.B.

## APPENDIX: GUIDE TO ACRONYMS

- ACs: Affiliated Contractors  
ACA: Patient Protection and Affordable Care Act  
ACOs: Accountable Care Organizations  
ARRA: American Recovery and Reinvestment Act of 2009  
ATCBs: Authorized Testing and Certification Bodies  
CER: Common Exchange Representation  
CERT: Comprehensive Error Rate Testing  
CMS: Centers for Medicare and Medicaid Services  
DHS: Department of Homeland Security  
DME: Durable Medical Equipment  
DMERCs: Durable Medical Equipment Regional Carriers  
DOJ: Department of Justice  
EHR or EMR: Electronic Health/Medical Records  
FDA: Food and Drug Administration  
GPO: Group Purchasing Organizations  
HHS: Department of Health and Human Services  
HIPAA: Health Insurance Portability and Accountability Act  
HIT: Health Information Technology  
HITECH: Health Information Technology for Economic and Clinical Health Act  
MACs: Medicare Administrative Contractors  
OIG: Office of the Inspector General  
ONC: Office of the National Coordinator for Health Information Technology  
PCAST: President's Council of Advisors on Science and Technology  
PHRs: Personal Health Records  
PPACA: Patient Protection and Affordable Care Act  
PSCs: Program Safeguard Contractors  
QIOs: Quality Improvement Organizations  
ZPICs: Zone Program Integrity Contractors