

# Patient Data: Property, Privacy & the Public Interest

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## I. INTRODUCTION

Changes in technology sometimes raise important public policy choices and require that we clarify key values and reexamine legal concepts. Such is the case with the development of electronic medical records (EMRs), which facilitate obtaining patient data from provider and insurer records. EMRs expand our ability to tap patient data and thereby create great potential benefits as well as risks. This new technology requires that we clarify the ambiguous property interests in patient data. How the law defines ownership of patient data will shape whether its benefits can be developed and also affects patient confidentiality.

EMRs make it feasible to collect aggregate patient data that can be used to vastly improve medical knowledge, patient safety and public health. Researchers have long used patient data from clinical trials to evaluate the benefits and risks of drugs and medical therapy, compare their relative effectiveness, and analyze health care cost and quality.<sup>1</sup> Tapping data from patient records would make possible similar evaluations at much lower costs, yield continually updated information, and facilitate rapid learning. It would provide information on populations and variables not included in clinical trials.<sup>2</sup>

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<sup>1</sup> See generally David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9 (2005).

<sup>2</sup> See Jonathan B. Perlin & Joel Kupersmith, *Information Technology and the Inferential Gap*, 26 HEALTH AFF. W192, W194 (2007).

National, longitudinal patient data could be used to monitor and respond to public health problems in ways that are not possible today.<sup>3</sup> We could track adverse effects from drug use.<sup>4</sup> The FDA could use data on physician prescribing to contact physicians who are prime users of a drug that receive a black box warning. The data could help identify the extent of the prescribing of drugs for unapproved uses that lack scientific support.<sup>5</sup> Moreover, the data could help identify a wide range of other public health and safety problems and track differences in various organized health care systems.<sup>6</sup> And it could help manage health care fraud and facilitate oversight of medical institutions.<sup>7</sup> At the same time, the use of patient data also creates risks to confidentiality. Today, although privacy laws restrict providers, hospitals, and insurers from disclosing confidential information, electronic technology and changes in ownership of patient data might compromise confidentiality.<sup>8</sup>

Whoever owns patient data will determine whether its benefits can be tapped. Currently, the law does not clearly define property interests in patient data. In most states, the law treats patient medical records as physical property that physicians and hospitals own, and it allows patients and

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<sup>3</sup> For numerous examples of how patient data is already used for beneficial secondary uses, and a thoughtful discussion of its potential, see generally CAN. INST. OF HEALTH RESEARCH, SECONDARY USE OF PERSONAL INFORMATION IN HEALTH RESEARCH: CASE STUDIES (2002).

<sup>4</sup> The FDA is developing a database to monitor adverse drug events. However, there are limitations in the database it is developing for this purpose. See Barbara J. Evans, *Authority of the Food and Drug Administration to Require Data Access and Control Use Rights in the Sentinel Data Network*, 65 FOOD & DRUG L.J. 67 (2010); Richard Platt et al., *The New Sentinel Network-Improving the Evidence of Medical-Product Safety*, 361 NEW ENG. J. MED. 645, 646 (2009); see also FDA'S SENTINEL INITIATIVE, <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm> (last updated Sept. 30, 2010); U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., THE SENTINEL INITIATIVE: NATIONAL STRATEGY FOR MONITORING MEDICAL PRODUCT SAFETY (2008), available at <http://www.fda.gov/oc/initiatives/advance/reports/report0508.pdf>.

<sup>5</sup> One research team purchased such data from IMS to identify such practices. See generally David W. Bates et al., *Using Computerized Data to Identify Adverse Drug Events in Outpatients*, 8 J. AM. MED. INFORMATICS ASS'N 254 (2001); David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES OF INTERNAL MEDICINE 1021 (2006).

<sup>6</sup> Some of the limitations of observational data from patient records can be addressed when the data is used in simulation models. See, e.g., Carol C. Diamond et al., *Collecting and Sharing Data For Population Health: A New Paradigm*, 28 HEALTH AFF. 454, 456 (2009); David M. Eddy, *Linking Electronic Medical Records to Large-Scale Simulation Models: Can We Put Rapid Learning on Turbo?*, 26 HEALTH AFF. W125, W125-36 (2007); Lynn M. Etheredge, *A Rapid-Learning Health System*, 26 HEALTH AFF. W107, W110-13 (2007); Ralph I. Horowitz et al., *Developing Improved Observational Methods for Evaluating Therapeutic Effectiveness*, 89 AM. J. MED. 630 (1990); Rita Kukafka et al., *Redesigning Electronic Health Record Systems to Support Public Health*, 40 J. BIOMEDICAL INFORMATICS 398, 403-05 (2007); John R. Lumpkin, *Archimedes: A Bold Step into the Future*, 26 HEALTH AFF. W137 (2007); Walter F. Stewart et al., *Bridging the Inferential Gap: The Electronic Health Record and Clinical Evidence*, 26 HEALTH AFF. W181, W184-90 (2007).

<sup>7</sup> See RTI INT'L, RECOMMENDED REQUIREMENTS FOR ENHANCING DATA QUALITY IN ELECTRONIC HEALTH RECORD SYSTEMS § 4.2.1, at 4-6 to -7 (2007), available at [http://www.rti.org/pubs/enhancing\\_data\\_quality\\_in\\_ehrs.pdf](http://www.rti.org/pubs/enhancing_data_quality_in_ehrs.pdf); see generally AM. HEALTH INFO. MGMT. ASS'N, DEVELOPMENT OF A NATIONAL HEALTH DATA STEWARDSHIP ENTITY (2007), available at [http://www.ahima.org/dc/documents/MicrosoftWord-AHIMANHDSERFIresponse-final\\_2007-08-03\\_.pdf](http://www.ahima.org/dc/documents/MicrosoftWord-AHIMANHDSERFIresponse-final_2007-08-03_.pdf).

<sup>8</sup> G.J. ANNAS, THE RIGHTS OF PATIENTS: THE AUTHORITATIVE ACLU GUIDE TO THE RIGHTS OF PATIENTS 224-45 (2004).

insurers access to records.<sup>9</sup> But the law does not grant providers exclusive ownership of the record's data, which can be readily transferred.<sup>10</sup> Just as an individual can own a book, but not the intellectual content printed in it, providers own records but not the patient data itself.

Nevertheless, today, organizations with medical, prescription and billing records treat patient data as if it were their private property, and they often sell it.<sup>11</sup> Typically, they sell patient data stripped of personal identifiers, which they refer to as *anonymized* or *de-identified* data. Data sellers sometimes use technology that restricts use of data to those whom they have granted permission. Data sellers frequently employ contracts that limit purchasers from disseminating the data to third parties without the original seller's authorization. If legislation does not create an alternative framework, courts might enforce these contracts and all the privatization of patient data, and thereby limit beneficial public uses.

Do entities that compile patient data from multiple records own the data set? American intellectual property law generally protects only creations or inventions. Patent law protects non-obvious inventions, and copyright law protects intellectual creations, such as writing, music and art.<sup>12</sup> This policy developed over time. The 1790 United States Copyright Act granted copyrights for compilations of information, known as "sweat of the brow" protection. However, the 1976 Copyright Act only granted copyright for original selection of data.

In the 1990s, there were legislative proposals in Europe and the U.S. to give compilers of databases protection from others making use of the data.<sup>13</sup> These proposals would have supplemented protection in trade secrecy law, which protected the work of compilers, but would not have precluded others from compiling the same database.<sup>14</sup> The strong versions of these proposals

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<sup>9</sup> Marc A. Rodwin, *The Case for Public Ownership of Patient Data*, 302 JAMA 86, 86 (2009); see Marc A. Rodwin, *Patient Data: Professionalism, Property & Policy*, in MEDICAL PROFESSIONALISM IN THE INFORMATION AGE (David Rothman & David Blumenthal eds.) (forthcoming 2010) (on file with author); see generally Mark A. Hall & Kevin A. Schulman, *Ownership of Medical Information*, 301 JAMA 1282 (2009); Adele A. Waller & Oscar L. Alcantara, *Ownership of Health Information in the Information Age*, 69 J. AHIMA 28 (1998).

<sup>10</sup> In most states, patients' medical records are available to patients, providers, as well as hospitals and other institutions that provide medical services. Patients have a right to obtain copies of their medical records. They may have their medical records transferred to another physician if they change doctors. Hospitals and other institutions can keep copies of patient medical records after patients are discharged. See generally Paul V. Stearns, *Access to and Cost of Reproduction of Patient Medical Records: A Comparison of State laws*, 21 J. LEGAL MED. 79 (2000); Hall & Schulman, *supra* note 9.

<sup>11</sup> See generally Robert Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 NEW ENG. J. MED. 2745 (2006).

<sup>12</sup> U.S. COPYRIGHT OFF., REPORT ON LEGAL PROTECTION FOR DATABASES (1997).

<sup>13</sup> For an overview of the European and American law, see MARK J. DAVISON, THE LEGAL PROTECTION OF DATABASES (William R. Cornish ed., 2003). See also P. Bernt Hugenholtz, Stephen M. Maurer & Harlan J. Onsrud, *Europe's Database Experiment*, 294 SCIENCE 789, 789-90 (2001).

<sup>14</sup> J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 49, 72-110 (1997). Moreover, once data are made public, trade secrecy law no longer protects the originator, except through two party contracts. See *Int'l News Serv. v. Associated Press*, 248 U.S. 215, 218-19 (1918); Wendy Gordon, *On Owning Information: Intellectual Property and the Restitutionary Impulse*, 78 VA. L. REV. 149 (1992); Dennis S. Karjala, *Misappropriation as a Third Intellectual Property Paradigm*, 94 COLUM. L. REV. 2594 (1994);

were not adopted.<sup>15</sup> Furthermore, in 1991, the Supreme Court held that only compilations of information involving creativity can be copyrighted.<sup>16</sup> Aggregate patient data is information that courts are unlikely to deem as involving creativity.<sup>17</sup> Although current law recognizes that private ownership of information often inappropriately restricts public use, today commercial interests are trying to turn patient data into private property. Moreover, even if the law does not allow copyright of patient databases, significant obstacles impede access to data for both public and private uses.

In this article, I argue that treating patient data as private property precludes forming comprehensive databases required for many of its most important public health and safety uses. Private ownership will also allow data monopolies that will increase the price of data and limit competition in the market for derived services. I propose that federal law require providers, medical facilities and insurers to report key patient data in anonymized and de-identified form to public authorities, which will create aggregate databases to promote public health, patient safety, and research. Public authorities should also make this data available for private entities to develop data-derived services, subject to public oversight. As we shall see, there is precedent for federal and state governments requiring reporting of data.

My proposal faces two important challenges. First, prevailing American thought favors private ownership and markets and a minimum role for the federal and state governments. I argue, however, that the economic, legal, and moral reasons typically invoked to justify treating a resource as private property do not support doing so here. There is no need to create private

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Jerome H. Reichman, *Electronic Information Tools: The Outer Edge of World Intellectual Property Law*, 17 U. DAYTON L. REV. 797 (1992).

<sup>15</sup> See Database Investment and Intellectual Property Antipiracy Act of 1996, H.R. 3531, 104th Cong. (2nd Sess. 1996); U.S. COPYRIGHT OFFICE, *supra* note 12, at 57-61; Council Directive 96/9, 1996 O.J. (L 077) 1-17 (EC); COMM. ON ISSUES IN THE TRANSBORDER FLOW OF SCIENTIFIC DATA, NAT'L RESEARCH COUNCIL, BITS OF POWER: ISSUES IN GLOBAL ACCESS TO SCIENTIFIC DATA (1997); Reichman & Samuelson, *supra* note 14, at 72-102. However, the EC did adopt a directive that protects the content of databases when, due to selection or arrangement of their contents, they are original. The directive extends this protection to nationals of other countries where the other country offers comparable protection to EU databases. Council Directive 96/9, 1996 O.J. (L 077) 1-17 (EC).

In 1996, legislation was introduced in the U.S. Congress to grant special protection for databases. The U.S. Copyright Office has studied the pros and cons of granting new legal protection for databases and analyzed the principles and interests at stake. It says that copyright should not harm science, research, education, or reporting but it also says that "substantial copying for commercial, competitive purposes should not be permitted." See H.R. 3531, Database and Collections of Information Misappropriation Act, H.R. 3261, 108th Cong. (2004). Those bills were not enacted, nor were similar bills introduced in 2003. "U.S. Copyright Office Report on Legal Protections for Databases" U.S. COPYRIGHT OFFICE, <http://www.copyright.gov/reports/dbase.html>. The Subcommittee on Courts, the Internet, and Intellectual Property, Committee on the Judiciary and the Subcommittee on Commerce, Trade and Consumer Protection Committee on Energy and Commerce. Statement of David O. Carson, General Counsel, United States Copyright Office, Sept. 23, 2003, <http://www.copyright.gov/docs/regstat092303.html>. Copyright Office for Senator Orrin Hatch, Executive Summary, U.S. Copyright Office Report on Legal Protections for Databases, ix, edited by U.S. Copyright Office. <http://www.copyright.gov/reports/exsum.pdf>.

<sup>16</sup> Feist Publ'n v. Rural Tel. Serv. Co., 499 U.S. 340, 340-41 (1991).

<sup>17</sup> Knowing this, some lawyers advise clients to arrange patient data in new formats to obtain copyright protection for their creative arrangement. See Waller & Alcantara, *supra* note 9, at 33.

property rights to encourage production of patient data because it already exists. Providers and medical organizations will continue to collect this data in order to perform their work, whether or not they must disclose it, and even if they cannot sell it. Furthermore, public ownership would ensure the aggregation of patient data and promote its beneficial public and private uses. In contrast, private ownership would preclude most public uses and restrict many private uses. Other economic, ethical and legal considerations also favor treating patient data as a public good.

Second, some people believe that public ownership of patient data creates risks for patient privacy. I contend, however, that the risks to privacy are no greater than when the data is private property owned by patients or firms and organizations. Whether publicly or privately owned, we need protective measures to ensure confidentiality. Public ownership, however, allows greater public oversight that can protect patient confidentiality.

To illuminate these issues, this article will describe how the market for patient data emerged and show that commercial interests and public policy have in the past, and continue today, to promote the data's privatization. It then makes the case for public ownership of patient data and responds to objections raised against public ownership of patient data. Next, it assesses the arguments for making patient data private as a means to protect patient confidentiality and finds these are not convincing. The article then suggests what data should be made public and how it should be done. It concludes by asking if the concept of the public interest can illuminate these choices.

## II. THE RISE OF PATIENT DATA MARKETS

Organized medicine took the lead in developing a market for medical data. In the 1950s, the American Medical Association (AMA) commissioned Ben Gaffin and Associates to conduct the Fond du Lac marketing study to determine the influence of advertising, pharmaceutical detailing, peer opinion and other factors on physician drug prescribing.<sup>18</sup> It distributed this study to the Pharmaceutical Manufacturers' Association and leading drug firms to encourage them to advertise in AMA journals and to form a partnership with the AMA on areas of mutual benefit. Then the AMA began to sell to pharmaceutical firms data that identified physicians by their license numbers, practice locations, and practice specialty. Pharmaceutical firms combined physician identifiers with prescription data from pharmacies that included the prescribing physician's license number. They then tracked individual physician prescribing, patient drug use, and pharmaceutical sales for their marketing and promotion.<sup>19</sup>

Later, specialized firms—now referred to as medical information organizations (MIOs)—emerged to broker the purchasing and selling of medical data.<sup>20</sup> They purchased data from the AMA to identify physicians by

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<sup>18</sup> BEN GAFFIN & ASSOC., REPORT ON A STUDY OF ADVERTISING AND THE AMERICAN PHYSICIAN, pt. 1 (1958) as reprinted in Drug Industry Antitrust Act: Hearings Before the Subcomm. on Antitrust and Monopoly of the S. Comm. on the Judiciary, 87th Cong. 490-520 (1961).

<sup>19</sup> Jeremy A. Green, *Pharmaceutical Marketing Research and the Prescribing Physician*, 146 ANNALS INTERNAL MED. 742, 743-46 (2007).

<sup>20</sup> Steinbrook, *supra* note 11, at 2746-47.

their license number and other information. They purchased data from pharmacies to identify drugs sold. MIOs combined this information to reveal prescribing patterns and market trends.<sup>21</sup> Pharmaceutical firms purchased the data from MIOs to track sales by individual physicians and medical detailers who visited them. They rewarded their medical detailers who were the best at promoting sales. They also used the data to target physicians for changing their prescribing practices and to evaluate the effect of their advertising and marketing—as well as that of their competitors. Such information also revealed the potential market for each class of drugs, current sales of their own products, the products of competitors and their respective market share.<sup>22</sup> Medical device manufacturers and other medical suppliers also purchased data for similar purposes.

Later, MIOs began to purchase patient data from hospital records stripped of patient identifiers. When combined with other data, these records reveal the diagnosis and profile of patients for which physicians prescribe various drugs and use various therapies. Pharmaceutical firms can thus promote drugs differently for each use and design different strategies to influence different physicians based on the way they use drugs and the patients they serve. The marketing literature explains in detail the uses of such data.<sup>23</sup>

Managed care organizations (MCOs), hospitals, and regulatory authorities can use this information to identify inappropriate drug uses by physicians; to learn whether pharmaceutical firms market drugs for unapproved uses; and to assess the effect of different medical treatments on patient care. Other users of patient data include health service researchers, health economists, the Food and Drug Administration (FDA), and public health departments.

Firms also started to purchase patient data as a tool for their policy advocacy. Regulatory agencies evaluate the safety and effectiveness of drugs and medical devices before approving their sale. Third-party payers, MCOs, and hospitals evaluate drugs before placing them on their formulary. Insurers often evaluate medical devices before covering them or encouraging their use.

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<sup>21</sup> Data obtained from the AMA identified physicians by their practice specialty, affiliations with hospitals and insurers, practice location and other variables. Information from pharmacies and other firms revealed information on drugs prescribed and sold. Combining such information reveals individual physician and aggregate prescribing patterns. Similar information allows firms to track the use of medical devices and other medical products. EMRs expand the kind and volume of patient data available. They reveal the profile of patients treated by individual physicians and hospitals and the particular diagnosis of patients for which drugs and medical devices are prescribed.

<sup>22</sup> Joe Priest, *Hospital-Centric Prescription Data Opens New Patient Level Insights and Marketing Opportunities*, PHARMACEUTICAL COM., Aug. 20, 2007, <http://www.pharmaceuticalcommerce.com/frontEnd/main.php?idSeccion=677>; Jean-Patrick Tsang, *Patient-Data Come of Age*, 23 PHARMACEUTICAL EXECUTIVE 84 (2003).

<sup>23</sup> Taryi Forni, *Using Patient-Level Data to Take Your Market Assessment to the Next Level*, J. LONGITUDINAL DATA, Jan. Feb. 2005, at 12, 12-17; Taryi Forni, *Using Anonymous Patient-Level Information to Inform the Brand-Planning Process: Part 2*, PRODUCT MGMT. TODAY, May 2006, at 14, 14-15; Julie Klossner & Jack Newson, *Studying Drug Utilization by Production Indication*, PRODUCT MGMT. TODAY, Oct. 2005, at 16, 16-17; Taryi Forni & Zohar Porat, *Assessing Treatment Patterns in Complex Disease Markets: An Example from the Mental Health Market*, PRODUCT MGMT. TODAY, Apr. 2005, at 12, 12-13; John Martin & Stephen J. Boccuzzi, *Analyzing Drug Utilization Patterns in the Oncology Market*, PRODUCT MGMT. TODAY, Mar. 2006, at 14, 14-15.

These entities consider the cost-effectiveness and value of medical drugs and devices compared to alternatives. Organizations that develop clinical practice guidelines also use patient data in forming their recommendations. Knowing this, firms that manufacture and sell medical products now purchase patient data for studies to make their case for their products.

IMS Health, the largest supplier of medical information for market research, now markets patient data for policy advocacy.<sup>24</sup> It promotes data from its General Practice Research Database, for studies of cost, effectiveness, impact on health care spending, and medical outcomes. Its web page says, “[a]chieving a favorable endorsement from healthcare authorities is critical to ensure that new innovations reach the market and patients more quickly and are incorporated into appropriate guidelines of care.”<sup>25</sup> It adds that product use is boosted by studies of “efficacy, safety, and cost-effectiveness as presented in peer-reviewed medical and scientific journals or via specialized conference[s].”<sup>26</sup> IMS also markets its consulting services, which write “manuscripts and reviews for submission to peer-reviewed journals, clinical trial reports, expert reports, investigator brochures, abstracts, posters, slide sets.”<sup>27</sup> In addition, consulting firms, group purchase organizations, software vendors and other commercial enterprises purchase patient data for various commercial uses.<sup>28</sup>

Already, the market for patient data is worldwide. IMS sells it for marketing in over 100 countries and earned over \$2 billion in 2006.<sup>29</sup> It sells data to all major pharmaceutical and biotechnology companies.<sup>30</sup> MIOs anticipate the emergence of a new industry of data warehouses, data exchanges, data-related products and services. In recent years, academic medical centers, such as Boston’s Massachusetts General Hospital and Brigham & Women’s Hospital, explored how to sell their patient data to biotech companies, insurers, consulting companies, investment analysts,

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<sup>24</sup> IMS HEALTH INC., ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 (2007), <http://sec.gov/Archives/edgar/data/1058083/000104746908001691/a2182946z10-k.htm>.

<sup>25</sup> IMS, HEALTH ECONOMICS AND OUTCOMES RESEARCH, GENERATING CREATIVE AND INFORMATIVE CONTENT FOR THE PHARMACEUTICAL, SCIENCE AND MEDICAL FIELDS, [http://www.imshealth.com/web/channel/0,3147,64576068\\_63872702\\_73163984,00.html](http://www.imshealth.com/web/channel/0,3147,64576068_63872702_73163984,00.html).

<sup>26</sup> IMS, HEALTH ECONOMICS AND OUTCOMES RESEARCH, MEDICAL WRITING AND COMMUNICATION, [http://www.imshealth.com/web/channel/0,3147,77141581\\_63872702\\_77140611,00.html](http://www.imshealth.com/web/channel/0,3147,77141581_63872702_77140611,00.html).

<sup>27</sup> *Id.*

<sup>28</sup> See AM. HEALTH MGMT. ASS’N, *Development of a National Health Data Stewardship Entity, Response to Request for Information 10* (Aug. 3, 2007), [http://google.ahima.org/search?q=Development+of+a+National+Health+Data+Stewardship+Entity&btnG=Search&client=AHIMA\\_ORG\\_NEWER&output=xml\\_no\\_dtd&proxystylesheet=AHIMA\\_ORG\\_NEWER&sort=date%3AD%3AL%3Ad1&entqr=3&oe=UTF-8&ie=UTF-8&ud=1&site=all\\_collection](http://google.ahima.org/search?q=Development+of+a+National+Health+Data+Stewardship+Entity&btnG=Search&client=AHIMA_ORG_NEWER&output=xml_no_dtd&proxystylesheet=AHIMA_ORG_NEWER&sort=date%3AD%3AL%3Ad1&entqr=3&oe=UTF-8&ie=UTF-8&ud=1&site=all_collection) (follow “August 3, 2007 Jonathan White, MD Health IT Director Agency for . . .” hyperlink).

<sup>29</sup> IMS, *supra* note 24, at 3; Press Release, IMS HEALTH INC., Wolters, Kluwer Health and Verispan, Comment on Federal Judge’s Decision to Grant Preliminary Injunction Blocking Enforcement of Main Prescription Restraint Law, (Dec. 26, 2007) <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnnextoid=e7eb1d3be7a29110VgnVCM10000071812ca2RCRD#>.

<sup>30</sup> IMS, *supra* note 24, at 8.

publishers, and government agencies.<sup>31</sup> Also, insurers, group medical practices, and other entities may commercialize patient data.

#### A. THE PROMOTION OF PRIVATE OWNERSHIP, MARKETS, AND VOLUNTARY INDUSTRY STANDARDS

Today, firms, foundations and government policy all promote private data markets. The conventional wisdom supports private ownership of patient data or maintaining current default rules. For example, a 2006 Heritage Foundation report advocates private ownership and contends that governmental authorities should have to purchase patient data on the same terms as all other parties.<sup>32</sup> In a similar vein, most writers hold that private entities should develop voluntary standards for confidentiality and stewardship of data instead of the government setting legal standards. While George W. Bush was president, the Office of the National Coordinator for Health Information Technology—part of the Department of Health and Human Services (DHHS)—promoted the development of voluntary standards for the sharing, aggregation and use of patient data by private for-profit and not-for-profit entities. Those who advocate for voluntarily sharing data typically ignore the obstacles to this occurring. As the Markle Foundation acknowledges in one report, “providers treat patient information as a highly proprietary asset that serves as a means of differential from the competition.”<sup>33</sup> This tendency creates an obstacle to voluntarily sharing data or to individuals purchasing it.

In 2006, the American Medical Informatics Association (AMIA) published a white paper of its expert panel that proposed a policy framework for the secondary use of patient data.<sup>34</sup> The AMIA asked the panel to address several questions, including, “Who owns health data and who has the right to access the data and for what purposes?”<sup>35</sup> The expert panel responded that “the focus needs to be on data access and control, not data ownership.”<sup>36</sup> Yet, the property rights in patient data will determine access and control. If legislation does not resolve the ownership of patient data, courts are likely to grant property interests to those who possess that data and preserve the status quo.

In a 2007 report, the AMIA advocated that stakeholders voluntarily adopt guidelines for data stewardship and shared access. The report included the

<sup>31</sup> Steve Bailey, *Your Data for Sale?*, BOSTON GLOBE, Mar. 24, 2006, at C1.

<sup>32</sup> Edmund F. Haislmaier, *Health Care Information Technology: Getting the Policy Right* THE HERITAGE FOUNDATION, 3 (June 16, 2006), <http://www.heritage.org/Research/Reports/2006/06/Health-Care-Information-Technology-Getting-the-Policy-Right>.

<sup>33</sup> David J. Brailer et al., *Financial, Legal and Organizational Approaches to Achieving Electronic Connectivity in Healthcare* 18 (Markle Foundation, Report by the Working Group on Financial, Organizational and Legal Sustainability of Health Information Exchange, Oct. 2004), available at <http://www.connectingforhealth.org/resources/professionals.html>.

<sup>34</sup> Charles Safran et al., *Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper*, 14 J. AM. MED. INFORMATICS ASS'N 1, 1 (2007).

<sup>35</sup> *Id.* at 3.

<sup>36</sup> Safran et al., *supra* note 34, at 6. AMIA reasserts that view recently. See AM. HEALTH INFO. MGMT. ASS'N, *supra* note 28, at 4.



following groups as stakeholders with rights to access data: provider organizations; personal health record service providers; insurance companies; health data exchanges; and health data banks, as well as patients.<sup>37</sup> Notably, governmental health authorities are not included as stakeholders. It assumed that firms that sell and purchase patient data should develop a consensus on their own oversight. The standards that these private entities develop will reflect the interests of those who want to sell data but not the interests of patients or the public.<sup>38</sup>

In June 2007, the Agency for Healthcare Research and Quality (AHRQ) proposed the creation of a National Health Care Data Stewardship Entity to set uniform operating rules for sharing and aggregating public and private sector data on quality and efficiency.<sup>39</sup> It assumed that private parties would hold the data and have no obligations to supply data to the national government or state authorities. Nevertheless, many groups responded to the AHRQ proposal by explicitly opposing the idea of public ownership. The AMIA commented that “there should be no central repository of aggregate data—whether at the national or regional level.”<sup>40</sup> The Markle Foundation’s *Connecting for Health* project stated, “A single data repository for aggregating and reporting quality data could fail to meet user needs, increase the risk of large scale privacy violations and undermine public trust.”<sup>41</sup>

In response to the AHRQ proposal, three private organizations—the National Commission on Quality Assurance, the National Quality Forum and the Joint Commission—suggested that they operate the national stewardship entity and charge fees for their work. They said they would determine data control and ownership rights. In brief, they would decide what data will be public, and what access would flow to data-contributors.<sup>42</sup> They explained that those “that have the most data . . . must be assured that their data will be properly protected,” and that those who contribute data “want to maintain a competitive advantage, based on the value of their data.”<sup>43</sup>

Writing in 2009, Enrico Coiera described current American health information policy as following a “bottom-up approach.” He explained that “service providers have formed regional coalitions to interconnect their

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<sup>37</sup> Jill Burrington-Brown, Beth Hjort & Lydia Washington, *Health Data Access, Use, & Control*, 78 J. AHIMA 63 (2007), [http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_034053.hesp?dDocName=bok1\\_034053](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_034053.hesp?dDocName=bok1_034053).

<sup>38</sup> The Department of Health and Human Services requested comments on a National Health Stewardship Entity in the summer of 2007. See Agency for Healthcare Research and Quality, National Health Data Stewardship, Request for Information, 72 Fed. Reg. 30, 803 (June 4, 2007). The idea was harshly criticized by industry in its comments to HHS.

<sup>39</sup> See AM. HEALTH INFO. MGMT. ASS’N, *supra* note 28.

<sup>40</sup> *Id.* at 17.

<sup>41</sup> Letter from Connecting for Health, Markle Found., to P. John White, Health Info. and Tech. Dir., Agency for Healthcare Research and Quality, 4 (July 30, 2007), [http://www.connectingforhealth.org/resources/cfh\\_ahrq\\_aqa\\_rfi\\_073007.pdf](http://www.connectingforhealth.org/resources/cfh_ahrq_aqa_rfi_073007.pdf) (responding to a request for information regarding a national data stewardship entity).

<sup>42</sup> Nat’l Comm’n on Quality Assurance, Nat’l Quality Forum & The Joint Comm’n, *Response to National Health Data Stewardship Request for Information* (FR Doc. 07-2733) (July 27, 2007), [http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS\\_0\\_3882\\_800781\\_0\\_0\\_18/NCQA-NQF-TJC%20Joint%20NHDSE%20AHRQ-AQA%20RFI%20Response%20072707.pdf](http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_3882_800781_0_0_18/NCQA-NQF-TJC%20Joint%20NHDSE%20AHRQ-AQA%20RFI%20Response%20072707.pdf).

<sup>43</sup> *Id.* at 15.

existing systems as best they can into health information exchanges (HIE). The expectation is that regional HIEs will eventually aggregate into a national-scale system.<sup>44</sup> This bottom-up approach is notable for its lack of success. Several attempts to create health information exchanges that voluntarily share data have failed. They faced numerous problems, including the lack of standards for reporting data and the lack of short term financial benefit for participants, even though there were significant long run societal benefits.<sup>45</sup>

In the winter of 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, which allocated \$32.7 billion to promote the adoption of EMRs, infrastructure and training over ten years.<sup>46</sup> The legislation will increase the speed with which practitioners and institutions will adopt EMRs and related technology. It authorizes over \$20 billion in financial incentives through the Medicare and Medicaid programs from 2011 through 2016 for physicians and medical facilities to adopt EMRs. These incentives will be phased out and replaced with penalties for physicians and hospitals that do not use certified EMRs and make “meaningful use” of them.

Regulations that will define what constitutes “meaningful use” of data under HITECH will encourage sharing of patient data for research and public uses.<sup>47</sup> However, tapping the real potential for patient data for secondary uses requires that it be aggregated into a national database. However, HITECH does not appear to authorize creating regulations that can achieve that goal. As a result, it is important whether the law makes aggregate patient data public or private property.

### III. THE CASE FOR PUBLIC OWNERSHIP

Evolving practice indicates the potential of a national aggregate patient database. Numerous organizations are beginning to mine patient data.<sup>48</sup> The Veteran’s Administration has tapped its sixteen million patient records to evaluate medical treatment.<sup>49</sup> Kaiser Permanente has created a research

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<sup>44</sup> Enrico Coiera, *Building a National Health IT System from the Middle Out*, 16 J. AM. MED. INFORMATICS ASS’N 271, 271 (2009).

<sup>45</sup> See Jonah Frohlich et al., *Retrospective: Lessons Learned from the Santa Barbara Project and Their Implications for Health Information Exchange*, 26 HEALTH AFF. 5 w589 (2007); Julia Adler-Milstein et al., *The State of Regional Health Information Organizations: Current Activities and Financing*, 27 HEALTH AFF. 1 w60 (2008); Joy M. Grossman et al., *Creating Sustainable Local Health Information Exchanges: Can Barriers to Stakeholders Participation Be Overcome?*, (Feb. 2008), <http://www.hschange.org/CONTENT/970/970.pdf>; Robert H. Miller & Bradley S. Miller, *The Santa Barbara County Care Data Exchange: What Happened?*, 26 HEALTH AFF. 5 w568 (2007).

<sup>46</sup> See Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) (enacted as part of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 115); STEVEN C. REDHEAD, CONG. RESEARCH SERV., R40892, PUBLIC HEALTH, WORKFORCE, QUALITY, AND RELATED PROVISIONS IN H.R. 3962 (2009).

<sup>47</sup> See Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Fed. Reg. 75 44314 (July 28, 2010) (to be codified at 42 C.F.R. pt. 412); David Blumenthal, *Launching HITECH*, 362 NEW ENG. J. MED. 382 (2010); David Brailer, *Guiding the Health Information Technology Agenda*, 29 HEALTH AFF. 586 (2010).

<sup>48</sup> See Etheredge, *supra* note 6.

<sup>49</sup> See Joel Kupersmith et al., *Advancing Evidence-Based Care for Diabetes: Lessons from the Veteran’s Health Administration*, 26 HEALTH AFF. 2 w156, 165 (2007).

database on its eight million enrollees. The Geisinger Health System uses its medical records for over two million patients to evaluate medical treatment and develop medical policies.<sup>50</sup> The Center for Disease Control (CDC) operates a program on vaccine safety using medical records on six million patients from seven health maintenance organizations (HMOs). The National Cancer Institute combines data from eleven health care systems for ten million patients. The DHHS Center for Medicare and Medicaid Services (CMS) plans to use data from its Medicare drug benefit program and other patient data to evaluate drug safety and effectiveness, and to track drug prescriptions for unapproved uses.<sup>51</sup> Other federal programs also plan to use patient data.<sup>52</sup> There are also recent examples of using data from electronic patient records to identify adverse drug reactions.<sup>53</sup>

Sometimes public authorities collect patient data and make it publicly available. The CDC policy is to make its data freely available to the public for research. It says, “The interest of the public . . . transcend[s] whatever claims scientists may believe they have to ownership of data acquired or generated using federal funds. Such data are, in fact, owned by the federal government and thus belong to the citizens of the United States.”<sup>54</sup> California requires all hospitals to report patient discharge data to a state agency, which sells it to the public for a nominal fee.<sup>55</sup>

Yet, each of these databases is partial and quite small compared to a database drawn from medical facilities and insurers nationally. Moreover, Academy Health, the health-service research association, reports that researchers have difficulty accessing population health data, even data from federal programs. It therefore advocates the “development and dissemination

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<sup>50</sup> See Stewart et al., *supra* note 6, at w185, w187.

<sup>51</sup> Judith Waltz & Lena Robins, *CMS Makes Medicare Part D Data Available for the FDA Sentinel Initiative, External Research, and Other Outside Uses*, 21 HEALTH LAW 31 (2009).

<sup>52</sup> Sean R. Tunis, Tanisha V. Carino, Reginald D. Williams II & Peter B. Bach, *Federal Initiative to Support Rapid Learning About New Technologies*, 26 HEALTH AFF. w140, w140-49 (2007).

<sup>53</sup> John S. Brownstein et al., *Rapid Identification of Myocardial Infarction Risk Associated with Diabetic Medications Using Electronic Medical Records*, 33 DIABETES CARE 526, 526-31 (2010).

<sup>54</sup> CTRS. FOR DISEASE CONTROL & PREVENTION & AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, POLICY ON RELEASING AND SHARING DATA MANUAL GUIDE: GENERAL ADMINISTRATION, CDC-102 (2003), available at <http://www.cdc.gov/od/foia/policies/sharing.htm>.

<sup>55</sup> The reporting began with the passage of the California Hospital Disclosure Act by the California Legislature, Senate Bill 283 in 1971. Since then the reporting requirements have been revised through legislation and regulation several times. For a history, see OFFICE OF STATEWIDE HEALTH PLANNING & DEVELOPMENT, CALIFORNIA INPATIENT DATA REPORTING MANUAL: MEDICAL INFORMATION REPORTING FOR CALIFORNIA VI, VI-IX (7th ed. 2010), available at [http://www.oshpd.ca.gov/HID/MIRCal/Text\\_pdfs/ManualsGuides/IPManual/Intro.pdf](http://www.oshpd.ca.gov/HID/MIRCal/Text_pdfs/ManualsGuides/IPManual/Intro.pdf). For information on the availability of the data see OFFICE OF STATEWIDE HEALTH PLANNING & DEVELOPMENT, CALIFORNIA INPATIENT DATA REPORTING MANUAL: MEDICAL INFORMATION REPORTING FOR CALIFORNIA § 97215(d) (7th ed. 2010), available at [http://www.oshpd.ca.gov/HID/MIRCal/Text\\_pdfs/ManualsGuides/IPManual/RptngReq.pdf](http://www.oshpd.ca.gov/HID/MIRCal/Text_pdfs/ManualsGuides/IPManual/RptngReq.pdf). For a manual that describes the data see OFFICE OF STATEWIDE HEALTH PLANNING & DEVELOPMENT, CALIFORNIA INPATIENT DATA REPORTING MANUAL: MEDICAL INFORMATION REPORTING FOR CALIFORNIA I, 1-22 (7th ed. 2010), available at [http://www.oshpd.ca.gov/HID/MIRCal/Text\\_pdfs/ManualsGuides/IPManual/RptngReq.pdf](http://www.oshpd.ca.gov/HID/MIRCal/Text_pdfs/ManualsGuides/IPManual/RptngReq.pdf).

of secondary health data as a public good.<sup>56</sup> Achieving that goal would require a change in public policy.

A well developed literature highlights the value of information in the public domain,<sup>57</sup> particularly for the growth of science,<sup>58</sup> which depends on access to knowledge, and the sharing of findings and information. For this reason, the United States federal government has usually treated scientific data as a public good, waived its ownership rights in government-generated information, and made the data available at nominal cost.<sup>59</sup> However, Harlan Osrund argues that today the information commons is jeopardized when business or government decision makers destroy the commons or do not allow

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<sup>56</sup> Letter from W. David Helms, President & CEO, Academy Health, to P. John White, Health IT Director, Agency for Healthcare Research and Quality (July 26, 2007) (in response to request for comments), available at <http://www.chsr.org/AHRQRFI.pdf>.

<sup>57</sup> See generally YOCHAI BENKLER, *THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM* (2006); Paul A. David, *The Economic Logic of "Open Science" and the Balance Between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, in *THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION IN THE PUBLIC DOMAIN: PROCEEDINGS OF A SYMPOSIUM 19*, 19-34 (Julie M. Esanu & Paul F. Uhlir eds., 2003); Paul A. David, *Common Agency Contracting and the Emergence of 'Open Science' Institutions*, 88 *AM. ECON. REV.* 15, 15-21 (1998); Paul A. David, *Reputation and Agency in the Historical Emergence of the Institutions of 'Open Science'* (Stanford U. Ctr. for Econ. Policy Research, Publication No. 261, 1994, revised 1998); Dana Dalrymple, *Scientific Knowledge as a Global Public Good: Contributions to Innovation and the Economy*, in *THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION IN THE PUBLIC DOMAIN: PROCEEDINGS OF A SYMPOSIUM 35*, 35-51 (Julie M. Esanu & Paul F. Uhlir eds., 2003); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 *L. & CONTEMP. PROBS.* 33, 33-74 (2003); Nicolas P. Terry, *Legal Barriers to Realizing the Public Good in Clinical Data*, in *INSTITUTE OF MEDICINE, CLINICAL DATA AS THE BASIC STAPLE OF HEALTH LEARNING: CREATING AND PROTECTING A PUBLIC GOOD* (forthcoming 2010); Paul A. David, *Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History*, in *GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 19*, 19-61 (Mary E. Wallerstein et al. eds., 1993); Paul A. David, & Dominique Foray, *Accessing and Expanding the Science and Technology Knowledge Base*, 16 *SCI. TECH. INDUSTRY REV.* 13, 13-68 (1995); Paul A. David, *The Digital Technology Boomerang: New Intellectual Property Rights Threaten Global 'Open Science'*, (Stanford U. Dep't of Econ., Working Paper No. 00-16, 2000); Paul A. David, *The Political Economy of Public Science: A Contribution to the Regulation of Science and Technology*, in *THE REGULATION OF SCIENCE AND TECHNOLOGY 33*, 33-57 (Helen L. Smith ed., 2002); Paul A. David et al., *Analysing the Payoffs From Basic Research*, 2 *ECON. INNOVATION & NEW TECH.* 73, 73-90 (1992); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation?: The Anti-commons in Biomedical Research*, 280 *SCIENCE* 698, 698-701 (1998). See also Jessica Litman, *The Public Domain*, 39 *EMORY L.J.* 965, 965-1023 (1990).

<sup>58</sup> See ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* (Norman W. Storer ed., 1973). Merton holds that the norms of science involve: communalism, universalism, disinterestedness, originality and skepticism. *Id.* at 270. He says that the accumulation of knowledge relies on cooperative enquiry and reporting of results. *Id.* at 316.

<sup>59</sup> Jerome H. Reichman, *Discussion Framework: A Contractually Reconstructed Research Commons for Science and Innovation*, in *THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION IN THE PUBLIC DOMAIN: PROCEEDINGS OF SYMPOSIUM 141*, 142 (Julie M. Esanu & Paul F. Uhlir eds., 2003); NATIONAL RESEARCH COUNCIL, *supra* note 15; J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 *L. & CONTEMP. PROBS.* 315, 315-462 (2003).

it to develop. He proposes imposing costs on parties whose actions have negative effects on the information commons.<sup>60</sup>

In a similar vein, Yochai Benkler and other scholars have explored the benefits of network effects, that is, the increasing benefits to users as the network increases in size.<sup>61</sup> With most tangible goods, one person's use diminishes another person's full enjoyment of the good. In contrast, with public goods, an individual's use does not diminish use by another person. However, when there are network effects, the benefits that an individual derives actually increase when the number of individuals in the network grows. For example, the value of a telephone for an individual increases as the number of other individuals who have telephones and can be called rises. Similarly, the internet increases in value when the number of people with access to it grows, because this expands each user's ability to share information and communicate. When there are network effects, public policy should promote access to expand benefits for all.

Patient data display network effects. Inferences derived from analysis of a few patient records lack the reliability of studies using a large database. Moreover, the benefit that any individual or group derives from contributing data to an aggregate database increases as the number of other patients contributing data increases. That is because it is easier for researchers to develop reliable inferences from the sample and to better control for the effect of different confounding variables that affect patient outcomes.

The grounds for a commons in science and to promote public health are particularly compelling.<sup>62</sup> But the acceptance of public ownership through a commons in certain situations is a longstanding part of property law. As legal scholar Carol Rose has shown, 19th century law treated some resources as

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<sup>60</sup> Harlan J. Onsrud, *The Tragedy of the Information Commons*, in 3 POLY ISSUES MODERN CARTOGRAPHY 141, 141-158 (D.R.F. Taylor ed., 1998).

<sup>61</sup> BENKLER, *supra* note 57; Michael L. Katz & Carl Shapiro, *Network Externalities, Competition, and Compatibility*, 75 AM. ECON. REV. 424, 424, 440 (1985); S. J. Liebowitz & Stephen E. Margolis, *Network Effects and Externalities*, in THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 671, 671-74 (Peter Newman ed., 1998); Mark A. Lemley & David McGowan, *Legal Implications of Network Economic Effects*, 86 CALIF. L. REV. 479, 479-611 (1998); JAMES BESSEN & MICHAEL J. MEURER, PATIENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK (2008); Mark A. Hall, *Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records*, 95 IOWA L. REV. 631, 631-63 (2010); RUSSELL HARDIN, COLLECTIVE ACTION (1982); CONGRESSIONAL BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY (2008), available at <https://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf>; PAUL G. SHEKELLE ET AL., COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY: EVIDENCE REPORT/TECHNOLOGY ASSESSMENT No. 132 (2006), available at <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1b.chapter.6986>; Randall Cebul et al., *Organizational Fragmentation and Care Quality in the U.S. Health Care System* (2008), available at <http://ssrn.com/abstract=1230840>.

<sup>62</sup> See Guilhem Fabre, *Propriété intellectuelle, sante Publique et innovation pharmaceutique*, in PROPRIÉTÉ INTELLECTUELLE, CONTREFAÇON ET INNOVATION: LES MULTINATIONALES FACE À L'ÉCONOMIE DE LA CONNAISSANCE 71, 71-104 (2009); PHILIPPE AIGRAIN, INNOVATION PARTAGÉE ET BIENS COMMUNS EN BIOLOGIE (2008), available at <http://paigrain.debatpublic.net/docs/pha-Autrement-complet.pdf>; <http://creativecommons.org/licenses/by-nc-nd/2.0/fr/>; OXFAM, CUT THE COST: FATAL SIDE EFFECTS: MEDICINE PATENTS UNDER THE MICROSCOPE (2001); OXFAM, PATENT INJUSTICE: HOW WORLD TRADE RULES THREATEN THE HEALTH OF POOR PEOPLE (2000). Arti Rai & James Boyle, *Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons*, 5 PUB. LIBR. SCI. BIOLOGY 389, 389-93 (2007).

“inherently public property” when “the properties themselves were most valuable when used by indefinite and unlimited numbers of persons—by the public at large.”<sup>63</sup> In recent years, a growing body of scholarship has criticized intellectual property law and policy for allowing the creation of private property in situations that deter innovation and are not needed to encourage investment.<sup>64</sup> They argue that open resources are needed to promote innovation.<sup>65</sup> In a similar vein, other scholars have argued that we should resist the efforts of private groups to privatize the internet and set rules that ensure open access.<sup>66</sup>

#### A. PUBLIC OWNERSHIP WOULD ENSURE DATA COLLECTION AND AVAILABILITY

A key reason to grant private property rights, particularly for non-tangible property that can be shared, is that it creates incentives for individuals to engage in creative activities. Without such incentives, individuals would not be fully financially rewarded for their work because they could not preclude others from freely using it, and thus could not earn its full income-generating potential. Moreover, since individuals can often obtain the benefit from the creative work of others without cost, they would also have less incentive to undertake such activity themselves. Private ownership can also encourage individuals to undertake work that is not creative, such as compiling information, since it protects their investment.<sup>67</sup>

This rationale, however, does not support granting property rights in most patient data. Physicians and medical institutions now routinely record patient data as part of their medical records, prescriptions and billing. Physicians and medical facilities necessarily generate patient data as part of their work to provide medical care, to comply with health care regulations,

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<sup>63</sup> Carol Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53 U. CHI. L. REV. 711, 774 (1986).

<sup>64</sup> David Lange, *Recognizing the Public Domain*, 44 LAW & CONTEMP. PROBS. 147, 147-78 (1981); JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996); James Boyle, *A Politics of Intellectual Property: Environmentalism for the Net?*, 47 DUKE L.J. 87, 87-116 (1997); Robert Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1031-52 (1998); LAWRENCE LESSIG, *THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD* (2001); SIVA VAIDHYANATHAN, *COPYRIGHTS AND COPYWRONGS: THE RISE OF INTELLECTUAL PROPERTY AND HOW IT THREATENS CREATIVITY* (2001); PETER DRAHAOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* (2002); PHILIPPE AIGRAIN, *CAUSE COMMUNE: L'INFORMATION ENTRE BIEN COMMUN ET PROPRIÉTÉ* (2005); JAMES BOYLE, *THE PUBLIC DOMAIN: ENCLOSING THE COMMONS OF THE MIND* (2008); GUILHEM FABRE, *PROPRIÉTÉ INTELLECTUELLE, CONTREFAÇON ET INNOVATION: LES MULTINATIONALES FACE À L'ÉCONOMIE DE LA CONNAISSANCE* (2009).

<sup>65</sup> See Jack Hirshleifer, *The Private and Social Value of Information and the Reward to Inventive Activity*, 61 AM. ECON. REV. 561 (1971); RICHARD R. NELSON & SIDNEY G. WINTER, *AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE* (1982).

<sup>66</sup> See LAWRENCE LESSIG, *CODE: AND OTHER LAWS OF CYBERSPACE* (2001); LAWRENCE LESSIG, *THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD* (2001); PHILIPPE AIGRAIN, *INTERNET & CRÉATION: COMMENT RECONNAÎTRE LES ÉCHANGES SUR INTERNET EN FINANÇANT LA CRÉATION* (2008); PHILIPPE AIGRAIN, *CULTURE AND THE ECONOMY IN THE INTERNET AGE* (forthcoming).

<sup>67</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* (2003).

and to receive payment. Thus, there is no need for new incentives, either through property interest or payment, to induce them to *record* patient data.<sup>68</sup>

Still, the creation of a population-wide anonymized database requires collecting data from multiple patient records, billing statements, prescriptions, and other sources. Would public or private ownership of data better facilitate this data collection? I contend not only that public ownership is more efficient, but also that without public ownership it will be very difficult and perhaps impossible to aggregate population-wide patient data.<sup>69</sup>

Legislation mandating that designated entities report specified data in a uniform manner to a single entity can ensure the collection of *all* relevant data in a useful form; in contrast, voluntary efforts to share data would not. If patient data was privately owned, it is very unlikely that most data would be aggregated. Some data owners would decline to share or even sell their data because the purchase price was too low or because they want to commercialize it independently. Other owners will want to conceal information to protect themselves from liability, oversight, or criticism. Pharmaceutical and medical device firms do not have an interest in disclosing data that might reveal their products' safety risk for the same reasons. Physicians, hospitals and MCOs and other insurers also often prefer to avoid scrutiny.

Furthermore, private aggregators will probably find it most profitable to collect only selected data that has the greatest and most immediate commercial value. They could collect data either from sub-populations or only for particular clinical issues. Once such profitable databases are collected, it will be less profitable (and maybe not economically feasible) for other entities to collect the remaining data. Thus, even if all entities with patient data consented to sell or share their data, it is uncertain whether private entities will aggregate all or most of it.

Private ownership could not ensure a stable source of data. Fluctuations in market demand and the fortunes of private firms could result in certain data not being collected during some periods of time. For example, from 1970 to 2000 the AMA surveyed physicians nationally and produced an authoritative source of information on medical practice costs, income, and numerous characteristics of medical practice in the U.S.<sup>70</sup> This definitive data was used by the federal government, private firms, and scholarly

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<sup>68</sup> I assume that databases will only use data already recorded so that there is no additional work to collect data. The situation is different if databases that will be used require collecting data that is not yet recorded. There is probably also some value to organizations generating additional data that might also have yield spillover benefits. There is thus a case for treating such new data as a merit good and the government subsidizing its production.

<sup>69</sup> The conventional wisdom is that private ownership is more efficient than public ownership. This is not necessarily so. For example, roads and waterways often more efficiently help as public rather than private property. See Rose, *supra* note 63, at 714 n.17, 774-78.

For a critique of the idea that private property is generally efficient see Duncan Kennedy & Frank Michelman, *Are Property and Contract Efficient?*, 8 HOFSTRA L. REV. 711 (1979-1980); Harold Demsetz, *When Does the Rule of Liability Matter?*, 1 J. LEGAL STUD. 13, 25-28 (1972); Uwe E. Reinhardt, *Can Efficiency in Health Care Be Left to the Market?*, 26 J. HEALTH POL. POL'Y & L. 967 (2001).

<sup>70</sup> See, e.g., J. D. WASSENAAR & S. L. THRAN (AM. MED. ASS'N) PHYSICIAN SOCIOECONOMIC STATISTICS 2000-2002 (2003); M. L. GONZALEZ AND P. ZHANG (AM. MED. ASS'N), PHYSICIAN SOCIOECONOMIC STATISTICS 1997/1998 (1998); S. G. VAHOVICH (AM. MED. ASS'N) PROFILE OF MEDICAL PRACTICE (1973).

researchers. However, after the AMA ceased collecting the data in 2000, no other entity has taken its place. When there is a strong public interest in having reliable data and it is uncertain whether the market will supply it, there are strong grounds for public authorities to shoulder the responsibility.

In addition, antitrust law would probably preclude any single firm from owning all data, thereby also hampering the ability to create a national database.<sup>71</sup> True, private ownership combined with a market for data might allow the creation of large databases by several entities, which could yield many beneficial uses. Yet a population-wide database is much more valuable than databases fractured among sub-populations. Furthermore, the creation of large privately owned databases would be very costly. Multiple entities would seek to create databases which would increase transaction costs. Each aggregator would have to negotiate with the data seller over price and other terms. Some owners will hold out selling data and seek exorbitant fees.

#### B. PRIVATE OWNERSHIP WOULD RESTRICT BENEFICIAL USES OF PATIENT DATA

Patient data has value in part due to the information it provides directly, but mostly due to services and products derived from it. Private ownership of patient data would create monopolies and restrain development of data-derived services and products. Data owners can tie their data to purchases of related services and products. Such tie-ins restrict competition in the market for data-derived services. Even if data owners sell their data independently, they could charge monopoly prices, also restricting access to data-derived services.

These problems disappear if the data is publicly available and multiple firms compete in providing data analysis, services and products. Public ownership of data would stimulate the development of data-related services and products by precluding data monopolies and ensuring the availability of data. Multiple entrepreneurs could add value by organizing data in original ways, facilitating its use, or combining it in software or simulation models. Individuals and firms would have incentives to develop data-related services and products because they could sell these.

Commercial firms often restrict access to data to protect their interests. Clinical trial data provides an example. Firms that develop drugs and medical devices conduct clinical trials to demonstrate that their products are safe and effective in order to receive governmental approval for their sale. Firms that undertake such costs want to preclude competitors from using this data to develop generic versions. Pharmaceutical and medical device firms therefore sought international legal protection from competing firms using their clinical test data for their own drug or medical device approval. They received it in 1994 under the agreement on Trade-Related Aspects of Intellectual Property (TRIPS).<sup>72</sup> Delaying generic drugs from coming to market may be justified

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<sup>71</sup> For a discussion of antitrust and intellectual property law, see LANDES & POSNER, *Antitrust and Intellectual Property*, in *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW*, *supra* note 67, at 372-402.

<sup>72</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T. 299; [hereinafter TRIPS Agreement]. Article, 39.3 of TRIPS Agreement applies to clinical



because the restriction rewards firms that invest in research. However, protecting the disclosure of clinical trial data also allows firms to suppress information about health risks of their products. This has led some writers to criticize TRIPS and argue that test data should be public to ensure public safety.<sup>73</sup>

In the late 20th and early 21st centuries, numerous scandals ensued when pharmaceutical firms delayed the disclosure of research data that revealed their products' health risks, or suppressed the data altogether. Some drug firms also published evaluations of drugs that included only partial trial data, thus distorting the results of studies published in medical journals and relied on by doctors and the FDA.<sup>74</sup> The International Committee of Medical Journal Editors believed such practices were inimical to good science and medicine. They decided, in 2005, not to consider for publication any studies based on clinical trials that had not been publicly registered.<sup>75</sup> In 2007, Congress required that sponsors of clinically directed therapeutic trials register all but phase 1 trials with the National Library of Medicine, which makes the information public.<sup>76</sup> Still, regulatory agencies cannot use test data to evaluate competing generic products; manufacturers can use test data exclusively for a period after marketing approval; and there are other restrictions on use of the data. Thus, the tension between commercial and public interest in disclosure of clinical trial data persists.

In a similar vein, physicians, hospitals, insurers (as well as drug and medical device firms) have incentives to limit the availability of data from clinical practice to insulate themselves from competition and oversight. In addition, firms that seek to sell their data may also try to prevent governmental efforts to develop their own data. For example, Boston's Partners Healthcare (a joint venture of Massachusetts General Hospital and Brigham and Women's Hospital) opposed the Massachusetts plan to amass and sell data at the time it was planning to commercialize its own data.<sup>77</sup>

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trial test data. See generally Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, in NEGOTIATING HEALTH INTELLECTUAL PROPERTY AND ACCESS TO MEDICINE 81 (Pedro Roffe, Geoff Tansey & David Vivas Eugui eds., 2006); Meir Perez Pugtach, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, in NEGOTIATING HEALTH INTELLECTUAL PROPERTY AND ACCESS TO MEDICINE, at 110-12; Robert Weisman, *Data Protection: Options for Implementation*, in NEGOTIATING HEALTH INTELLECTUAL PROPERTY AND ACCESS TO MEDICINE, at 151.

<sup>73</sup> Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?*, in NEGOTIATING HEALTH INTELLECTUAL PROPERTY AND ACCESS TO MEDICINE, *supra* note 72, at 133-34, 133.

<sup>74</sup> Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, *Expression of Concern: Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," New Engl. J. Med. 2000; 343:1520-8, 353 NEW ENG. J. MED. 2813, 2813 (2005); see also JOHN ABRAMSON, False and Misleading: The Misrepresentation of Celebrex and Vioxx*, in OVERDOSHED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE 23, 23-28 (2004).

<sup>75</sup> Catherine DeAngelis et al., *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, 351 NEW ENG. J. MED. 1250, 1250 (2004); Christine R. Laine et al., *Clinical Trial Registration—Looking Back and Moving Ahead*, 356 NEW ENG. J. MED. 2734, 2734 (2007).

<sup>76</sup> Jeffrey M. Drazen, Stephen Morrissey & Gregory D. Curfman, *Open Clinical Trials*, 357 NEW ENG. J. MED. 1756, 1756 (2007).

<sup>77</sup> Steve Bailey, *supra* note 31, at C1.

Private data owners would often undermine the public's interest in generating longitudinal and national data and making it accessible.

C. PUBLIC OWNERSHIP AVOIDS THE ANTI-COMMONS PROBLEM, PATENT THICKETS AND HOLD OUTS

Scholars in economics and other fields have explored the *tragedy of the anti-commons*, a situation in which private ownership leads to underuse or development that is detrimental to both individual owners and the public. The problem is the reverse of the more widely discussed *tragedy of the commons*, which occurs when collective ownership of natural resources results in their depletion.<sup>78</sup> If a non-renewable natural resource is publicly available and no one pays fees based on individual use, individuals have no incentive to use the resource prudently. As a result, they are likely to overuse and even deplete the resource. The tragedy of the commons often occurs in commonly owned grazing fields and fishing grounds.

Writers frequently invoke the tragedy of the commons as grounds to favor private rather than public ownership.<sup>79</sup> Private owners bear the full cost and benefit of using and maintaining their resource. Therefore, they have incentives to limit the resource's use to sustain its continued value, and to invest in its protection and development. That helps prevent the tragedy. Still, private ownership does not guarantee that natural resources will not be depleted. Owners may be interested in short-term profit rather than sustained growth, or be short-sighted or not aware of how to preserve their resource. Moreover, private ownership is not required to avoid the tragedy of the commons. Professor Elinor Ostrom was awarded the Nobel Prize in economics for demonstrating that in certain circumstances, collective users of common, pooled resources can avoid tragedies of the commons, sustain resources, and manage them productively.<sup>80</sup> Similarly, public ownership combined with public management of natural resources can also avoid a commons tragedy.<sup>81</sup>

In the late 1990s, legal scholar Michael Heller and others revealed the presence of anti-commons problems when "multiple owners each have a right

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<sup>78</sup> The term "tragedy of the commons" was coined by Garret Hardin in his classic essay, Garrett Hardin, *The Tragedy of the Commons*, 162 *SCIENCE* 1243 (1968). The issue has generated a large scholarly literature. See, e.g., James E. Krier, *The Tragedy of the Commons, Part Two*, 15 *HARV. J.L. & PUB. POLY* 325 (1992). Frank I. Michelman defines a commons as the opposite of private property, *NOMOS XXIV*. Frank I. Michelman, *Ethics, Economics and the Law of Property*, in *ETHICS, ECONOMICS AND THE LAW* 3, 9 (J. Roland Pennock & John W. Chapman eds., 1982).

<sup>79</sup> GARY D. LIBECAP, *CONTRACTING FOR PROPERTY RIGHTS* 29, 29-114 (James Alt & Douglass C. North eds., 1989). Harold Demsetz, *Toward a Theory of Property Rights*, 57 *AM. ECON. REV.* 347 (1967).

<sup>80</sup> ELINOR OSTROM, *GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION* (James Alt & Douglass C. North eds., 1990); ELINOR OSTROM, ROY GARDNER & JAMES WALKER, *RULES, GAMES, AND COMMON-POOL RESOURCES* (1994); see also Rose, *supra* note 63, at 711.

<sup>81</sup> Many writers emphasize the value of private ownership to avoid the tragedy of the commons but management of the publicly owned resource can be equally effective. The later possibility is often forgotten, but Garret Hardin discusses this subject in his thoughtful review of the issue 30 years later. See Garret Hardin, *Extensions of "The Tragedy of the Commons"*, 280 *SCIENCE* 682 (1998).

to exclude others . . . and no one has an effective privilege of use.” Under these circumstances private ownership often stifles innovation and effective use of the property.<sup>82</sup> Heller observed anti-commons problems in post-Soviet Russia during the transition from state-owned to private property.<sup>83</sup> After several years many storefronts were empty and languishing while street kiosks were filled with goods and thriving. He explains this paradox by showing that the property rights in storefronts were divided among several owners and did not give any individual the full rights over the economic unit needed to operate them. In contrast, property rights for kiosks were individually owned.

Anti-commons problems do not often occur because frequently one individual can buy out other property owners and develop the property. That has prompted economist Ronald Coase to argue that no matter to whom property rights are initially assigned, in the absence of high transaction costs, individuals will voluntarily trade or sell their rights to those who could put them to the most productive use.<sup>84</sup> However, Coase acknowledges that in practice high transaction costs often prevent the optimal reallocation of property rights through markets.<sup>85</sup> In addition, individuals often make cognitive errors or have biases that impede their reaching mutually beneficial agreements, particularly when individuals do not know each other or lack a long term continuing relationship.<sup>86</sup> Thus, the designation of property rights often creates path dependency that favors existing arrangements, even if other uses are more productive.<sup>87</sup>

Heller and Rebecca Eisenberg have found anti-commons problems in biomedical research where ownership of basic building blocks for innovations is divided among numerous parties. These problems occur when a new product relies on several patents and the cost of combining the patents precluded the end use.<sup>88</sup> Heller says that this occurred with increasing

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<sup>82</sup> See generally Michael A. Heller, *The Tragedy of the Anti-commons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998); James M. Buchanan & Yong J. Yoon, *Symmetric Tragedies: Commons and Anti-commons*, 43 J.L. & ECON. 1 (2000); Margaret Jane Radin, *Property Evolving in Cyberspace*, 15 J.L. & COM. 509 (1996); Hanoch Dagan & Michael A. Heller, *The Liberal Commons*, 110 YALE L.J. 549 (2001); Fiona E. Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* (NBER, Working Paper No. 11465, 2005); Heller & Eisenberg, *supra* note 57.

<sup>83</sup> Andrzej Rapaczynski, *The Roles of the State and the Market in Establishing Property Rights*, 10 J. ECON. PERSP. 87 (1996).

<sup>84</sup> R.H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 2-6 (1960).

<sup>85</sup> R.H. COASE, *THE FIRM, THE MARKET AND THE LAW* 174-76 (1988).

<sup>86</sup> DOUGLAS G. BAIRD, ROBERT H. GERTNER, & RANDAL C. PICKER, *GAME THEORY AND THE LAW* 143 (1994); ROBERT C. ELLICKSON, *ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES* 180-83 (1991). Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer In Government-Sponsored Research*, 82 VA. L. REV. 1663, 1725 (1996).

<sup>87</sup> W. Brian Arthur, *INCREASING RETURNS AND PATH DEPENDENCE IN THE ECONOMY* (1994); Mark J. Roe, *Chaos and Evolution in Law and Economics*, 109 HARV. L. REV. 641, 646-47 (1996).

<sup>88</sup> Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, 27 REGULATION 54 (2004); Richard A. Epstein & Bruce N. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch Waxman* (John M. Olin L. & Econ., Working Paper No. 209, 2004); Heller & Eisenberg, *supra* note 57.

frequency after 1980, when biomedical research shifted from being largely based on a commons model to one that emphasized private property.<sup>89</sup>

Until then, the U.S. federal government sponsored most premarket research. Research results were part of the public domain and were relied on and incorporated into later discoveries and inventions to advance basic research and create marketable products. Then, hoping to facilitate technology transfer and commercial development, the 1980 Bayh Dole Act and other legislation allowed research institutions to patent discoveries conducted with federal grants. Yet these changes also led to “a proliferation of intellectual property rights upstream [that] may be stifling life-saving innovations further downstream in the course of research and product development.”<sup>90</sup>

Heller and Eisenberg explain that in the 1980s, biological patents on genes corresponded closely to foreseeable products, but that more recently individuals and firms have patented gene fragments and sequences without identifying a potential use.<sup>91</sup> The value of these biomedical processes and tools is realized only when they are combined and result in new uses. Yet, each such patent creates a monopoly for raw material needed to create a product that combines the patents, thereby making the cost of end products much higher than if there were one owner.<sup>92</sup> The cost of combining all patents related to products therefore increases and sometimes prevents the development of end products.<sup>93</sup>

Professor Lori Andrews has documented anti-commons problems in the patenting of genetic sequences.<sup>94</sup> In recent years, companies have patented gene sequences associated with diseases that are key to genetic testing and research. Athena Neuroscience, Inc. holds a patent on apolipoprotein E, a gene related to Alzheimer’s disease.<sup>95</sup> Myriad Genetics was granted a European patent related to breast cancer that protects all methods for diagnosing the cancer that compares the patient’s BRCA1 gene with the patented BRCA1 sequence.<sup>96</sup> Researchers searching for cures or treatments of these genetic diseases will have to obtain rights from the patent owners of those gene sequences and the hundreds of genetic mutations of those genes that are also patented. Moreover, the United States Patent and Trademark Office requires that individuals who discover a gene should not develop

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<sup>89</sup> Eisenberg, *supra* note 86, at 1663-64.

<sup>90</sup> Heller & Eisenberg, *supra* note 57, at 698.

<sup>91</sup> *Id.* at 699.

<sup>92</sup> Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 *INNOVATION POLICY AND THE ECONOMY* 119, 124 (Adam B. Jaffe, Josh Lerner, & Scott Stern eds., 2001), available at <http://www.nber.org/chapters/c10778.pdf>.

<sup>93</sup> Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *COLUM. L. REV.* 839, 875-77 (1990).

<sup>94</sup> These examples and discussions are based on Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 *NATURE REVIEWS GENETICS* 803 (2002). The analysis of these problems is developed further in Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 403 (2005); Jordan Paradise, Lori B. Andrews & Timothy Holbrook, *Intellectual Property: Patents on Human Genes: An Analysis of Scope and Claims*, 307 *SCIENCE* 1566 (2005).

<sup>95</sup> U.S. Patent No. 5,508,167 (filed Apr. 13, 1994).

<sup>96</sup> E.U. Patent No. EP699754 (filed Aug. 11, 1995).

products based on the gene or undertake mutual testing of the gene without the permission of those who hold patents on expressed sequence tags created from the gene. Negotiating such rights creates an obstacle to research on curing genetic diseases.

Similarly, private ownership of patient data would probably preclude its most valuable uses by fracturing population data.<sup>97</sup> If each patient had exclusive property rights to his or her medical data, aggregators would have to purchase data from each individual to create a national database. The cost of paying each individual would probably be prohibitive.<sup>98</sup> In addition to the purchase price, data aggregators would also incur significant transaction costs in contracting with individual owners, negotiating transfer rights, and competing with other data aggregators. Moreover, multiple parties could purchase data dividing the databases by region, or type of provider, or institution, or by different kinds of patient information. This too will fracture the information available among multiple owners that may impede their combined use.

If physicians, hospitals, or insurers were owners rather than patients, the data would be fractured into larger segments, but it would still require high costs to purchase patient data for a population-wide database. The expense would increase as the database became larger. Yet it is precisely national or large databases that are most useful in assessing patient and drug safety, in addressing public health issues, and in producing medical knowledge.

Some providers or organizations may demand exorbitant prices to purchase or use data that they control. Such holdouts are often referred to as *patent thickets*, *patent hold ups*, or *patent trolls*.<sup>99</sup> The potential for an injunction against a whole product can permit so-called patent trolls to hold up defendants by threatening to enjoin products that are predominantly non-infringing.<sup>100</sup> The impediments from holdouts are “magnified in presence of royalty stacking, i.e., when multiple patents read on a single product.”<sup>101</sup> The need to obtain permission from multiple patent holders raises the cost of creating the final product.

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<sup>97</sup> Onsrud, *supra* note 60, at 146.

<sup>98</sup> Vera Bergelson, *It's Personal but Its Mine? Toward Property Rights in Personal Information*, 37 U.C. DAVIS L. REV. 379, 418 (2003); Daniel D. Branhizer, *Symposium: Cyberpersons, Propertization, and Contract in the Information Culture: Propitiation Metaphors for Bargaining Power and Control of the Self in the Information Age*, 54 CLEV. ST. L. REV. 69, 104 (2006); Pamela Samuelson, *Privacy as Intellectual Property*, 52 STAN. L. REV. 1125, 1137 (2000); Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 804-05 (2004). For a sample of those opposed to making personal information property, see Anita L. Allen, *Coercing Privacy*, 40 WM. & MARY L. REV. 723 (1999); Julie E. Cohen, *Examined Lives: Informational Privacy and the Subject as Object*, 52 STAN. L. REV. 1373 (2000); Mark A. Lemley, *Private Property*, 52 STAN. L. REV. 1545 (2000); Marc Rotenberg, *Fair Information Practices and the Architecture of Privacy*, 2001 STAN. TECH. L. REV. 1 (2001).

<sup>99</sup> F. Scott Kieff, *Coordination, Property and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 391, 395-68 (2006); Heller & Eisenberg, *supra* note 57, at 700; Mark A. Lemley & Carl Shapiro, *Patient Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2008-11 (2007).

<sup>100</sup> Lemley & Shapiro, *supra* note 99, at 2008.

<sup>101</sup> *Id.* at 1992.

Holdouts are also a classic problem in real estate.<sup>102</sup> When a developer needs to purchase multiple parcels of land for a project, a single seller can hold out and block the entire project or extract near prohibitive prices.<sup>103</sup> If the purchaser has obtained all or most of the other development rights needed, the holdout is in a particularly strong position to demand a price disproportionate to its contribution to the total development. A similar phenomenon occurs when multiple permits are required from public authorities to develop a project.<sup>104</sup> The common element among these related problems is that granting ownership or control rights can reduce resource productivity and innovation.<sup>105</sup>

Even if private owners developed comprehensive patient databases, governmental authorities are unlikely to be able to afford to purchase the data needed for public health and important public uses. Unlike commercial firms that are likely to purchase limited data related to a particular market or commercial use, many beneficial public uses require comprehensive data, which will probably be more expensive than limited data. Moreover, commercial firms can often afford to pay high prices for data or other materials if it helps them develop profitable products and services. Public authorities, in contrast, do not purchase data to develop profits. Furthermore, some organizations may earn more by selling data to one or a few purchasers exclusively than by making it generally available.

#### D. CAN MARKETS RESOLVE ANTI-COMMONS PROBLEMS?

Some legal scholars have argued that private transactions can overcome anti-commons problems.<sup>106</sup> F. Scott Kieff and Troy Paredes argue that anti-commons problems created when multiple parties own intellectual property can be resolved through contracts, joint ownership and negotiation. They take as a paradigm case a DNA chip that would contain information on thousands of pieces of DNA, each of which is owned by different entities. Marketing the chip requires that the chip maker obtain rights of all the owners; one or several owners can jeopardize the project by refusing to sell or license their property.

Kieff and Paredes say that lawyers can develop private legal arrangements that create incentives for owners to cooperate, raise the cost of those who do not, and often solve the holdout problem. They suggest that a promoter create a limited liability company and allow all property owners a share in profits and management in return for licensing use of their intellectual property. That will create incentives for all to cooperate. They also suggest that the business can be directed in ways that minimize the benefits of infringement suits by distributing most assets to owners immediately, so there will be few assets available to those who sue the entity for patent infringement. They say

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<sup>102</sup> Lloyd Cohen, *Holdouts and Free Riders*, 20 J. LEGAL STUD. 351 (1991).

<sup>103</sup> Thomas J. Miceli & C.F. Sirmans, *The Holdout Problem, Urban Sprawl, and Eminent Domain*, 16 J. HOUSING ECON. 309, 311-12 (2007).

<sup>104</sup> Richard A. Epstein, *The Permit Power Meets the Constitution*, 81 IOWA L. REV. 407, 414-15 (1995).

<sup>105</sup> See Lemley & Shapiro, *supra* note 99, at 2010.

<sup>106</sup> F. Scott Kieff & Troy A. Paredes, *Engineering a Deal: Toward a Private Ordering Solution to the Anti-commons Problem*, 48 B.C. L. REV. 111 (2007).

that this strategy will reduce the number of holdouts. Most property owners who join the venture can then exert peer and social pressure to convince holdouts to end their blocking action. Even if some holdouts remain, the venture will still be able to produce a chip or other product of significant value. That fact will further undercut the incentive for the remaining few to hold out. They will be unable to stop the whole project and their own property will not be worth much independently.

To summarize, Kieff and Paredes argue that even when multiple parties can block a project, that does not preclude it from coming to fruition, because private ownership and markets create incentives to cooperate. This is certainly true. Still, the risk that a development will be blocked increases with the number of property owners who must agree on the terms of its use. Divided private ownership presents obstacles to beneficial common uses that do not exist with public ownership.

In a similar vein, Professor Mark Hall argues that private ownership can overcome anti-commons problems that block the adoption of integrated EMRs and networks.<sup>107</sup> Hall says that the best way to capture the network benefits of compiling data is to give “the compiler or custodian [the] right to sell or to license access to medical information under terms controlled by the patient.” Without this right, he argues, no one will have “enough incentive to invest in the construction of [interoperable] EMRs.”<sup>108</sup> Hall says the reason for this is, where there is no clear owner or there are multiple owners, no individual has clearly defined rights in all of a patient’s data. Therefore, either each owner can exclude all of the others, or no one can exclude others from using the data or from developing or transferring meaningful economic rights in data. He proposes granting to patients property rights in their medical data sufficient to commercialize it, subject to the government’s traditional authority over public health. “[P]roperty rights’ in medical information could be defined in a way that is nonexclusive and that permits free government access for public health and research purposes without having to pay ‘just compensation.’”<sup>109</sup> Patients could then sell their data rights or compel providers to cooperate with persons who want access to it. Firms could then invest in compiling patient data.

Granting property rights in data to patients would allow compilers to purchase it to create a database. However, this will not eliminate the obstacles to creating a comprehensive database that arise from the high transaction cost of collecting and aggregating patient data or from holdouts. Nor would it ensure that private firms have an incentive or the ability to create a *national* patient database.

The brunt of Hall’s article supports granting patients property rights in *all* their medical data. But he acknowledges the public benefits that would flow from common ownership of aggregate patient data. In concluding his article, Hall says that he would limit patients’ property rights to data “that can be linked to them personally,” not to data that is “anonymized (or de-identified).”<sup>110</sup> Hall says he does not object to public ownership of

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<sup>107</sup> See Hall, *supra* note 61, at 631.

<sup>108</sup> *Id.* at 660.

<sup>109</sup> *Id.* at 657.

<sup>110</sup> *Id.* at 661.

anonymized patient data, so long as individuals can own and transfer rights to their identified data.<sup>111</sup>

Limiting ownership to data that identifies patients, however, provides a weak incentive to aggregate patient data, particularly if anonymized data is public. Aggregate patient data is valuable for purposes that do not require identifying individuals; the market for patient data is virtually all for anonymized data. Moreover, privacy laws limit the market for identifiable data. If firms require private ownership as an incentive to aggregate patient data, then limiting ownership to data that identifies patients will probably be insufficient.

#### E. OTHER OBJECTIONS TO PUBLIC OWNERSHIP

Public ownership, of course, can entail costs as well as benefits. We must not ignore these. Professor Mark Hall contends that public ownership of patient data is unappealing because “the economic benefits derived from the information would not flow back to patients.”<sup>112</sup> Three critiques can be raised to this view. First, patients would benefit from contributing their data to a public database. They would share the fruits of medical research and analysis of patient data that produce new knowledge and improve medical care and patient safety. Moreover, I argue, private ownership of patients data would certainly impede, and probably preclude, the creation of these medical benefits.

Second, patients lack solid legal grounds to demand compensation for public use of their anonymized data. The law does not currently grant patients property rights in their data. In addition, public ownership would not deprive them of any currently-protected legal interest. Although currently most patient data is not publicly owned, insurers, physicians, and hospitals already sell it without paying patients. Courts are unlikely to find that government-mandated reporting of anonymized patient data constitutes a taking of property from patients in violation of the U.S. Constitution’s Fifth Amendment. Nor do patients have strong moral claims to receive payment. They benefit from what physicians and researchers learn from data from other patients without paying for use of such data. What grounds could they then have to demand compensation for others learning from data routinely collected as part of their medical care?

Third, patient data has economic value only if it is part of a system that can use it. Without such a system, there would be no market for patient data. However, if there are grounds for compensating patients individually for the economic value of the data they contribute to an aggregate database, there are equal grounds for charging them for the economic value they receive from having a medical data system that makes it possible for them to sell their data. The economic value that each patient produces by contributing data is probably no more than the economic value he or she receives from being able to make use of collective patient data. As a practical matter, separating the

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<sup>111</sup> Email from Mark Hall, Fred D. & Elizabeth L. Turnage Professor of Law, Wake Forest University School of Law, to Marc A. Rodwin, Professor of Law, Suffolk University Law School (Oct. 31, 2010 10:50 EST) (on file with author).

<sup>112</sup> Hall, *supra* note 61, at 654.



economic contribution of each patient's data and the economic benefit that each patient receives from use of other patients' data is not feasible. In fact, the monetary value that each patient could earn from selling his or her data would be very small since no compiler of a population-wide database could afford to pay each individual much. It is preferable for patients to reap in-kind benefits from use of their data rather than to seek a small payment.

#### IV. WOULD PUBLIC OWNERSHIP OF PATIENT DATA COMPROMISE PRIVACY?

The protections that patients have from physicians disclosing their personal information do not arise from the law deeming the information as their property. The same is true for privacy protections for individuals in other contexts. Instead, privacy law and other principles supply the governing standards.<sup>113</sup> Scholars have articulated numerous other grounds for protecting informational privacy, including civil rights, personal dignity, and default rules for licensing use of personal data.<sup>114</sup> Nevertheless, some people argue that one way to ensure privacy is to treat personal data as the individual's property with rights to prevent others from using it without permission.<sup>115</sup>

<sup>113</sup> PAUL SCHWARTZ & JOEL R. REIDENBERG, *DATA PRIVACY LAW: A STUDY OF UNITED STATES DATA PROTECTION 31-90* (1996).

<sup>114</sup> For civil rights as developed in European law, see Council Directive 95/46, art. 1, 1995 O.J. (L 281) (EC) (protecting individuals regarding use of personal data). For discussion of default licensing rules, see Samuelson, *supra* note 98, at 1151-67.

<sup>115</sup> Kenneth C. Laudon, *Markets and Privacy*, 39 COMM. ASS'N OF COMPUTING MACHINERY 92, 92-93 (1996) ("[T]o ensure the protection of individual privacy beyond 2000 we should consider market-based mechanisms based on individual ownership of personal information and a National Information Market (NIM) in which individuals can receive fair compensation for the use of information about themselves"); see also LAWRENCE LESSIG, *CODE AND OTHER LAWS OF CYBERSPACE* (1999) (discussing property rights to protect privacy on the internet); Bergelson, *supra* note 98, at 442 ("In a nutshell, the suggested legal regime would give individuals property rights in their personal information. They would own this information during their lifetime, subject to a (i) non-exclusive automatic inalienable license to the original collector and (ii) limited non-exclusive automatic license to the general public"); A. Machael Froomkin, *The Constitution and Encryption Regulation: Do We Need a "New Privacy"?*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 34 (1999) ("We would personalize ownership of facts about us in transitions, perhaps even sometimes in public, and we would try to use the property regime and intellectual property regime to take back some control over personal data"); Jerry Kang, *Information Privacy in Cyberspace Transactions*, 50 STAN. L. REV. 1193, 1246-94 (1998); Kenneth C. Laudon, *Extensions to the Theory of Market and Privacy: Mechanics of Pricing Information*, in *PRIVACY AND SELF-REGULATION IN THE INFORMATION AGE* 78 (U.S. Dep't of Commerce ed., 1997), <http://www.ntia.doc.gov/reports/privacy/selfreg1.htm>; Lawrence Lessig, *The Architecture of Privacy*, 1 VAND. J. ENT. L. & PRAC. 56, 63 (1999) ("A better solution, [to protect privacy] I suggest, is one that links the protection of architecture with the incentives of the market. Information is an asset. It is a resource which has become extremely valuable. And as it has become extremely valuable, commerce has tried to exploit it. This use has a cost—an externality borne by those who would prefer that this data not be used. So the trick is to construct a regime where those who would use the data internalize this cost, by paying those whose data are used. The laws of property are one such regime. If the law gave individuals the rights to control their data, or more precisely, if those who wanted to use that data had first to secure the right to use it, then a negotiation would occur over whether, and how much, data should be used. The market could negotiate these rights, if a market in these rights could be constructed."); Patricia Mell, *Seeking Shade in a Land of Perpetual Sunlight: Privacy as Property in the Electronic Wilderness*, 1 BERKELEY TECH. L.J. 1, 10 (1996) ("I describe the scope of the individual's right or privacy as being a type of property right in his electronic

Most of these writers discuss information that is not obtained from patient records, and their concern is with data that identifies individuals, rather than data that is anonymized. Still, some of their arguments might apply to anonymized patient data.

Typically these writers refer to personal information that identifies the individual name, residence, telephone number or other unique information, along with features or behaviors, such as purchasing habits, web page searches, income, organizational affiliation, employment, and financial information. They argue that granting individuals ownership of their personal data would allow them to block others acquiring or making use of it without their permission. Individuals would be able to allow others to use or own information about them if they wished, typically by licensing or selling their data. Proponents of this approach say it would make possible what they call a *market for privacy*, although a more accurate description is probably a market for personal information.<sup>116</sup> As part of this approach, some scholars urge that the law be changed so that it implies contract default rules that would protect privacy of personal information in the absence of other explicit agreements.<sup>117</sup> Surveying typical arrangements by which firms obtain personal information, Professor Paul Schwartz finds market failure. Individuals lack meaningful choices as to whether third parties collect their personal information. To the extent that a choice exists, it is either to refrain from disclosing any information, or to sell it. They do not have the option of disclosing only certain items of information, or selling it for limited purposes.

Schwartz also notes that informational privacy has aspects of a public good. He concludes that in order for markets for personal information and privacy to work as advocates propose, we must regulate the sale of personal data. He proposes several conditions that would facilitate a market for propertied personal information.<sup>118</sup>

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persona . . . [E]ach of four interest groups—the individual, the commercial, the public and government—could have a property interest in the individual's persona . . . . The rights of any other entity . . . that might obtain, access, or make use of or disclose the persona would be subordinate to those of the individual. As with other forms of property, the individual's right to restrict the use of his person by others would vary depending on the reasons for their use"); Richard S. Murphy, *Property Rights in Personal Information: An Economic Defense of Privacy*, 84 GEO. L.J. 2381, 2383-84 (1996) ("Such [personal] information, like all information, is property. The question that law must answer is: Who owns the property rights to such information . . . ?"); Paul M. Schwartz, *Property, Privacy and Personal Data*, 117 HARV. L. REV. 2056 (2003); Paul Schwartz, *Beyond Lessig's Code for Internet Privacy: Cyberspace Filters, Privacy Control and Fair Information Practices*, 2000 WIS. L. REV. 743, 744 (2000); see also Alan F. Westin *Developments in the Law—the Law of Cyberspace*, 112 HARV. L. REV. 1574, 1644-45 (1999).

Some special considerations arise in privacy/property issues concerning genetic information. See Suter, *supra* note 98; George J. Annas, Leonard H. Glantz & Patricia A. Roche, *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 J.L. MED. & ETHICS 360 (1995).

<sup>116</sup> Schwartz, *Property, Privacy and Personal Data*, *supra* note 115, at 2094-2128.

<sup>117</sup> See, e.g., Murphy, *supra* note 115, at 2407-16; Steven A. Bibas, *A Contractual Approach to Data Privacy*, 17 HARV. J.L. & PUB. POL'Y 591, 606-07 (1994); Craig Martin, *Mailing Lists, Mailboxes, and the Invasion of Privacy: Finding a Contractual Solution to a Transnational Problem*, 35 HOUS. L. REV. 801, 830-31 (1998); Schott Schorr, *Personal Information Contacts: How to Protect Privacy Without Violating the First Amendment*, 80 CORNELL L. REV. 1756, 1759 (1995).

<sup>118</sup> Schwartz, *Property, Privacy and Personal Data*, *supra* note 115, at 2126.

Privacy proponents disagree as to whether granting individuals property interests in their personal data is an effective way to protect privacy. Critics of the private ownership approach note that property rights are incorrectly “perceived as a-regulatory,” self-enforcing, and thus as avoiding the “objections raised against significant government regulation.”<sup>119</sup> Some scholars argue that a market in personal data would involve very high transaction costs.<sup>120</sup> Professor Kenneth Laudon, an advocate of personal information markets, acknowledges that in order for them to function well, we would need to develop a significant infrastructure to oversee the market, and that this will entail enormous costs.<sup>121</sup>

Even more important, several legal scholars argue that treating personal data as private property would not increase privacy protection.<sup>122</sup> Pamela Samuelson, for example, explains that when individuals transfer their property interest in data, they lose control over its use; the purchaser can in turn sell it without restraint. Property interests in information would therefore remove existing restraints on confidentiality if individuals sold their personal information.<sup>123</sup> Individuals may be willing to sell data to one purchaser for a particular purpose, but such restrictions will be very hard to enforce after the sale, particularly if the purchaser sells or otherwise transfers the data to others. Monitoring compliance with initial restrictions to future purchasers will be difficult. Other scholars, therefore, argue that if the law grants property rights in personal data, it should restrict, at least in part, the right to resell it.<sup>124</sup> These arguments suggest that private ownership of personal data would not eliminate the risks to violation of privacy.

Some issues and rules regarding privacy apply generally, but others are specific to medicine. State laws generally prohibit health care providers and institutions from disclosing confidential patient information to third parties without the consent of patients. Yet, there are limits on patient confidentiality and control over their medical information.<sup>125</sup> Society has an

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<sup>119</sup> Jessica Litman, *Information Privacy/Information Property*, 52 STAN. L. REV. 1283, 1293 (2000).

<sup>120</sup> Samuelson, *supra* note 98, at 1135.

<sup>121</sup> Laudon, *Markets and Privacy*, *supra* note 115, at 101-03.

<sup>122</sup> Allen, *supra* note 98, at 733-34; Cohen, *supra* note 98, at 1423-28; Rochelle Cooper Dreyfuss, *Warren and Brandeis Redux: Finding (More) Privacy Protection in Intellectual Property Lore*, 8 STAN. TECH. L. REV. 8, ¶ 8-13 (1999), available at WESTLAW; Lemley, *supra* note 60, at 1545-55; Litman, *supra* note 111; Rotenberg, *supra* note 98 (“A property-based regime [for personal information] . . . lacks any commitment to an institutional structure (or more broadly democratic institutions) that could be established to protect an underlying public interest.”); Samuelson, *supra* note 98.

<sup>123</sup> Samuelson, *supra* note 98, at 1145.

<sup>124</sup> See Litman, *supra* note 119; Hal R. Varian, *Economic Aspects of personal Privacy*, in U.S. DEPT. OF COM., PRIVACY AND SELF REGULATION IN THE INFORMATION AGE 35-37 (1997), <http://www.ntia.doc.gov/reports/privacy/selfreg1.htm#1C>.

<sup>125</sup> Even when patient privacy interest is not compromised, patients still have other interests in how information from their medical records is used. They have interests in such information being used to improve medical care for themselves and others. They may also have interests in sharing the commercial gain from such information or in restricting the use of such information in ways that harm patients or compromise good medical practice. The interest in data resembles, in part, that of research subjects in how their tissue or cells are used. For analysis of the interest of research subjects see Lori Andrews & Julie Burger, *A Pound of Flesh: Patient Legal Action for Human Research Protection in the Biotech Age*, in

interest in public health that sometimes conflicts with patient confidentiality. The law requires that physicians and health care institutions report certain communicable diseases. Sometimes a statute or court order requires disclosure for other purposes. Courts have required physicians to breach confidentiality to protect identifiable individuals from clear and direct harm.<sup>126</sup> In addition, third-party payers have a right to certain patient information to ensure the appropriateness of claims for reimbursement.<sup>127</sup>

Since 1996, the federal Health Insurance Portability and Accountability Act (HIPAA) regulates the disclosure of patient information by designated entities. However, HIPAA allows a significant amount of disclosure and sale of patient data. The HIPAA amendments in 2003 allow covered entities to share patient medical information with health care-related businesses (including employers, drug and insurance companies, marketing firms, accountants, banks and financial service companies, data warehouse, medical transcribers, data processing firms, consumer reporting agencies, pharmacies and legal services).<sup>128</sup> It also allows sharing information that does not identify the individual patient's identity.<sup>129</sup> Moreover, HIPAA does not include as a covered entity personal health records that Google, Microsoft, and other firms are now developing.<sup>130</sup>

As a result, today many medical organizations share confidential patient data with health care-related businesses. They also freely sell to a wide range of entities patient data that does not state the patient's identity. Yet even with such data, there are risks to patient privacy. A patient medical record that does not state the patient's identity may indicate his or her physician, pharmacy, hospital, zip code, or insurer. By combining this with other information that is either public or purchased from private parties, it is often possible to identify the patient. In short, what has previously been assumed to be anonymized data usually is not.<sup>131</sup> We therefore need to develop means to encrypt data, and to oversee its use, regardless of its status as property and the uses made of it. Whatever the potential benefits for privacy from private ownership of patient data, there are risks of unauthorized disclosure both when anonymized patient data is deemed to be private property and when the data is publicly owned.

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IMPATIENT VOICES: PATIENTS AS POLICY ACTORS (Beatrice Hoffmaan et al., eds.) (forthcoming 2011).

<sup>126</sup> *Tarasoff v. Regents of the Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).

<sup>127</sup> Medical institutions, insurers, and governmental agencies also use patient information to oversee the quality of medical care.

<sup>128</sup> See Privacy of Individually Identifiable Health Data, 47 C.F.R. § 164, 500-34 (2009).

<sup>129</sup> See Other Requirements Relating to Uses and Disclosures of Protected Health Information, 45 C.F.R. § 164.514 (2009).

<sup>130</sup> ROBERT GELLMAN, THE WORLD PRIVACY FORUM, PERSONAL HEALTH RECORDS: WHY MANY PHRS THREATEN PRIVACY 3-4 (Feb. 20, 2008), [http://www.worldprivacyforum.org/pdf/WPF\\_PHR\\_02\\_20\\_2008fs.pdf](http://www.worldprivacyforum.org/pdf/WPF_PHR_02_20_2008fs.pdf); Nicolas P. Terry, *Personal Health Records: Directing More Costs and Risks to Consumers?*, 1 DREXEL L. REV. 216, 239-40 (2009).

<sup>131</sup> Arvind & Vitaly Shamatikov, *Myths and Fallacies of "Personally Identifiable Information"*, 53 COMM'N OF THE ACM 24, 24-26 (2010); Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701, 1716-31 (2010).

Public reporting and ownership of anonymized patient data could be done in a way that creates greater privacy protections than currently exist. Public authorities could ensure that no data is publicly released that does not comply with privacy safeguards. They are more likely to implement such policies than private firms because they do not have a profit motive to sell confidential information, while private firms do. In addition, when the data is publicly owned, it will be overseen using a uniform standard, which is not the case when it is sold by private organizations, each of which may have its own policies and operating methods.

Public ownership of patient data would allow greater oversight of data use than would federal regulation of patient data that is privately owned. The United States Constitution's Fifth Amendment restricts the government from *taking* private property without compensating the owner. Courts have held that regulation of property often constitutes a *taking* of the property because it restricts rights to the property's use.<sup>132</sup> As a result, sometimes the government cannot regulate property use because it lacks the financial means to compensate the property owner.

## V. WHAT DATA TO MAKE PUBLIC AND HOW TO DO IT

There is precedent for federal and state governments to require reporting of data, starting with census data. Since the New Deal, the federal government has played a significant role in the national economy and has developed and disseminated authoritative statistical data on economic, agricultural and other trends.<sup>133</sup> Federal law requires reporting and public disclosure of information in many contexts. For example, the Securities and Exchange Act of 1934 requires that all firms that sell securities on stock exchanges must disclose all information that is relevant to investors deciding whether to purchase their stock.<sup>134</sup> Publicly traded firms must supply significant information on their operations, finances, liability, market competition, market strategy, and their legal and financial risk. Firms must disclose the release of toxic chemicals as part of the Toxics Release Inventory, under the Emergency Planning and Community Right-to-Know Act of 1986.<sup>135</sup> The Medicare program requires hospitals to report cost information, analyzes it to revise reimbursement, and makes the data public.<sup>136</sup> Massachusetts, Maine, New Hampshire, and some other states already have data based on patient billing records from all payers.<sup>137</sup> State public health law typically requires providers to report certain communicable diseases.

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<sup>132</sup> See *Lucas v. S. Carolina Coastal Council*, 505 U.S. 1003 (1992); Joseph L. Sax, *Takings, Private Property and Private Rights*, 81 YALE L.J. 149 (1971).

<sup>133</sup> ALASDAIRE ROBERTS, *BLACKED OUT: GOVERNMENT SECRECY IN THE INFORMATION AGE* 11-14, 201 (2006). See, e.g., *THE STATISTICAL ABSTRACT OF THE UNITED STATES*, <http://www.census.gov/compendia/statab/>.

<sup>134</sup> Securities and Exchange Act of 1934, 15 U.S.C. § 78b (2006).

<sup>135</sup> 42 U.S.C. § 11004 (2006).

<sup>136</sup> See *Research, Statistics and Data Systems*, CENTER FOR MEDICARE AND MEDICAID SERVICES, <http://www.cms.hhs.gov/home/rsds.asp> (last visited Oct. 1, 2010) (providing links to the results of various CMS studies).

<sup>137</sup> See, e.g., An Act Providing Access to Affordable, Quality, Accountable Health Care, 2006 MASS. ACTS 77, 80-87 (creating the Massachusetts Health Care Quality and Cost Council to promote quality and cost control). The Council created an all-payer claims database which

A public requirement to report some patient data already exists in California, which requires all its hospitals to report data on patients within thirty days of discharge. Hospitals report patient diagnosis, therapy, drug use, and other information about patient care and medical condition without identifying the patient. California makes this information from all hospitals available in a single database for a small fee.<sup>138</sup>

Federal law could require all United States hospitals to report the same data that California requires to the DHHS or a public authority created for this purpose. It could expand hospital reporting to include ambulatory care data as well as inpatient data. Hospitals should report patient discharge data in a way that allows analysis of patient care by hospital, physician, diagnosis, procedure, therapy and drugs prescribed. Other medical institutions (ambulatory care surgery centers, rehabilitation facilities, nursing homes, and community health centers) should be required to report similar data. Third-party payers, MCOs, and self-funded health benefit plans created under the Employee Retirement Income Security Act of 1974 (ERISA) should report patient data, dispensing data, and billing information that they receive from their providers and from dispensing organizations.

Pharmacies and all others that dispense drugs (including pharmaceutical benefit managers, clinics, and physicians and nurses that dispense drugs) should report the drugs they dispense by dosage, provider ID number, and diagnosis when this information is available. Dispensers that submit data to third-party payers for reimbursement should provide the same data to DHHS at the same time. Firms not reimbursed by third-party payers should also report dispensing data monthly.

Providers should submit the same patient information to DHHS as they do to third-party payers when seeking payment. In addition, providers should submit to DHHS on a quarterly basis current patient profile data. All data should protect patient confidentiality by not revealing the patient's identity. However, providers should submit their data with their own tracking number so that it is possible to analyze the physician's care for the patient over time by analyzing quarterly reports.

To ensure confidentiality, the federal government should develop reporting procedures that eliminate patient identifiers before they are reported to DHHS. In addition, DHHS should review submitted data and scrub it to eliminate patient identifiers before releasing it. DHHS should make patient data available to the public, perhaps charging modest user fees.

The details of what kind of data to make public, how to implement data reporting, and what measures should be put in place to ensure patient confidentiality require further work. However, these issues are already being

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is publicly available, some of it online as of 2008. MYHEALTHCAREOPTIONS, <http://hcqcc.hcf.state.ma.us> (last visited Oct. 1, 2010).

<sup>138</sup> The reporting began with the passage of the California Hospital Disclosure Act by the California Legislature in 1971. Since then the reporting requirements have been revised through legislation and regulation several times. For a history, see CAL. OFFICE OF STATEWIDE HEALTH PLANNING AND DEV., INPATIENT DATA REPORTING MANUAL vi-xi (7th ed. 2010), available at <http://www.oshpd.ca.gov/HID/MIRCal/IPManual.html>. For information on the availability of the data and a manual that describes the data, see generally CAL. OFFICE OF STATEWIDE HEALTH PLANNING AND DEV., INPATIENT DATA REPORTING MANUAL (7th ed. 2010), available at <http://www.oshpd.ca.gov/HID/MIRCal/IPManual.html>.

discussed by the health information industry and providers as they collect and sell patient data today and as they explore future data sharing among private markets. Their analysis and conversations can be a starting point for examining these issues. Public reporting initially will be restricted by what data is available in electronic format. Currently, billing records are most often in electronic format, but many providers do not yet use EMRs or electronic prescribing. As standards for EMRs evolve, this too will affect what and how data should be reported, and by whom.

Patient data currently available has significant limitations for the purpose of promoting public health and patient safety.<sup>139</sup> For example, hospital data is typically based on billing information rather than by medical records, and on individual episodes of care, rather than by individual patient. Often data available from patient records is not linked to billing information. It is thus difficult to track information on patients across health care settings and over time. Furthermore, there is no uniform system of collecting or recording such information; there are multiple formats, and kinds of software, all of which complicates working with data across institutions. Creating, maintaining and administering such databases is difficult and costly. These are significant impediments to effective use of patient data for patient safety and health promotion. But they affect implementation, not the value of such data or the arguments for public reporting and ownership. In addition, some implementation problems may be resolved as technology develops that integrates the use of patient records, prescribing information, and billing, and also as technology for managing data develops.

Moreover, requirements for public reporting are likely to help resolve these problems. The use of electronic data has developed rapidly and effectively where governmental policy or large private institutions have set a single standard of information, specifying the data that must be collected and the technology that must be used. Several European countries have developed electronic record keeping and are ahead of the United States. France, for example, has a uniform system for recording patient data; Taiwan, too, has developed a uniform electronic system for patient records.<sup>140</sup> In the United States, the Veteran's Administration health system is a national leader in using patient data and in quality assurance in large part because it has been able to require a uniform standard across all facilities and providers. Other leaders in collecting and using patient information are large, integrated HMOs and health care systems, such as Kaiser Permanente and Geisinger Health System. But for much of the United States, the presence of competing insurers and private health care institutions, combined with the absence of uniform reporting requirements, leads to incompatible standards that prevent the collection of useful data. Many of these problems would disappear or become much easier to address if the federal government set standards for what must be collected and reported.

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<sup>139</sup> I am indebted to Eugene Declercq for helping me understand the limitations of data.

<sup>140</sup> See *Frontline: Sick Around the World* (PBS television broadcast Apr. 15, 2005), available at <http://www.pbs.org/wgbh/pages/frontline/sickaroundtheworld/view>.

## VI. CONCLUDING OBSERVATION: A PUBLIC INTEREST?

This article states the case for public rather than private ownership of certain patient medical data. Public ownership of patient data, I maintain, is necessary to ensure the supply of data required for key governmental activities that promote public health, individual patient safety, and the development of medical knowledge. The public ownership of such data is also necessary for effective public and private oversight of medical facilities, insurers, providers, and firms that supply drugs, medical devices and medical supplies. And it is necessary to ensure that data monopolies do not preclude the full development of analysis, services, and products derived from patient data in the private sector.

This inquiry raises broader issues regarding the role of the state and private firms in society. One way to frame these broader issues—although it is out of fashion—is in terms of the public interest. There are two main conceptions of the public interest. One conception predominates in European social thought. Beginning in the ancient world, Roman law defined the public good as occupying a sphere distinct from individual interests that were governed by private law. In medieval Europe the Catholic Church developed this idea and clothed monarchy with a moral mission by advancing the idea that rulers should govern for the public good. Jean-Jacques Rousseau's 1762 book, *The Social Contract*, conceived of the public interest as a norm about the collective good that is distinct from the sum of individual interests.<sup>141</sup> During the French Revolution, the state assumed the Catholic Church's moral authority and charitable functions and enshrined the idea of the common good in secular public law.<sup>142</sup> Influenced by Rousseau, the modern French state defined the public interest as the good of the nation. Today, in France and other civil law jurisdictions, public law is premised on the idea of a public good different from private interests.<sup>143</sup>

In line with this idea of the public interest, several American writers have analyzed public policy. Steven Kelman and others have examined the role of *public spirit* as a force in policymaking.<sup>144</sup> In a similar vein, Deborah Stone has explored the idea of *social solidarity* as a basis for organizing health insurance.<sup>145</sup> Robert Bellah, Michael Waltzer, Dan Beauchamp, and other writers often referred to as communitarians illuminate the value of collective social choices and shared responsibility.<sup>146</sup>

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<sup>141</sup> JEAN-JACQUES ROUSSEAU, *THE SOCIAL CONTRACT AND DISCOURSES* 10-11 (G. D. H. Cole, trans., 2003).

<sup>142</sup> See ELISABETH ZOLLER, *INTRODUCTION TO PUBLIC LAW: A COMPARATIVE STUDY* 1-23 (2008).

<sup>143</sup> See *id.*

<sup>144</sup> E.g., Steven Kelman, *The Wellspring of Public Behavior: Alternative Views*, in *MAKING PUBLIC POLICY: A HOPEFUL VIEW OF AMERICAN GOVERNMENT* 239-47 (James Q. Wilson ed., 1987); DEBORAH STONE, *THE SAMARITAN'S DILEMMA: SHOULD GOVERNMENT HELP YOUR NEIGHBOR?* (2008).

<sup>145</sup> Deborah Stone, *The Struggle for the Soul of Health Insurance*, 18 *J. HEALTH POL., POL'Y & L.* 287, 290-92 (1993).

<sup>146</sup> See, e.g., DAN E. BEAUCHAMP, *THE HEALTH OF THE REPUBLIC: EPIDEMICS, MEDICINE, AND MORALS AS CHALLENGES TO DEMOCRACY* (1990); ROBERT N. BELLAH ET AL., *HABITS OF THE HEART* (1985); MICHAEL WALTZER, *SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY* (1983); Dan E. Beauchamp, *Community: The Neglected Tradition in Public Health*, 26 *HASTINGS CENTER REP.* 28 (1985); Jean Forster, *A Communitarian Ethical Model for*



A second conception of the public interest is associated with the liberal state and is more popular in the United States. Under this conception, the public interest is understood as the sum of individual interests reconciled through competition and negotiation among interest groups.<sup>147</sup> According to this idea, all social value arises from the value of independent, atomized individuals. Many American economists and social theorists support this view and have criticized the idea of a collective public interest. Various writers debunk the idea of a common good and that individuals ever act for public-spirited motives or for the public good. They argue that private parties and elected representatives pursue their self interest and that it is good that they do.<sup>148</sup> Some writers favor a minimum role for government, mainly to correct market failures.

In line with the liberal conception of the public interest, contemporary American policy thinkers often understand the state's role as ensuring conditions necessary for markets to function well. Some writers see the state's role as creating rules and institutions necessary for markets to function and policing the conduct of private parties. Others say that the state must ensure the supply of information necessary for individual actors to make informed decisions. Another line of thought sees the state as supplying funds for those who lack means so that they can participate in the market and overcome market failure created by unequal distribution of income. Still others maintain that the state should supply some collective benefits, particularly for public goods.

The case for public ownership of patient data that this article makes does not depend on using or accepting the robust European conception of the public interest in place of the more limited liberal conception. Nevertheless, ideas affect the way people see the world. Those who view the world through the prism of the liberal model of the public interest carry its conceptual baggage. They start with the idea that normally, property is private and interests are individual. They take as a premise that this is the natural state of affairs and demand justification for any departure from it. They have a predilection to limit the government's sphere and collective decision-making. That way of thinking can skew their assessment of the ability of markets to perform, the merits of governmental action and public ownership, and the values at stake in policy choices. These biases are not always readily apparent. Therefore, it is a useful experiment to discuss some policy choices, such as those that this article discusses, using the language of the more robust European concept of the public interest to see how it might affect our thinking. I leave that thought experiment to the reader.

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*Public Health Interventions: An Alternative to Individual Behavioral Change Strategies*, 3 J. PUB. HEALTH POL'Y 150 (1982).

<sup>147</sup> See Anthony Downs, *The Public Interest: Its Meaning in a Democracy*, 29 SOC. RES. 1, 18-25 (1962).

<sup>148</sup> See, e.g., JAMES BUCHANAN & GORDON TULLOCK, *THE CALCULUS OF CONSENT* 11-15 (1962); ANTHONY DOWNS, *AN ECONOMIC THEORY OF DEMOCRACY* 4-11 (1957); MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION* 1-3 (1965); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971) (applying the self-interest model to industry regulation). For a critique of this view, see Amartya K. Sen, *Rational Fools: A Critique of the Behavioral Foundations of Economic Theory*, 6 PHIL. & PUB. AFF. 317 (1977).