Rights in Health Data

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Introduction

"Health data," as we will use the term, refers to information about a person's body relevant to that person's health. Types include medical records; test results; information concerning medications, treatments, and the results thereof; genetic information; vital statistics; and demographic information.[1]

In recent years, the potential uses of such data have grown rapidly. Three developments have contributed to this trend. First, the technologies for gathering information of these sorts have improved. For example, genetic testing has become increasingly feasible and affordable, and growing numbers of people (at least in developed countries) now wear devices that monitor their vital signs. Second, the percentage of hospitals and health-care professionals who store information in electronic rather than paper form has increased sharply. In the United States, for example, usage of electronic health records grew from one in ten doctors in 2009 to nine in ten in 2018, spurred by federal incentivizing of the practice.[2] Third, software that facilitates "mining" aggregations of that data has become increasingly sophisticated.

The net result is that health data are now being harnessed in myriad ways. They include:

- *Diagnosis*. Already algorithms developed using machine learning and large databases of test results have proven to be at least as accurate as trained pathologists in detecting tumors.[3]
- *Treatment*. For instance, analysis of data on patients' responses to drugs are enabling identification of hitherto unknown adverse interactions between drugs, which in turn prompts physicians and pharmacies to avoid prescribing them in combination.[4] Another example: several companies are now at work analyzing databases concerning multiple aspects of cancer patients and their treatment histories to create increasingly personalized treatment plans for future patients.
- *Reducing Medical Costs*. For example, hospitals assess trends in bed use when considering how to allocate physical space.[5]

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[1] Cf. Jorge Contreras, "The False Promise of Health Data Ownership" (2019), n.2 (using the term, "individual health information" in a similar sense).

[2] http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-White-Paper.pdf at 2.

[3] See Yun Liu et al., "Detecting Cancer Metastases on Googlepixel Pathology Images" (2017), https://arxiv.org/abs/1703.02442.

[4] One of the most ambitious of these initiatives is FDA's Sentinel System. Launched in 2008, it aspires to improve safety monitoring of FDA-approved treatments. Its priorities for the five years from 2019–23 center on innovations emerging from new data science disciplines, such as natural language processing and machine learning, and expanding its access to and use of electronic health records. https://www.fda.gov/media/120333/download. In fact, much of what the Sentinel System does is aggregate and analyze patient data: "Within a privacy preserving 'distributed data system,' the Sentinel Initiative applies data science to patient data derived from health insurance companies, healthcare systems and academic institutions (with electronic health record systems). Sentinel allows the FDA to better understand post-market safety issues and inform regulatory decisions to improve patient safety." https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/advancing-human-data-science.pdf.

[5] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2861647/.

- *Curbing Infectious Diseases*. Very recently, some companies have begun to draw upon multiple sources of data to predict and thus block the transmission pathways of the COVID-19 pandemic.[6]
- *Insurance and Advertising*. Companies selling health insurance and medical treatments have an obvious economic interest in data concerning the health of their potential customers. Such companies typically disavow using data for these purposes, but some consumers and public-interest organizations are skeptical.[7]

The profits or savings associated with these various uses have given rise to a growing global market for health data. Estimates of the size of that market vary, but it surely now exceeds $20 billion per year.[8]

As these uses of health data have multiplied, controversies concerning who should have what rights to control or profit from them have become more common. This module considers how the law has resolved such controversies and how it could do so better.

Part I describes four recent business initiatives that implicate in different ways these issues. Part II summarizes the legal rules that currently govern uses of health data in the United States and the European Union. Part III contains some proposals for reforming those rules.

As you read these materials, try to answer the following questions:

1) In what ways can we expect that health data will be used in the future?
2) Which of the existing or potential uses of health data are socially beneficial?
3) To what extent should a person be entitled to prevent uses of data derived from his, her, or their body?
4) To what extent should a person be entitled to share in the revenue generated by uses of data derived from his, her, or their body?
5) To what extent should health-care providers be entitled to control or profit from uses of the information generated through the services they provide?
6) What does or should "privacy" entail in this new environment?

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[6] See, for example, Jessica Kent, "Machine Learning Tools Predict Impact of Quarantive on COVIS-19," Health Analytics, April 22, 2020, https://healthitanalytics.com/news/machine-learning-tools-predict-impact-of-quarantine-on-covid-19; Christine Wei-Li Lee, "UCLA Machine Learning Model is Helping CDC Predict Spread of COVID-19," UCLA Newsroom, May 18, 2020, https://newsroom.ucla.edu/releases/machine-learning-model-cdc-covid19 ; "How to Fight COVID-19 with Machine Learning," https://www.datarevenue.com/en-blog/machine-learning-covid-19.

[7] *See, e.g.*, Nitasha Tiku, "Facebook has a Prescription: More Pharmaceutical Ads," Washington Post, March 4, 2020, https://www.washingtonpost.com/technology/2020/03/03/facebook-pharma-ads/.

[8] See https://bisresearch.com/industry-report/global-big-data-in-healthcare-market-2025.html; https://www.bloomberglaw.com/product/blaw/document/X6EB134G000000.

I. Business Initiatives

"Sloan Kettering's Cozy Deal with Start-Up Ignites a New Uproar"

By Charles Ornstein and Katie Thomas
New York Times, Sept. 20, 2018

An artificial intelligence start-up founded by three insiders at Memorial Sloan Kettering Cancer Center debuted with great fanfare in February, with $25 million in venture capital and the promise that it might one day transform how cancer is diagnosed.

The company, Paige.AI, is one in a burgeoning field of start-ups that are applying artificial intelligence to health care, yet it has an advantage over many competitors: The company has an exclusive deal to use the cancer center's vast archive of 25 million patient tissue slides, along with decades of work by its world-renowned pathologists.

Memorial Sloan Kettering holds an equity stake in Paige.AI, as does a member of the cancer center's executive board, the chairman of its pathology department and the head of one of its research laboratories. Three other board members are investors.

The arrangement has sparked considerable turmoil among doctors and scientists at Memorial Sloan Kettering, which has intensified in the wake of an investigation by ProPublica and The New York Times into the failures of its chief medical officer, Dr. José Baselga, to disclose some of his financial ties to the health and drug industries in dozens of research articles. He resigned last week, and Memorial Sloan Kettering's chief executive, Dr. Craig B. Thompson, announced a new task force on Monday to review the center's conflict-of-interest policies.

At a staff meeting Thursday morning, Dr. Thompson and others, including Dr. Lisa DeAngelis, the acting physician-in-chief who replaced Dr. Baselga, described the recent events as a disruption and acknowledged that the hospital was under a microscope, according to several people who attended. Doctors said they were concerned about a lack of communication from hospital leadership, and one said patients were nervous that their health data was being commercialized by the institution.

Hospital pathologists have strongly objected to the Paige.AI deal, saying it is unfair that the founders received equity stakes in a company that relies on the pathologists' expertise and work amassed over 60 years. They also questioned the use of patients' data — even if it is anonymous — without their knowledge in a profit-driven venture.

In addition, experts in nonprofit law and corporate governance have questioned whether Memorial Sloan Kettering, one of the nation's leading cancer centers, complied with federal and state law governing nonprofits when it set up the deal. The experts pointed out that charitable institutions like Memorial Sloan Kettering must show that they didn't provide assets to insiders for less than the fair market value.

Cancer center officials said that they acted properly in approving the deal with Paige.AI and that if successful, the venture could change the future of cancer diagnosis. "This is an incredibly expensive undertaking — it needs a lot of money," Dr. Gregory Raskin, the hospital's vice

president of technology development, said in an interview. “We feel this is a really valuable and important technology to get developed.”

Officials said that some board members invested only after early efforts to generate interest from outside companies and investors had failed. But they acknowledged that they did not seek an independent valuation of the tissue archive, nor did they put the proposal out for competitive bidding before licensing it to a single company. In exchange for sharing its voluminous database, Memorial Sloan Kettering received ownership shares amounting to about nine percent in the company.

“It just seems awfully coincidental that the individuals involved happen to be people in control and influence of that asset, and they ended up with an exclusive use of it,” said Marcus S. Owens, a Washington lawyer who ran the Internal Revenue Service division that oversees tax-exempt organizations. “It seems to create a cascading series of conflicts for the operation of Sloan Kettering.”

The decision to license images of the patients’ tissue slides to a for-profit company also highlights the broader debate over the use of personal medical data, ranging from genetic information to, in this case, images of a person’s cells, for research and commercial purposes.

After ProPublica and The Times began asking questions about the arrangement, one of the founders — Dr. David Klimstra, the chairman of the pathology department — said he would divest his ownership stake.

Dr. Klimstra and another co-founder, Dr. Thomas Fuchs, the head of the computational pathology laboratory, pursued the idea for Paige.AI in 2015, hospital officials said. Dr. Fuchs had previously worked for NASA developing algorithms that would teach the Mars rovers to navigate terrain, and has said some of the same algorithms can differentiate cancerous tumors from benign ones. In a statement, he called the AI start-up the culmination of his “life’s work.”

Universities and teaching hospitals have long sought to turn their scientific discoveries into lucrative business deals. Indeed, 10 cancer drugs approved by the Food and Drug Administration originated at Memorial Sloan Kettering. But the Paige.AI arrangement is different because what’s being commercialized is not an invention, per se, but rather access to raw materials — notes and slides — gathered over decades.

Paige.AI is among a growing number of companies, including Google and Microsoft, that are exploring ways to use artificial intelligence to improve health care. Pathology has been a focus because it remains a time-consuming, error-prone and often subjective process, where doctors examine tissue slides to decide whether cancer is present, and which type. Other start-ups in the field include PathAI, based in Boston, and SpIntellx, which is working in partnership with the University of Pittsburgh.

The Paige.AI project finally took off after enlisting the help of Norman Selby, a member of the hospital board’s executive committee and a longtime health care consultant, manager and investor. He is listed as a founder and executive chairman of Paige.AI and holds an equity stake.

Jim Breyer, the early Facebook investor and venture capitalist, also agreed to invest. At a New York Times conference in February on artificial intelligence, he said Paige's goal would be "to provide predictive data and help to cancer physicians around the country — as second opinions, in many cases as well, because not everyone of course has access to a Sloan Kettering."

The three other hospital board members who became investors are Stanley Druckenmiller, Alexander T. Robertson and Marie-Josée Kravis, according to Richard Beattie, honorary chairman of the cancer center's board and a member of its executive committee. "We were desperate," he said in an interview. "This is more risky than most transactions, and we couldn't find investors."

The board investors in Paige.AI, and Mr. Breyer, either declined to comment or did not return calls and emails. Mr. Selby has pledged to donate some of his profits to the hospital, Mr. Beattie said.

Experts in nonprofit law and corporate governance questioned whether Memorial Sloan Kettering, which is a charity, acted properly in what is known as a related party transaction with the founders of Paige.AI.

While federal law does not specifically require seeking bids from competitors or independent appraisals of the assets in such a transaction, nonprofit groups that make deals with companies associated with board members or employees must demonstrate that they have taken steps to ensure that insiders don't get preferential treatment. If nonprofits are found not to have complied, they or the individuals involved could face tax repercussions.

Mr. Beattie said the hospital relied on some investors to set a value for licensing the slides, with guidance from hedge fund leaders on its board. A law firm, which he did not identify, evaluated the documents and said it was a good deal.

Nell Minow, vice chair of ValueEdge Advisors who has written books about corporate governance, said the center's process was "inadequate." "They could be throwing a dart at the wall to figure out what the valuation is," she said. "They're accepting somebody's word for it and that's very, very risky."

Mr. Beattie said the cancer center would follow I.R.S. rules requiring it to list the transaction on financial forms, which won't be public until next year. He also said the hospital had set up plans to manage conflicts for the three company founders. All four members who are invested, including Mr. Selby, must recuse themselves from any board actions about the company, Mr. Beattie said. A review of the hospital's I.R.S. filings does not show any similar transactions in recent years.

In two meetings this month, staff pathologists confronted hospital leaders over the cancer center's relationship with Paige.AI, some of them angered by the deal that would allow others to profit from their work. At a tense meeting Sept. 12, some pathologists said they only learned about the deal online after it was announced, two people in attendance said.

As for how the deal came about, Dr. Klimstra told colleagues that Google had twice approached the hospital about securing access to the pathology slides and was turned down. Mr. Beattie said there were never serious conversations with Google. A spokeswoman for Google declined to comment.

Doctors also expressed concerns about whether patients had consented to have images of their tissue used in this way. Dr. Klimstra told them the project had been approved by an institutional review board, which considers ethical issues involving patients. Patients who had not given their consent to having their readings shared would have all personal health information stripped from the images and notes, he said. Dr. Raskin said that between 30 to 40 percent of patients typically do not consent. And Paige.AI will not have exclusive access to slides that resulted from federally funded research, he added.

Alexander Capron, a professor who teaches medical ethics at the University of Southern California, said courts have generally ruled against patients in disputes over ownership of human tissue, but that institutions should be as transparent as possible with patients.

Internal concerns about the deal and how patients would perceive it escalated after Dr. Klimstra wrote an email in August informing the pathology staff of his involvement. It elicited a mocking response from Dr. Marc K. Rosenblum, a neuropathologist and former chairman of the department, who suggested in a reply that the center was auctioning its expertise to the highest bidder. The email included a tongue-in-cheek fight song. "To PAIGE I pledge my self entire and promise to be true," he wrote in the email. "I had a thing for MSK but now that thing is THROUGH!" It then says, "(contemplate consulting fees, repeat with feeling.)"

In an interview last week, Dr. Rosenblum said he wasn't seeking financial compensation, but felt "the leadership had not been particularly transparent with us about the founding of this company, and I feel that we were not sufficiently credited with what had been our intellectual input in this."

Kathryn Martin, the hospital's chief operating officer, said the cancer center did not anticipate the pathologists' objections. "I think we could have done a better job communicating it," she said in an interview.

Dr. Klimstra said in a statement that the project represented a "quantum leap" in the pathology field. "Other than my family, there is nothing more important to me than running my department," he said, and added, "I sincerely regret the fact that my equity ownership in Paige has served as a distraction to my primary leadership role at M.S.K."

Dr. Fuchs, the head of the computational pathology lab, defended his role in a separate statement. "Computer scientists like myself very seldom get the chance to really help patients," he said.

Details for distributing any profits or proceeds from Paige.AI have not been worked out, officials said. Ms. Martin suggested that if the deal is successful, some funds could be set aside for the pathology department to finance research projects. For now, much of the talk is theoretical — the company is years away from selling a finished product, with a staff of fewer than 20 employees.

The roster of other key advisers also appears to be in flux. Until recently, Dr. Baselga was listed as the chairman of Paige's scientific advisory board. But his name disappeared from the company's website last week, the day after he resigned from Memorial Sloan Kettering. He also recently resigned from board positions at the pharmaceutical company Bristol-Myers Squibb and Varian Medical Systems, a radiation equipment manufacturer.

"Hu-manity Wants to Create a Health Data Marketplace with Help from Blockchain"
By Ron Miller
Tech Crunch, July 18, 2018

Imagine a world where you could sell your medical information to a drug company on your terms for a specific purpose like a drug trial. Then imagine you could restrict the company from using that data for anything else, including selling it to other medical data brokers, and enforcing those ownership rules on the blockchain.

That's what Hu-manity.co, a data ownership startup wants to do and they are putting the pieces in place to create a data marketplace. This is not an easy problem to solve, but co-founder and CEO Richie Etwaru, sees it as a crucial cultural shift in how we treat data.

Etwaru, who wrote a book on using the blockchain and smart contracts in a business context called Blockchain Trust Companies, sees the blockchain as just a small piece of a much broader solution. It can provide a rules engine and enforcement mechanism, but he doesn't see this as the gist of the company at all.

For Etwaru and Hu-manity it's about viewing your data as your property, and giving you legal control of it. "We're starting with the idea that your data is your digital property, and we are allowing you to have the equivalent of a title, like you have for your car," he explained.

You may be wondering how they can bring this notion to business, which after all has been allowed to use your data for some time without your explicit permission, never mind pay you for it under a set of specific contractual terms. To achieve that, Hu-manity wants to create large pools of users that would make it attractive to the data buyers.

"We are pooling large communities together to be able to notify corporations that don't respect digital data streams of property, because they take a very business centric view of regulations to opt out, then invite them back into a property centric view of data within the new terms and conditions defined by the marketplace," he said.

They are starting with health data because Etwaru says that this data is often sold for medical studies, whether you know it or not — albeit with PII removed. The other thing besides market pressure, which could drive companies like big pharma to make contracts with individuals to buy their data, is that they get much better data when they understand the whole patient. Even if they could figure out who the patient is, and it's becoming increasingly possible with digital fingerprinting, they are legally prohibited from contacting an individual to correct the record or to get a better understanding of their history.

Hu-manity plays a couple of roles here according to Etwaru, For starters, they are attaching a traceable title number to the data. Then they plan to set up the marketplace and help put the seller and buyer together, all the while providing a track and trace mechanism that allows the data owner to ensure their data is being used in a way they wish. In that sense, they are acting as a broker between buyer and seller.

Interestingly, Etwaru admits there is no set market value for this data, at least as of yet, although he believes an individual's medical data sets could sell for between $200-$400. For now, the company is working with a group of economists to determine the best way to approach pricing. He doesn't believe it's a good idea for individuals to negotiate their own terms, and that we should let these market cooperatives determine the value. His company will take 25 percent of the selling price as a brokerage fee, regardless of how it ultimately works.

The company was founded last spring and has raised $5.5 million on a $50 million valuation. There are many issues to work out before that happens, and many ways to stumble along the way, but the company has a compelling vision and it will be interesting to see if it can pull this together and gain market traction.

For additional information concerning Hu-manity and its ambitions, watch "We Are Hu-manity.co" (4 minutes): https://youtu.be/r8B4aqQTnpo. The company is currently trying to persuade the legislature of Oregon to adopt a statute consistent with its vision and business model. A draft of the bill is set forth in Part III, below.

"GlaxoSmithKline strikes $300 million deal with 23andMe for genetics-driven drug research"
By Meg Tirrell
CNBC, July 25, 2018

British drug giant GlaxoSmithKline is investing $300 million in consumer genetics company 23andMe, forging a four-year collaboration to discover medicines using human genetics as a guide.

The partnership establishes GSK as 23andMe's exclusive collaborator for drug target discovery, the companies said Wednesday. It comes with an option to extend for a fifth year, and funding and proceeds will be split equally.

The announcement comes as GSK embarks on a new research strategy under new Chief Scientific Officer Hal Barron, a drug industry veteran. The new approach focuses on the immune system, genetics and advanced analytics and technology.

It's not the first time a pharmaceutical company has turned to genetics to improve its drug development. Amgen acquired Iceland's deCODE Genetics in 2012 for $415 million to benefit from its unique genetic database, while Regeneron has partnered with Geisinger Health and the UK Biobank to do the same.

23andMe is a different kind of partner. It's a direct-to-consumer genetic testing company that charges $199 for certain health and ancestry data ($99 just for ancestry). The company has more than 5 million customers, 80 percent of whom have consented to participating in research.

It doesn’t have the traditional health records that a system like Geisinger does, but conducts surveys of its users, and says, on average, one person in its database contributes to 200 different research studies.

The company has been focused on drug development of its own, hiring Genentech veteran Richard Scheller in 2015 as chief scientific officer and head of therapeutics.

Together, the companies aim to use 23andMe’s genetic database to improve selection of drug targets, finding medicines that are more likely to work and carry a lower safety risk. The collaboration is also designed to speed identification and recruitment of patients for clinical trials.

“Google's 'Project Nightingale' Gathers Personal Health Data on Millions of Americans”

By Rob Copeland
Wall Street Journal, November 11, 2019

Google is engaged with one of the U.S.'s largest health-care systems on a project to collect and crunch the detailed personal-health information of millions of people across 21 states.

The initiative, code-named "Project Nightingale," appears to be the biggest effort yet by a Silicon Valley giant to gain a toehold in the health-care industry through the handling of patients' medical data. Amazon.com Inc., Apple Inc. and Microsoft Corp. are also aggressively pushing into health care, though they haven't yet struck deals of this scope.

Google began Project Nightingale in secret last year with St. Louis-based Ascension, a Catholic chain of 2,600 hospitals, doctors' offices and other facilities, with the data sharing accelerating since summer, according to internal documents.

The data involved in the initiative encompasses lab results, doctor diagnoses and hospitalization records, among other categories, and amounts to a complete health history, including patient names and dates of birth.

Neither patients nor doctors have been notified. At least 150 Google employees already have access to much of the data on tens of millions of patients, according to a person familiar with the matter and the documents.

In a news release issued after The Wall Street Journal reported on Project Nightingale on Monday, the companies said the initiative is compliant with federal health law and includes robust protections for patient data.

Some Ascension employees have raised questions about the way the data is being collected and shared, both from a technological and ethical perspective, according to the people familiar with the project. But privacy experts said it appeared to be permissible under federal law. That law, the Health Insurance Portability and Accountability Act of 1996, generally allows hospitals to share data with business partners without telling patients, as long as the information is used "only to help the covered entity carry out its health care functions."

Google in this case is using the data in part to design new software, underpinned by advanced artificial intelligence and machine learning, that zeroes in on individual patients to suggest changes to their care. Staffers across Alphabet Inc., Google's parent, have access to the patient information, internal documents show, including some employees of Google Brain, a research science division credited with some of the company's biggest breakthroughs.

Google Cloud President Tariq Shaukat said the company's goal for health care is centered on "ultimately improving outcomes, reducing costs, and saving lives."

Eduardo Conrado, an executive vice president at Ascension, said: "As the health-care environment continues to rapidly evolve, we must transform to better meet the needs and expectations of those we serve as well as our own caregivers and health-care providers."

Google and nonprofit Ascension have parallel financial motives. Google has assigned dozens of engineers to Project Nightingale so far without charging for the work because it hopes to use the framework to sell similar products to other health systems. Its end goal is to create an omnibus search tool to aggregate disparate patient data and host it all in one place, documents show.

The project is being developed under Google's cloud division, which trails rivals like Amazon and Microsoft in market share. Google Chief Executive Sundar Pichai has said repeatedly this year that finding new areas of growth for cloud is a priority.

Ascension, the second-largest health system in the U.S., aims in part to improve patient care. It also hopes to mine data to identify additional tests that could be necessary or other ways in which the system could generate more revenue from patients, documents show.

Ascension is also eager to have a system that is faster than its existing decentralized electronic record-keeping.

Google, like many of its Silicon Valley peers, has at times drawn criticism for not doing enough to protect user privacy. Its YouTube unit agreed in September to pay $170 million in fines and change its practices in response to complaints that it illegally collected data on children to sell ads. YouTube neither admitted nor denied wrongdoing.

Last year, the Journal reported that Google opted not to disclose to users a flaw that exposed hundreds of thousands of birth dates, contact information and other personal data of subscribers in its now-defunct social-networking website Google Plus, in part because of fears that the incident could trigger regulatory scrutiny. Google said at the time it went beyond legal requirements in determining not to inform users.

Regulators are now scrutinizing the company on a number of fronts. Federal and state investigators over the summer made public separate antitrust inquiries into Google. The federal probe is examining whether Google's existing trove of data amassed from its flagship search engine, home speakers, free email service and numerous other arms give the company an unfair advantage over competitors, people familiar with the matter said.

Google has said its products increase consumer choice and that it is committed to cooperating with the inquiries. This year, Mr. Pichai has touted new privacy protections for Google's billions of users.

The company made public this month a $2.1 billion deal for wearable fitness maker Fitbit Inc., which makes watches and bracelets that track health information like a person's heart rate. Politicians of both parties quickly criticized the deal; Rep. David Cicilline (D., R.I.), chairman of the House Antitrust Subcommittee, warned that the Fitbit deal would give Google "deep insights into Americans' most sensitive information." The companies said they would be transparent about any Fitbit data they collect.

Google appears to be sharing information within Project Nightingale more broadly than in its other forays into health-care data. In September, Google announced a 10-year deal with the Mayo Clinic to store the hospital system's genetic, medical and financial records. Mayo officials said at the time that any data used to develop new software would be stripped of any information that could identify individual patients before it is shared with the tech giant.

Google was founded with the goal of organizing the world's information, and health has been a fascination of its top executives from the early days. Google Health, a fledgling effort to digitize existing medical records, was shut down in 2011 after three years of limited adoption. Alphabet has since poured millions of dollars into its under-the-radar Calico and Verily divisions, which aim to combat aging and manage disease, respectively.

Google co-founder Larry Page, in a 2014 interview, suggested that patients worried about the privacy of their medical records were too cautious. Mr. Page said: "We're not really thinking about the tremendous good that can come from people sharing information with the right people in the right ways."

II. Laws

A. United States

1. General Principles

Greenberg v. Miami Children's Hosp. Research Inst., Inc.
264 F. Supp.2d 1064 (S.D.Fla. 2003)

Moreno, J.: This case presents an unfortunate legal dilemma set against the backdrop of a historic breakthrough in the treatment of a previously intractable genetic disorder. Both parties in this case were jointly engaged in a noble and dogged pursuit to detect and find a cure for a fatal genetic disorder called Canavan disease, a rare genetic disease that occurs most frequently in Ashkenazi Jewish families.

Plaintiffs, a group of individuals and non-profit institutions, are attempting to assert legal rights against Defendant researcher and his research institution's commercialization of the fruits of their Canavan disease research. Before the Court is Defendants' Motions to Dismiss pursuant to *Fed. R. Civ. P. 12(b)(6)* for failure to state a claim upon which relief may be granted. Because the Court finds that Plaintiffs have failed to allege sufficient facts as to all their claims except unjust enrichment, the motions are GRANTED in part.

I. BACKGROUND

Plaintiffs Daniel Greenberg ("Greenberg"), Fern Kupfer ("Kupfer"), Frieda Eisen ("Eisen"), David Green ("Green"), Canavan Foundation, Dor Yeshorim, and National Tay-Sachs and Allied Diseases Association, Inc. (collectively "Plaintiffs") brought this diversity action for damages and equitable and injunctive relief to redress Defendants' alleged breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets. The individual plaintiffs Greenberg, Kupfer, Eisen, and Green are parents of children who were afflicted with Canavan disease. The other Plaintiffs are non-profit organizations that provided funding and information to Defendants to research and discover the Canavan disease gene. Defendants are the physician-researcher, Dr. Reuben Matalon ("Matalon"), Variety Children's Hospital d/b/a Miami Children's Hospital ("MCH"), and the hospital's research affiliate, Miami Children's Hospital Research Institute ("MCHRI").

The Complaint alleges a tale of a successful research collaboration gone sour. In 1987, Canavan disease still remained a mystery -- there was no way to identify who was a carrier of the disease, nor was there a way to identify a fetus with Canavan disease. Plaintiff Greenberg approached Dr. Matalon, a research physician who was then affiliated with the University of Illinois at Chicago for assistance. Greenberg requested Matalon's involvement in discovering the genes that were ostensibly responsible for this fatal disease, so that tests could be administered to determine carriers and allow for prenatal testing for the disease.

At the outset of the collaboration, Greenberg and the Chicago Chapter of the National Tay-Sachs and Allied Disease Association, Inc. ("NTSAD") located other Canavan families and convinced them to provide tissue (such as blood, urine, and autopsy samples), financial support, and aid in identifying the location of Canavan families internationally. The other individual Plaintiffs began supplying Matalon with the same types of information and samples beginning in the late 1980s.

Greenberg and NTSAD also created a confidential database and compilation - the Canavan registry - with epidemiological, medical and other information about the families.

Defendant Matalon became associated in 1990 with Defendants Miami Children's Hospital Research Institute, Inc. and Variety Children's Hospital d/b/a Miami Children's Hospital. Defendant Matalon continued his relationship with the Plaintiffs after his move, accepting more tissue and blood samples as well as financial support.

The individual Plaintiffs allege that they provided Matalon with these samples and confidential information "with the understanding and expectations that such samples and information would be used for the specific purpose of researching Canavan disease and identifying mutations in the Canavan disease which could lead to carrier detection within their families and benefit the population at large." Plaintiffs further allege that it was their "understanding that any carrier and prenatal testing developed in connection with the research for which they were providing essential support would be provided on an affordable and accessible basis, and that Matalon's research would remain in the public domain to promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure for Canavan disease." This understanding stemmed from their "experience in community testing for Tay-Sachs disease, another deadly genetic disease that occurs most frequently in families of Ashkenazi Jewish descent."

There was a breakthrough in the research in 1993. Using Plaintiffs' blood and tissue samples, familial pedigree information, contacts, and financial support, Matalon and his research team successfully isolated the gene responsible for Canavan disease. After this key advancement, Plaintiffs allege that they continued to provide Matalon with more tissue and blood in order to learn more about the disease and its precursor gene.

In September 1994, unbeknownst to Plaintiffs, a patent application was submitted for the genetic sequence that Defendants had identified. This application was granted in October 1997, and Dr. Matalon was listed as an inventor on the gene patent and related applications for the Canavan disease, Patent No. 5,679,635 (the "Patent"). Through patenting, Defendants acquired the ability to restrict any activity related to the Canavan disease gene, including without limitation: carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations.

Although the Patent was issued in October 1997, Plaintiffs allege that they did not learn of it until November 1998, when MCH revealed their intention to limit Canavan disease testing through a campaign of restrictive licensing of the Patent. Specifically, on November 12, 1998, Plaintiffs allege that Defendants MCH and MCHRI began to "threaten" the centers that offered Canavan testing with possible enforcement actions regarding the recently-issued patent. Defendant MCH also began restricting public accessibility through negotiating exclusive licensing agreements and charging royalty fees.

Plaintiffs allege that at no time were they informed that Defendants intended to seek a patent on the research. Nor were they told of Defendants' intentions to commercialize the fruits of the research and to restrict access to Canavan disease testing.

Based on these facts, Plaintiffs filed a six-count complaint on October 30, 2000, against Defendants asserting the following causes of action: (1) lack of informed consent; (2) breach of fiduciary duty; (3) unjust enrichment; (4) fraudulent concealment; (5) conversion; and (6) misappropriation of trade secrets. Plaintiffs generally seek a permanent injunction restraining Defendants from enforcing their patent rights, damages in the form of all royalties Defendants have received on the Patent as well as all financial contributions Plaintiffs made to benefit Defendants' research. Plaintiffs allege that Defendants have earned significant royalties from Canavan disease testing in excess of $ 75,000 through enforcement of their gene patent, and that Dr. Matalon has personally profited by receiving a recent substantial federal grant to undertake further research on the gene patent….

II. LEGAL STANDARD

A court will not grant a motion to dismiss unless the plaintiff fails to allege any facts that would entitle the plaintiff to relief. When ruling on a motion to dismiss, a court must view the complaint in the light most favorable to the plaintiff and accept the plaintiff's well-pleaded facts as true.

III. ANALYSIS

Defendants have moved to dismiss the entire Complaint pursuant to *Fed. R. Civ. P. 12(b)(6)* for failure to state a claim upon which relief may be granted. The Court will discuss each count sequentially.

A. Lack of Informed Consent

In Count I of the Complaint, the individual Plaintiffs, who served as research subjects, and the corporate plaintiff Dor Yeshorim claim that Defendants owed a duty of informed consent. The Complaint alleges a continuing duty of informed consent to disclose any information that might influence their decision to participate or decline to participate in his research. Defendants breached this duty, Plaintiffs claim, when they did not disclose the intent to patent and enforce for their own economic benefit the Canavan disease gene. The duty was also breached by the misrepresentation of the research purpose that Matalon had included on the written consent forms. Finally, the Plaintiffs allege that if they had known that the Defendants would "commercialize" the results of their contributions, they would not have made the contributions.

1. Duty to Obtain Informed Consent for Medical Research

Defendants first assert that the Complaint fails to state a claim because the duty of informed consent is only owed to patients receiving medical treatment. Furthermore, they claim that even if the duty extends to non-therapeutic research, it does not extend beyond the actual research to research results.

The doctrine of informed consent grew out of a treating physician's fiduciary duty to disclose to the patient all facts which might affect the patient's decision to allow medical treatment. The basic principle of informed consent has been embraced by tort law in order to guard a patient's control over decisions affecting his or her own health. *See* *Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990)*. The state common law of informed consent is often fortified by statute. Florida's medical consent law, for example, applies to the patient/treating doctor relationship. *Fla. Stat. §*

766.103.

The question of informed consent in the context of medical research, however, is a relatively novel one in Florida. Medical consent law does not apply to medical researchers. *Id; See also* *Cedars Med. Ctr., Inc. v. Jose R. Gomez, 738 So. 2d 362, 366 (Fla. 3d DCA 1999)* (excluding Hospital from statutory duty of informed consent). *Florida Statute § 760.40* does require, however, that a person's informed consent must be obtained when any genetic analysis is undertaken on his or her tissue.

Defendants argue that this statute is inapplicable to the case at bar because the statute does not apply to medical research, only test results. Moreover, none of the individual Plaintiffs have alleged that they were personally tested, just that they donated their genetic material. Furthermore, although Federal regulations do mandate that consent must be obtained from the subjects of medical research, the informed consent does not cover more than the research itself. *See, e.g.*, *21 C.F.R. §§ 50.1-50.27 (2000)*. Other courts in New York and Pennsylvania have dismissed attempts by patient plaintiffs to stretch the informed consent doctrine to cover medical research. *See* *Hecht v. Kaplan, 221 A.D.2d 100, 645 N.Y.S.2d 51, 53 (N.Y. App. Div. 1996)* (blood test performed on unused vial of blood does not constitute human research sufficient to trigger informed consent law); *Doe v. Dyer-Goode, 389 Pa. Super. 151, 566 A.2d 889, 892-93 (Pa. Super. Ct. 1989)* (additional test conducted on extracted sample of blood insufficient to permit action ground in battery (*i.e.* informed consent)). Plaintiffs contend these cases are distinguishable because they do not address informed consent in the research setting or the related issue of commercialization.

With Florida statutory law at best unclear on the duty of informed consent relating to medical research, Plaintiffs refer to cases in other jurisdictions where courts have found that researchers face a duty to obtain informed consent from their research subjects. *See* *Grimes v. Kennedy Krieger Inst., 366 Md. 29, 782 A.2d 807 (Md. 2001)* (medical researchers had duty to disclose that children participating in research study were subject to lead-based paint); *In re Cincinnati Radiation Litig., 874 F. Supp. 796 (S.D. Ohio 1995)* (non-disclosure to patients about exposure to radiation).

Defendants counter that these cases are inapposite because Plaintiffs miss the crucial distinction between the use of medical research and human experimentation. Each of the cases cited by Plaintiffs as providing a duty of informed consent regarding medical research was based on some egregious practice, which Defendants argue is absent here. Additionally, there was no actual human experimentation as part of an ongoing relationship alleged in the Complaint.

Since the law regarding a duty of informed consent for research subjects is unsettled and fact-specific and further, Defendants conceded at oral argument that a duty does attach at some point in the relationship, the Court finds that in certain circumstances a medical researcher does have a duty of informed consent. Nevertheless, without clear guidance from Florida jurisprudence, the Court must consider whether this duty of informed consent in medical research can be extended to disclosure of a researcher's economic interests.

2. Extension of Duty of Informed Consent to the Researcher's Economic Interests

Defendants assert that extending a possible informed consent duty to disclosing economic interests has no support in established law, and more ominously, this requirement would have pernicious

effects over medical research, as it would give each donor complete control over how medical research is used and who benefits from that research. The Court agrees and declines to extend the duty of informed consent to cover a researcher's economic interests in this case.

Plaintiffs cite a variety of authorities in support of their contention that the duty of informed consent mandates that research subjects must be informed of the financial interests of the researcher. They first rely on *Moore v. Regents of the University of California*, where the court held that a physician/researcher had a duty of informed consent to disclose that he was both undertaking research and commercializing it. *793 P.2d 479, 486 (Cal. 1990)*. Plaintiffs also reference a Florida law that requires health care providers to provide written disclosures to patients of potential financial conflicts of interest. *Fla. Stat. § 456.052* (precluding referrals by health care providers unless their financial interest is disclosed). Finally, in *Grimes*, the Maryland Court of Appeals found that researchers must provide "all material information" to their subjects. *Grimes, 782 A.2d at 844*.

These authorities do not control the outcome here, however, and the Court is not persuaded that they can be synthesized into a viable extension of the duty of informed consent. Moreover, Defendants correctly contest Plaintiffs' interpretation of *Moore*, the case that is most analogous to the situation at hand. *Moore* involved a physician breaching his duty when he asked his patient to return for follow-up tests after the removal of the patient's spleen because he had research and economic interests. The doctors did not inform their patient that they were using his blood and tissue for medical research. The allegations in the Complaint are clearly distinguishable as Defendants here are solely medical researchers and there was no therapeutic relationship as in *Moore*.

In declining to extend the duty of informed consent to cover economic interests, the Court takes note of the practical implications of retroactively imposing a duty of this nature. First, imposing a duty of the character that Plaintiffs seek would be unworkable and would chill medical research as it would mandate that researchers constantly evaluate whether a discloseable event has occurred.[2] Second, this extra duty would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses. Finally, the these Plaintiffs are more accurately portrayed as donors rather than objects of human experimentation, and thus the voluntary nature of their submissions warrants different treatment. Accordingly, the Court finds that Plaintiffs have failed to state a claim upon which relief may be granted, and this count is DISMISSED.

B. Breach of Fiduciary Duty

The individual Plaintiffs allege in Count II of the Complaint that all the Defendants were in a fiduciary relationship with them, and as such, they should have disclosed all material information relating to the Canavan disease research they were conducting, including any economic interests

[2] Plaintiffs claim that disclosure of a commercial interest is already mandated by the American Medical Association's Code of Ethics professional guidelines for physicians/researchers. It provides that "potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials" and "human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material." AMA Code of Ethics, E-208. Yet these regulations were only promulgated in 1994 and there is no evidence that they bind the parties in this case.

of the Defendants relating to that research.

As a threshold issue, Defendants argue that if the Court finds that there is no claim for informed consent, then the claim for breach of fiduciary duty evaporates as both claims have the same elements. Courts routinely hold that where a patient's claim that the doctor breached his fiduciary duty arises from the same operative facts and results in the same injury as another claim asserted against the doctor, then the breach of fiduciary claim is duplicative and should be dismissed. *See Neade v. Portes, 193 Ill. 2d 433, 445 (Ill. 2000)*. Defendants argue that the two claims are virtually identical, because the damages and liability allegations are very similar, and are both premised on the same duty of disclosure. The Court finds, nevertheless, that a full treatment of this claim is still appropriate as the two claims are not fully congruent.

1. Fiduciary Relationship

Defendants have moved to dismiss this count because Plaintiffs did not plead the elements of a fiduciary relationship. Fiduciary relations are either expressly or impliedly created. A fiduciary duty implied in law is premised upon the specific factual set of circumstances surrounding the transaction and the relationship of the parties. Florida courts have found fiduciary relationships in this context when "confidence is reposed by one party and a trust accepted by the other." This is a two-way relationship, and a fiduciary relationship will only be found when the plaintiff separately alleges that the plaintiff placed trust in the defendant and the defendant accepted that trust. In Florida, once a fiduciary relationship is established, a fiduciary has a legal duty to "disclose all essential or material facts pertinent or material to the transaction in hand."

Defendants assert that the Complaint does not allege any facts that show that the trust was recognized and accepted. Plaintiffs allege, however, that Defendants accepted the trust by undertaking research that they represented as being for the benefit of the Plaintiffs. Plaintiffs rely on other state courts which have held that researchers and research institutions are fiduciaries for their research subjects. For example, in *Grimes*, the Maryland Supreme Court held that "the very nature of nontherapuetic scientific research on human subjects can, and normally will, create special relationships out of which duties arise." *Grimes, 782 A.2d at 834-35*.

Taking all the facts alleged as true, the Court finds that Plaintiffs have not sufficiently alleged the second element of acceptance of trust by Defendants and therefore have failed to state a claim. There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given. Accordingly, this claim is DISMISSED.

C. Unjust Enrichment

In Count III of the Complaint, Plaintiffs allege that MCH is being unjustly enriched by collecting license fees under the Patent. Under Florida law, the elements of a claim for unjust enrichment are (1) the plaintiff conferred a benefit on the defendant, who had knowledge of the benefit; (2) the defendant voluntarily accepted and retained the benefit; and (3) under the circumstances it would be inequitable for the defendant to retain the benefit without paying for it. *Tooltrend, Inc., v. CMT Utensili SRL*, 198 F.3d 802, 805 (11th Cir. 1999); *Duncan v. Kasim, Inc., 810 So. 2d 968, 971 (2002).* The Court finds that Plaintiffs have sufficiently alleged the elements of a claim for unjust

enrichment to survive Defendants' motion to dismiss.

While the parties do not contest that Plaintiffs have conferred a benefit to Defendants, including, among other things, blood and tissue samples and soliciting financial contributions, Defendants contend that Plaintiffs have not suffered any detriment, and note that no Plaintiff has been denied access to Canavan testing. Furthermore, the Plaintiffs received what they sought - the successful isolation of the Canavan gene and the development of a screening test. Plaintiffs argue, however, that when Defendants applied the benefits for unauthorized purposes, they suffered a detriment. Had Plaintiffs known that Defendants intended to commercialize their genetic material through patenting and restrictive licensing, Plaintiffs would not have provided these benefits to Defendants under those terms.

Naturally, Plaintiffs allege that the retention of benefits violates the fundamental principles of justice, equity, and good conscience. While Defendants claim that they have invested significant amounts of time and money in research, with no guarantee of success and are thus entitled to seek reimbursement, the same can be said of Plaintiffs. Moreover, Defendants' attempt to seek refuge in the endorsement of the U.S. Patent system, which gives an inventor rights to prosecute patents and negotiate licenses for their intellectual property fails, as obtaining a patent does not preclude the Defendants from being unjustly enriched. *See* *Chou v. Univ. of Chicago, 254 F.3d 1347, 1363 (Fed. Cir. 2001)* (recognizing claim for unjust enrichment in context of gene patent dispute). The Complaint has alleged more than just a donor-donee relationship for the purposes of an unjust enrichment claim. Rather, the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene. Therefore, given the facts as alleged, the Court finds that Plaintiffs have sufficiently pled the requisite elements of an unjust enrichment claim and the motion to dismiss for failure to state a claim is DENIED as to this count.

D. Fraudulent Concealment

Count IV of the Complaint alleges that MCH fraudulently concealed from the Plaintiffs that (1) the Hospital would economically benefit from Canavan research; (2) it would patent the Canavan gene mutation; and (3) it would license the testing under the Patent.

The elements of a claim for fraudulent concealment under Florida law are:

> (1) a misrepresentation of material fact or suppression of the truth; (2) [a] knowledge of the representor of the misrepresentation, or [b] representations made by the representor without knowledge as to either the truth or falsity, or [c] representations made under circumstances in which the representor ought to have known, if he did not know, of the falsity thereof; (3) an intention that the representor induce another to act on it; and (4) resulting injury to the party acting in justifiable reliance on the; representation.

Jones v. General Motors Corp., 24 F. Supp. 2d 1335, 1339 (M.D. Fla. 1998). A fraudulent concealment claim is subject to *Fed. R. Civ. P. 9(b)*'s requirement that the circumstances constituting fraud shall be stated with particularity.

As a threshold matter, the Court finds that Plaintiffs have not satisfied this heightened pleading

standard. None of the elements constituting fraudulent concealment are sufficiently pled in the Complaint. …

Finally, as to the damages element, Plaintiffs point to the specific injury that they have suffered; namely, the denial of their prolonged efforts in contributing time and resources to research that they thought was designed for non-commercial purposes. This is not any sort of cognizable injury, however, since the Complaint does not allege any individualized denial of testing nor does it claim any other economic injury.

Plaintiffs contend that, but for the fraudulent non-disclosure, they would have acted differently. Nevertheless, fraud must be specially pled, and the Complaint does not adequately allege a claim based on a special relationship or of injury nor does it allege more specifics about efforts at concealment or about any representations made by Matalon as to what he would do with the test results. … Accordingly, the fraudulent concealment claim is DISMISSED.

E. Conversion

The Plaintiffs allege in Count V of their Complaint that they had a property interest in their body tissue and genetic information, and that they owned the Canavan registry in Illinois which contained contact information, pedigree information and family information for Canavan families worldwide. They claim that MCH and Matalon converted the names on the register and the genetic information by utilizing them for the hospitals' "exclusive economic benefit." The Court disagrees and declines to find a property interest for the body tissue and genetic information voluntarily given to Defendants. These were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples, and thus conversion does not lie as a cause of action.

In Florida, the tort of "conversion is an unauthorized act which deprives another of his property permanently or for an indefinite time." *Nat'l Union Fire Ins. Co. of Penn. v. Carob. Aviation, Inc., 759 F.2d 873, 878 (11th Cir. 1985)*. Using property given for one purpose for another purpose constitutes conversion. *See All Cargo Transport, Inc. v. Florida E. C. R. Co., 355 So. 2d 178, 179 (Fla. 3d DCA 1978)*.

First, Plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion. This case is similar to *Moore v. Regents of the University of California*, where the Court declined to extend liability under a theory of conversion to misuse of a person's excised biological materials. The plaintiff in *Moore* alleged that he had retained a property right in excised bodily material used in research, and therefore retained some control over the results of that research. The California Supreme Court, however, disagreed and held that the use of the results of medical research inconsistent with the wishes of the donor was not conversion, because the donor had no property interest at stake after the donation was made. The Court also recognized that the patented result of research is "both factually and legally distinct" from excised material used in the research.

Second, limits to the property rights that attach to body tissue have been recognized in Florida state courts. For example, *in State v. Powell, 497 So. 2d 1188, 1192 (Fla. 1986),* the Florida Supreme Court refused to recognize a property right in the body of another after death. Similarly,

the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party.

Plaintiffs rely on *Pioneer Hi-Bred v. Holden Foundation, 1987 U.S. Dist. LEXIS 18286, 1987 WL 341211 (S.D. Iowa, Oct. 29, 1987)*, *aff'd, 35 F.3d 1226 (8th Cir. 1994)*, for their assertion that genetic information itself can constitute property for the purposes of the tort of conversion. In that case, the Court held that a corn seed's property interest in the genetic message contained in a corn seed variety is property protected by the laws of conversion. Plaintiffs argue that giving permission for one purpose (gene discovery) does not mean they agreed to other uses (gene patenting and commercialization). Yet, the *Pioneer* court recognized that, "where information is gathered and arranged at some cost and sold as a commodity on the market, it is properly protected as property." This seemingly provides more support for property rights inherent in Defendants' research rather than the donations of Plaintiffs' DNA. Finally, Plaintiffs cite a litany of cases in other jurisdictions that have recognized that body tissue can be property in some circumstances. *See, e.g., Brotherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991)* (aggregate of rights existing in body tissue is similar to property rights); *York v. Jones, 717 F. Supp. 421, 425 (E.D. Va. 1989)* (couple granted property rights in their frozen embryos). These cases, however, do not involve voluntary donations to medical research.

Additionally, the Florida statute on genetic testing is cited by Plaintiffs in support of their contention that persons who contribute body tissue for researchers to use in genetic analysis do not relinquish ownership of the results of the analysis. *Fla. Stat. § 760.40* (2002). This statute, however, is inapplicable under a common law theory of conversion, because by its plain meaning, it only provides penalties for disclosure or lack of informed consent if a person is being genetically analyzed. Plaintiffs have not cited any case that interprets the statute as applying to an analogous factual situation, and this Court's investigation did not find any relevant case either. Moreover, even assuming, *arguendo*, that the statute does create a property right in genetic material donated for medical research purposes, it is unclear whether this confers a property right for conversion, a common law cause of action.

Finally, although the Complaint sets out that Plaintiff Greenberg owned the Canavan Registry, the facts alleged do not sufficiently allege the elements of a *prima facie* case of conversion, as the Plaintiffs have not alleged how the Defendants' use of the Registry in their research was an expressly unauthorized act. The Complaint only alleges that the Defendants "utilized the information and contacts for their exclusive economic benefit." There is no further allegations of the circumstances or conditions that were attached to the Defendants' use of the Canavan Registry. Nor are there any allegations about any of the Plaintiffs' entitlement to possess the Registry.

The Court finds that Florida statutory and common law do not provide a remedy for Plaintiffs' donations of body tissue and blood samples under a theory of conversion liability. Indeed, the Complaint does not allege that the Defendants used the genetic material for any purpose but medical research. Plaintiffs claim that the *fruits* of the research, namely the patented material, was commercialized. This is an important distinction and another step in the chain of attenuation that renders conversion liability inapplicable to the facts as alleged. If adopted, the expansive theory championed by Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital. At the core, these were donations to research without any contemporaneous expectations of return. Consequently, the

Plaintiffs have failed to state a claim upon which relief may be granted on this issue. Accordingly, this claim is DISMISSED.

F. Misappropriation of Trade Secrets

The Plaintiffs' final claim is that MCH misappropriated a trade secret - the registry of people who had Canavan disease. *Florida's Trade Secrets Act* defines a trade secret as:

> information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (a) Derive(s) independent economic value, actual, or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Fla. Stat. § 688.002(4). Whether a particular type of information constitutes a trade secret is a question of fact and cannot be resolved on a motion to dismiss.

Florida courts have repeatedly held that lists comprising information, such as names of patients, blood donors, and customers can qualify as trade secrets. However, to qualify as a trade secret, information that the Plaintiff seeks to protect must derive economic value from not being readily ascertainable by others and must be the subject of reasonable efforts to protects its secrecy.

At the outset, Defendants dismiss Plaintiffs' characterization of the Canavan registry as a trade secret. First, Defendants assert that Plaintiffs have not alleged that the registry belonged to any Plaintiff. Second, Defendants argue that the registry itself was not alleged to have any independent "economic value" for the purposes of Florida law since the Complaint does not allege the registry had any economic value derived from the confidentiality. *Fla. Stat. § 688.002*. Finally, a trade secret must be the subject of efforts "reasonable under the circumstances to maintain its secrecy." Defendants claim that there is nothing in the Complaint which indicates that any efforts were made to keep secret the Registry.

Plaintiffs counter Defendants' assertion that the Canavan registry is not a trade secret because it had value, in that it streamlined Matalon's research and was treated as confidential because it contained confidential information such as contact details, pedigree, and familial information for families worldwide.

While it is clear that the Complaint does allege that the Plaintiffs Greenberg and NTSAD created the list, "expending time, money, and other efforts," other key indicia of a trade secret are missing. Plaintiffs do not allege that the list derived economic value from not being generally known to others. The Complaint merely states that it had "substantial economic value" in streamlining Matalon's research. Second, there is no allegation that the Plaintiffs undertook measures to keep the list confidential. Plaintiffs only allege that there was an "expectation that it would remain confidential."

Even assuming, *arguendo*, that the Court finds that the Canavan Registry is a trade secret, Plaintiffs have not sufficiently alleged how the trade secret was misappropriated. To establish a claim for misappropriation of trade secrets under Florida law, Plaintiffs must show that (1) they possessed

valuable confidential information and took reasonable steps to protect it and (2) the information was "misappropriated," either by one who knew or had reason to know that secret was improperly obtained or by one who used improper means to obtain it. Misappropriation includes "disclosure or use of a trade secret of another without express or implied consent by a person who … at the time of the disclosure or use, knew or had reason to know that knowledge of the trade secret was … acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use." *Fla. Stat. § 688.002(2)*.

The Canavan Registry was not misappropriated by MCH because there is no allegation that MCH knew or should have known that the Canavan Registry was a confidential trade secret guarded by Plaintiffs, and furthermore, that Matalon had acquired through improper means. Plaintiffs' theory that Defendants misappropriated the Registry once Matalon and MCH chose to use the Registry beyond the use for which it was authorized does not pass muster, since there was no explicit authorization that the Registry be used for a certain purpose in the first place. Plaintiffs cannot donate information that they prepared for fighting a disease and then retroactively claim that it was a protected secret.

Accordingly, the Court finds that Plaintiffs have failed to state a claim regarding misappropriation of trade secret as the they have not sufficiently alleged the requisite elements to convert the Registry into an actionable trade secret. This claim is therefore DISMISSED.

Note on Patent Protection for DNA Sequences

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), the United States Supreme Court held for the first time that naturally occurring genetic sequences could not be patented. The result is that, today, Dr. Matalon could not obtain a patent on his discovery. However, in the same case, the Supreme Court ruled that complementary DNA ["cDNA"] sequences can still be patented. The Court reasoned: "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments…. [C]reation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring." Because most innovations in the field of biotechnology – including many ways of harnessing information concerning genetic predispositions to particular diseases – involve the preparation and use of non-naturally occurring sequences, controversies similar to the one that gave rise to the *Greenberg* case can still arise.

Questions

Consider each of the plaintiffs' claims: to what extent did the court reject it on doctrinal grounds as opposed to functional grounds? What interests are implicated in recognizing a privacy right or a right to informed consent, as compared to a property right under the conversion theory? What is the market dynamic that the court's decision assumes and implicitly endorses in this decision? Does recognizing property or property-like rights in health information help or harm innovation, according to the court's opinion? On what attributes of the property rights does the answer to that question depend?

2. The HIPAA Framework

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related implementing regulations create the basic federal framework governing the use of patient data in the United States.[9] Later legislation such as the HITECH Act (the "Health Information Technology for Economic and Clinical Health Act") of 2009 and the 21st Century Cures Act of 2016, along with follow-on administrative regulations, have refined and extended this framework.

HIPAA is best conceptualized as primarily a privacy law. The basic tradeoff from the Act is a balancing of limited privacy rights in the individual against promoting data portability and use for research. Despite its aims, it has been criticized as "notoriously weak because of its incomplete coverage, numerous exclusions and exemptions, and limited rights for individuals."[10]

HIPAA does not provide any clear sense of ownership of the health data it regulates. Instead of utilizing a property framework, it creates a somewhat sui generis assortment of rights and privileges in the patient and the healthcare provider. Many of these rights are defined by relevant administrative rules, including the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules.[11] According to the Department of Health & Human Services, the HIPAA Privacy Rule—the chief implementing rule of the statute—aims to balance allowing information to flow in ways that promote individual and public health with respecting privacy interests of individual patients.[12]

The rights for individuals in the HIPAA-based framework include:

- **Right of Access:**[13] Under the HIPAA Privacy Rule, "an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set," subject to a few, limited exceptions.[14] This right allows individuals to inspect or obtain a copy of such records within thirty days,[15] and to obtain copies in any reasonable format that is requested.[16]

- **Right to Privacy (A Limited Right of Control):**[17] Covered Entities may not disclose or sell a patient's Protected Health Information (PHI) without either anonymizing it or

[9] Specifically, the parts of the legislation most relevant to the treatment of health data are sections 261 to 264. Pub. L. 104-191, §§ 261–62, 264, 110 Stat. 1936, 2021–31, 2033–34 (1996) (codified at 42 USC §§ 1320d–1320d-8), https://www.govinfo.gov/content/pkg/STATUTE-110/pdf/STATUTE-110-Pg1936.pdf.

[10] Mark A. Rothstein, *The End of the HIPAA Privacy Rule?*, 44 J.L. Med. & Ethics 352, 352 (2016).

[11] *See* https://www.hhs.gov/hipaa/for-professionals/index.html.

[12] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

[13] HHS provides a guide to this right at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

[14] 45 C.F.R. § 164.524(a)(1) (2019).

[15] 45 C.F.R. § 164.524(b)(2) (2019).

[16] 45 C.F.R. § 164.524(c)(2)(ii) (2019).

[17] HHS provides an overview of the Privacy Rule at https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

obtaining a patient's consent.[18] This gives patients a limited right of control over the use of their data in identifiable form, although they have virtually no ability to control its use if it is de-identified.[19] Notwithstanding this limitation, entities may still disclose the "minimum necessary" PHI required for treatment, payment, or healthcare operations. They may also disclose PHI to government health agencies "authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability," subject to the same "minimum necessary" rule.

- **Right of Security:** The HIPAA Security Rule requires Covered Entities to implement certain safeguards to protect sensitive health data.[20] The separate Breach Notification Rule requires notification to affected individuals, media outlets, and the Secretary of Health & Human Services in cases of substantial data breaches of PHI.[21]

- **Right to Amend:** The HIPAA Privacy Rule also gives individuals the right to correct PHI about them that is held by Covered Entities. Requested amendments can be rejected if the record is already accurate.[22]

It is important to also note rights that are either excluded entirely from HIPAA or sharply limited. Because de-identified data falls outside the scope of what is protected by HIPAA, this curtails many of the rights held by individuals regarding their data:

- **Right to Control is Limited:** Consent is not required for a healthcare provider or other Covered Entity to strip HIPAA-regulated data of its individually identifying information and use it in any way it sees fit—including by selling de-identified data to other parties and data brokers. An individual's right to control the use of their medical data only applies while that data remains personally identifiable.

- **Right to Exclude is Limited:** Individuals are not able to control which outside parties are able to gain access to their PHI as "Business Associates" of their main healthcare provider or other HIPAA Covered Entity. Furthermore, individuals may not control which entities get access to their de-identified data or on what terms.[23]

- **Notice of Use is Limited:** Individuals' inability to exclude third parties from access to their (de-identified) data is paired with a lack of obligation on the part of Covered Entities to notify individuals when they send their de-identified data to a third party.[24] Covered Entities are required to have a privacy policy disclosing how they handle PHI,[25] which may

[18] 45 C.F.R. § 164.502(a)(1), (5)(ii) (2019).

[19] 45 C.F.R. § 164.502(d) (2019).

[20] https://www.hhs.gov/hipaa/for-professionals/security/index.html.

[21] *See* 45 C.F.R. § 164.400–164.414 (2019).

[22] 45 CFR § 164.526 (2019).

[23] However, some sellers of de-identified data may choose to offer opt out rights. Genetic testing firm 23andMe does, for example. https://www.pcmag.com/how-to/how-to-prevent-23andme-from-sharing-your-dna-for-research.

[24] However, the entity must send a notice about possible uses of the data, per 45 C.F.R. § 164.520.

[25] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

impose additional notice obligations pertaining to de-identified data if the company chooses to include them. In that case, the Federal Trade Commission Act would prohibit violations of that policy as deceptive.[26] Individuals may also obtain an accounting of most disclosures of their PHI to third parties or Business Associates within the past six years, but again, this only covers data that remains individually identifiable.[27]

- **Transferability and Alienability of These Rights is Limited:** Individuals can potentially sit at the center of an ecosystem of health data, able to request copies of their medical records and then consent to other companies or researchers using it. One could conceptualize this as a power in the individual to grant a non-exclusive right of possession to a new party. Furthermore, the individual could condition that grant on payment. Still, the core rights under HIPAA are neither alienable nor transferable. A patient could not sell her right to access the medical records held by the original entity or to amend them in cases of inaccuracy. She also could not transfer a right to impose liability upon violations of the Privacy Rule (such as a Covered Entity disclosing PHI without consent) or Security Rule (such as through a data breach). There are also restrictions on the conditions in which an individual can give consent to use of their PHI—the Privacy Rule provides that, in general, "[a] covered entity may not condition treatment, payment, enrollment, or benefits eligibility on an individual granting an authorization."[28]

- **No General Liability Rule:** There is no general right under HIPAA of individuals to be compensated when their data is used. Once again, the boundaries of the Act's protections track the divide between personally identifiable and de-identified data. Those who violate the HIPAA Privacy Rule face civil monetary penalties of $100 to $50,000 per violation, and knowingly obtaining or disclosing personally identifiable health data can trigger criminal financial penalties and jail time of a year or more.[29] The criminal consequences make this far from the type of liability rule that permits continued use of a resource subject to ongoing damages, as in *Boomer v. Atlantic Cement*. For de-identified data, there is effectively no way to be compensated at all.

The federal framework has far less than universal scope, covering only a subset of health data. "Protected Health Information" only includes health information that is (1) individually identifiable[30] and (2) created by certain types of entities including healthcare providers, insurers, employers, and schools.[31] Furthermore, HIPAA's protections apply to a narrow set of "Covered Entities": health plans, health care clearinghouses, health care providers, and their Business Associates.[32]

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[26] *See* 15 U.S.C. § 45(a) (2018).

[27] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

[28] *Id.*

[29] *Id.*

[30] *See* 45 C.F.R. § 160.103 (2019) (definition of "protected health information").

[31] *See* 45 C.F.R. § 160.103 (2019) (definition of "health information").

[32] *See* 45 C.F.R. § 160.103 (2019) (definitions of "covered entity" and "business associate").

Thus, rights in the HIPAA framework do not apply to medical records that have had individually identifying information removed, nor do they apply to many types of patient-generated health data like fitness and wellness tracker data. Entities outside the traditional provision of health care, such as advertisers or large tech companies such as Google, also stand outside the scope of the legal framework.[33]

3. State Systems

When creating the HIPAA framework, Congress did not preempt state statutes concerning the legal status of health data. Many states have exercised the discretion that Congress left them by adopting supplementary rules. Three such state regimes are described below.

New Hampshire

Two New Hampshire statutes, both adopted in 1989, purport to clarify ownership rights in medical information:

N.H. Rev. Stat. Ann. § 332-I:1(I):

> "*All medical information contained in a health care provider's medical records is deemed to be property of the patient*. A patient is entitled to a copy of his medical records upon request at a reasonable cost. The patient may not be charged more than $15 for the first 30 pages or $.50 per page, whichever is greater. A health care provider may not use patient identifiable medical information for marketing purposes without written authorization."[34]

N.H. Rev. Stat. Ann. § 151:21(X):

> "The patient shall be ensured confidential treatment of all information contained in the patient's personal and clinical record, including that stored in an automatic data bank, and *the patient's written consent shall be required for the release of information to anyone not otherwise authorized by law to receive it*. *Medical information contained in the medical records at any facility licensed under this chapter shall be deemed to be the property of the patient*. The patient shall be entitled to a copy of such records upon request. The charge for the copying of a patient's medical records shall not exceed $15 for the first 30 pages or $.50 per page, whichever is greater; provided, that copies of filmed records such as radiograms, x-rays, and sonograms shall be copied at a reasonable cost."[35]

In 2010, the Supreme Court of New Hampshire held in *State v. Davis* that the property right in medical information established by these provisions did not create a reasonable expectation of privacy in that information.[36] In part, this was because of a tension with a prior statute that established a general right of privacy between a physician and patient but carved out an exception

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[33] Note, though, that technology companies must be compliant insofar as they serve as Business Associates of HIPAA Covered Entities.

[34] Available at: http://www.gencourt.state.nh.us/rsa/html/xxx/332-i/332-i-mrg.htm (emphasis added).

[35] Available at: http://www.gencourt.state.nh.us/rsa/html/XI/151/151-21.htm (emphasis added).

[36] 12 A.3d 1271, 1276 (N.H. 2010).

for the release of information like blood alcohol test results for use in criminal proceedings—although that provision does not interact directly with the property right in sections 332-I:1(I) and 151:21(X). More fundamentally, the opinion found that the legislative history of the property right provisions evinced a narrow intent to enhance patients' ability to access their medical records—not to generate ancillary interests in that data.

> "We reject the defendant's argument that RSA 332–I:1, I (Supp.2010) supports the conclusion that he had a reasonable expectation of privacy in his medical records. . . . *While the statute deems the information contained in medical records to be the property of the patient, it does not necessarily follow that this is property in which the defendant has a reasonable expectation of privacy*. Indeed, such a reading would be at odds with RSA 329:26. Furthermore, the legislative history supplied by the State illustrates that RSA 332–I:1, I was enacted in response to concerns that some patients were having difficulty obtaining copies of their medical records, and was intended to facilitate patients' access to medical records. . . . The legislative history does not contain any suggestion that the legislature intended to create a new right of privacy, independent of the physician-patient privilege."[37]

In 2016, a New Hampshire Superior Court ruled that these provisions also failed to give a patient a right to his original medical records:

> "The plain meaning of this statute clearly indicates that *a patient is entitled only to the information contained within the medical records*, not the healthcare provider's original records themselves. Under New Hampshire law, then, *the medical records at issue here are clearly the property of Greenbriar, as Mr. Whitney's prior healthcare provider*. The estate is entitled to a copy of these medical records as clearly provided in the statute…. It seems abundantly clear to the Court that the plaintiff has no claim to the original medical records."

These rulings limit the impact of the statutes. However, in at least one setting, they seem to have had an effect: New Hampshire law appears to bar discovery of non-party medical records in litigation.[38] This stands in contrast to other states, which either allow for discovery of redacted non-party records if relevant or base the non-discoverability of non-party records in patient-physician privilege.[39]

Other New Hampshire statutes supplement or qualify the property right in medical data. They include:

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[37] *Id.*

[38] *A Practical Guide to Discovery & Depositions in New Hampshire* § 18.3: Determining What Medical Records To Request (Gary E. Hicks & Daniel E. Will, eds.) (2018), 2011 WL 6012852 ("The information contained in medical records is confidential and cannot be discovered without the patient's consent, unless otherwise authorized by law. See, e.g., Rev. Stat. Ann. § 151:21, X.").

[39] Rachel E. Brown, *Balancing Privacy and Proof: Discovery of Nonparty Medical Records*, 21 J. Health Care L. & Pol'y 189, 189–90 (2018)).

- Patients have a right to an audit trail of access to their medical information for the prior three years (compare to the HIPAA right to an audit of access for the preceding six years).[40]

- Healthcare facilities in New Hampshire must hold a patient's medical records for at least seven years.[41]

- Victims of unauthorized disclosures of medical information have a private right of action against the disclosing party. Minimum damages are $1,000 per violation.[42]

Colorado

Colorado Revised Statutes § 10-3-1104.7(1)(a).

(1) The general assembly hereby finds and determines that recent advances in genetic science have led to improvements in the diagnosis, treatment, and understanding of a significant number of human diseases. The general assembly further declares that:

> (a) Genetic information is the unique property of the individual to whom the information pertains;
>
> (b) Any information concerning an individual obtained through the use of genetic techniques may be subject to abuses if disclosed to unauthorized third parties without the willing consent of the individual to whom the information pertains;
>
> (c) To protect individual privacy and to preserve individual autonomy with regard to the individual's genetic information, it is appropriate to limit the use and availability of genetic information;
>
> (d) The intent of this section is to prevent information derived from genetic testing from being used to deny access to group disability insurance or long-term care insurance coverage.

(2) For the purposes of this section:

> (a) "Entity" means any entity that provides group disability insurance or long-term care insurance coverage and is subject to the jurisdiction of the commissioner of insurance.
>
> (b) "Genetic testing" means any laboratory test of human DNA, RNA, or chromosomes that is used to identify the presence or absence of alterations in genetic material which are

[40] *Compare* N.H. Rev. Stat. Ann. § 332-I:2(g) (2020), *with* https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

[41] N.H. Code Admin. R. Ann. Med § 501.02(f)(8) (2020).

[42] N.H. Rev. Stat. Ann. § 332-I:6 (2020). Unlike most other states in its region, New Hampshire law does not require an individual to prove actual damages to prevail on such a claim. *See* https://masshrm.starchapter.com/images/downloads/don_t_get_byrned.pdf

associated with disease or illness. "Genetic testing" includes only such tests as are direct measures of such alterations rather than indirect manifestations thereof.

(3) (a) Information derived from genetic testing shall be confidential and privileged. Any release, for purposes other than diagnosis, treatment, or therapy, of genetic testing information that identifies the person tested with the test results released requires specific written consent by the person tested.

(b) Any entity that receives information derived from genetic testing may not seek, use, or keep the information for any nontherapeutic purpose or for any underwriting purpose connected with the provision of group disability insurance or long-term care insurance coverage.

(4) Notwithstanding the provisions of subsection (3) of this section, in the course of a criminal investigation or a criminal prosecution, and to the extent allowed under the federal or state constitution, any peace officer, district attorney, or assistant attorney general, or a designee thereof, may obtain information derived from genetic testing regarding the identity of any individual who is the subject of the criminal investigation or prosecution for use exclusively in the criminal investigation or prosecution without the consent of the individual being tested.

(5) Notwithstanding the provisions of subsection (3) of this section, any research facility may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual to whom the information pertains is not disclosed to any third party; except that the individual's identity may be disclosed to the individual's physician if the individual consents to such disclosure in writing.

(6) This section does not limit the authority of a court or any party to a parentage proceeding to use information obtained from genetic testing for purposes of determining parentage pursuant to section 13-25-126, C.R.S.

(7) This section does not limit the authority of a court or any party to a proceeding that is subject to the limitations of part 5 of article 64 of title 13, C.R.S., to use information obtained from genetic testing for purposes of determining the cause of damage or injury.

(8) This section does not limit the authority of the state board of parole to require any offender who is involved in a sexual assault to submit to blood tests and to retain the results of such tests on file as authorized under section 17-2-201 (5)(g), C.R.S.

(9) This section does not limit the authority granted the state department of public health and environment, the state board of health, or local departments of health pursuant to section 25-1-122, C.R.S.

(10) Notwithstanding any provision of this section to the contrary, the only requirements that shall apply to an insurer in connection with life insurance or individual disability insurance are as follows:

(a) Except as otherwise specifically authorized or required by another section of state or federal law, an insurer shall not require the performance of or perform a genetic test without

first receiving the specific, written, informed consent of the subject of the test who has the capacity to consent or, if the person subject to the test lacks the capacity to consent, of a person authorized by law to consent on behalf of the subject of the test. Written consent shall be in a form prescribed by the commissioner.

(b) The results of a genetic test performed pursuant to this subsection (10) are privileged and confidential and shall not be released to any person except as specifically authorized under applicable state or federal law.

(11) Any violation of this section is an "unfair practice", as defined in section 10-3-1104 (1), and is subject to the provisions of sections 10-3-1106 to 10-3-1113.

(12) Any individual who is injured by an entity's violation of this section may recover in a court of competent jurisdiction the following remedies:

(a) Equitable relief, which may include a retroactive order, directing the entity to provide group disability insurance or long-term care insurance coverage, whichever is appropriate, to the injured individual under the same terms and conditions as would have applied had the violation not occurred; and

(b) The greater of:

(I) An amount equal to any actual damages suffered by the individual as a result of the violation; or

(II) Ten thousand dollars per violation.

(13) The prevailing party in an action under this section may recover costs and reasonable attorney fees.

Similar statutes have been adopted in Alaska, Georgia, Louisiana, and Florida.[43]

Indiana

Ind. Code § 16-39-5-3(c)–(d) (2020):

"(c) . . . *the original health record of the patient is the property of the provider* and as such may be used by the provider without specific written authorization for legitimate business purposes, including the following:

(1) Submission of claims for payment from third parties.

(2) Collection of accounts.

[43] See Anya E.R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOKLYN L. REV. 175, 195–98 (2013).

(3) Litigation defense.

(4) Quality assurance.

(5) Peer review.

(6) Scientific, statistical, and educational purposes.

"(d) In use under subsection (c), the provider shall at all times protect the confidentiality of the health record and may disclose the identity of the patient only when disclosure is essential to the provider's business use or to quality assurance and peer review."[44]

Similar provisions can be found in 20 other states.[45]

Question

Consider the four business models described in Part I. How would the approaches exemplified by New Hampshire, Colorado, or Indiana have applied to those models? For each of the state laws consider: would it have made those business ventures harder or easier to defend against a lawsuit by patients whose medical records were used? What would you recommend to a state that approaches you about how to design its own statutes concerning use of medical records in developing new diagnostic tools or treatments? Should it adopt one of these approaches? How might you improve on whichever one you think is most useful to achieve the normative result you seek to support.

B. European Union

The General Data Protection Regulation (GDPR) made effective in 2018 creates a broad set of new individual rights in personal data, including health data. GDPR creates a comprehensive privacy framework that gives eight basic rights to individuals regarding their data. Some of those are analogous to rights in HIPAA, like rights of access and rectification. Others are simply stronger. GDPR's consent requirement restricts the use of data to a tightly defined purpose of which the data controller has already informed the individual.

Some of the rights do not find analogues in the U.S. framework. For instance, the GDPR right to restrict processing and right of erasure afford individuals the ability to withdraw their consent and to place restrictions on the future use of their data or cause its deletion.[46] However, these rights are

[44] Ind. Code § 16-39-5-3(c)–(d) (2020) (emphasis added).

[45] *See* http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison.

[46] Lara Cartwright-Smith et al., *Health Information Ownership: Legal Theories and Policy Implications*, 19 Vand. J. Ent. & Tech. L. 207, 238 (2016); https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-restrict-processing/.

subject to caveats—the right to erasure, for instance, only applies when there is not a compelling reason to continue holding the data.

Elevated protections apply to "special category data," including genetic, biometric, and health data. This data can be used only if one of nine conditions is met, including application to health care or having explicit consent.[47] However, the consensus appears to be that GDPR does not apply to anonymized health data, a significant similarity to HIPAA.[48]

Another EU directive created an interesting set of sui generis "database rights" that can apply to electronic health records or any type of health data. Unlike the American *Feist Publications* rule this right is distinct from copyright and no creativity or originality is required—only a "substantial investment in obtaining, verifying, or presenting" the data.[49] The contents of that database are then protected for fifteen years, with indefinite renewals available upon continued addition and investment.[50] There does not appear to be any reason why these rights would not extend to databases containing health data, although there is a curious dearth of public discussion explicitly making that connection.[51]

[47] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/.

[48] *See, e.g.*, https://www.brown.edu/research/gdpr-and-human-subjects.

[49] Directive 96/9/EC on the Legal Protection of Databases, ch. III, art. 7, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31996L0009#d1e757-20-1.

[50] https://www.cooleygo.com/what-you-need-to-know-about-uk-database-rights/.

[51] *But see* https://www.maucherjenkins.com/news-and-events/2018/ip-considerations-in-digital-health.

III. Reform Proposals

Many lawmakers and scholars contend that none of the legal systems reviewed in Part II is adequate to handle fairly and efficiently business initiatives of the sort described in Part I. They disagree, however, concerning what system of rules would be better. This Part presents a few of the major competing proposals.

Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records

Mark A. Hall
95 Iowa L. Rev. 631 (2010).

IV. Should Patients Have Property Rights?

A. In Favor of Property

When confronted with similar issues, lawmakers have created intellectual property rights—such as copyrights and patents—as exceptions to the general rule that information is in the public domain. These legal rights serve the focused goal of generating private incentives to invest time, energy, and resources into creating, discovering, and developing valuable information. Should a similar approach be used for medical information? Even though incentives are not needed to create medical information since it is created when patients seek treatment, similar financial rewards are needed to compile and transform it into useful forms. Property rights are an ideal way to bundle patients' rights into a legal form that can be monetized and put into a stream of commerce. Fully realizing the economic potential of valuable assets is, in modern times, property law's primary purpose: "We deem something property in order to facilitate its transfer."

Blackstone famously intoned that "[t]here is nothing which so generally strikes the imagination, and engages the affections of mankind, as the right of property." Even when noneconomic values loom large, some civil-rights advocates favor property protections because of their strength and resonance in our modern legal system. For instance, civil libertarian George Annas and his colleagues advocate giving people property rights in their own DNA in order to protect infringements from commercial interests. Even propertization opponent Sonia Suter concedes that "[p]roperty has always been a powerful tool to protect important interests because it is familiar and effective. [It] has teeth and 'symbolic force."

The opposite of propertization is placing information in the public domain. That route is unappealing for a variety of reasons. Providers' and insurers' existing property rights would be eliminated. That might pose significant constitutional issues and spark strong political opposition. Moreover, since privacy protections would remain, public-domain access would still be very limited. And, any economic benefits derived from this information would not flow back to patients. Conferring additional and superior property rights to patients appears to be a more feasible and appropriate route.

Calebresi and Melamed's seminal economic theory also supports this route. Their classic article outlines the general criteria by which society should prefer a property regime over a liability, or,

in our case, regulatory regime for determining access to and use of valuable resources. In general, property rules are preferable when markets determine best uses more efficiently than courts or regulatory agencies. Markets are generally preferred in economic arenas unless "market valuation of the entitlement is deemed inefficient," or when a liability or regulatory rule "facilitates a combination of efficiency and distributive results which would be difficult to achieve under a property rule."

In medical settings, these obviously are large questions that demand wide-ranging analysis, but much of that can be short-circuited by observing that we do not face an all-or-nothing choice. Medical privacy law already contains much of the normative content missing from property law in its plethora of restrictions on access to and use of medical information. The issue, then, is whether the law governing medical records should be overwhelmingly normative--under a legal regime that specifies most of the allowable and unallowable uses--or instead should have a neutral zone that permits individuals more leeway to decide what uses to make of their medical information and what value those uses should have. Adding property rights to privacy protections moves us in that direction.

The main concern of privacy law is controlling access to information rather than putting information to innovative uses. Therefore, it does not embrace a set of norms and practices that countenance financial transactions. Privacy law facilitates the ready release of information only for narrow and specific treatment purposes. Thus, it primarily expresses negative liberties: the rights to exclude, limit, and refuse. Property law, in contrast, embraces a broader set of positive liberties: the rights to use, transfer, and develop.

Also, medical privacy rights grow out of the special nature of the relationships between patients and clinicians. Therefore, privacy rights are enforceable only against the particular providers who generate and possess this information. It is difficult to anticipate and specify all the conditions needed to allow the free flow of medical information since this depends on who possesses and controls the information and on its variety of potential uses. The same is true for specifying necessary protections. Building these rights and protections into the legal status of the information itself is therefore an advantage. The other option is for freedoms and protections to derive only from the origins or location of the information--that is, a patient's particular relationship with the person who holds the information.

Property law addresses these enforcement concerns by creating rights that "run with the chattel." In other words, the rights are enforceable against the world at large and not just against particular parties based on their relationship with the patient. Also, property law provides a strong legal basis for seeking injunctive remedies against infringements. To these extents, property law might confer more extensive rights than privacy law alone.

Finally, property law invokes a fairly standard bundle of protections that are well-established and understood in the law, rather than requiring specification and interpretation of each stick in the bundle. This relative simplicity and ease of recognition facilitate more efficient development. Using examples from for the former Soviet bloc, property law scholar Michael Heller concludes that productive use "emerges more successfully in resources that begin transition [into a newly created market economy] with a single owner holding a near-standard bundle of market legal rights." It is always possible to craft more tailored legal specifications that fit a particular subject

area more exactly, but perfection should not be pursued to the detriment of workable improvements. Property law theorist Henry Smith explains that standardized legal bundles can ultimately be more efficient because they are recognizable and so conserve on information costs: legal "lumpiness has its advantages" because "the on/off quality of [property law] allows complexity to be managed through modularity."

B. Against Property

There are several substantial arguments against giving patients property rights in their medical information. Many privacy advocates view propertization of personal information as "morally obnoxious . . . anathema" because of the law's expressive or symbolic function. They feel that property law connotes a crass commercial attitude about information that inherently has deeply emotional and existential human significance. Sonia Suter articulates this position most forcefully. In her view, medical information is "integral to the self" because it "is about us in very central and personal ways." Rather than protecting "the wholeness of the self and of relationships through which the self flourishes," property "by definition, commodifies and disaggregates the parts from the self." Therefore, "conceptualizing [medical] information as property distorts and impoverishes our understanding of the dignitary, personhood interests we have in this information and the nature of relationships we hope will be built around and through its disclosure."

Those who stress the special significance of personal medical information are adamantly opposed to governing its use primarily through marketplace norms. Intellectual property and privacy law scholars are rightly concerned that reducing the exchange of information to purely transactional legal analysis will permit commercial practices that give people little or no choice over what becomes of their vital information. According to Jessica Litman, the assumption "that initial legal ownership of [information] would enable individuals to restrain their downstream use by negotiating conditions of use before disclosing them . . . . seems to be inspired by a fairy-tale picture of easy bargaining in cyberspace through the use of intelligent agents . . . . [t]hat's nonsense." Mark Lemley agrees that, "from a privacy perspective, an intellectual property right that is regularly signed away may turn out to be less protection than we want to give individuals. To do any good, the right might have to be inalienable and waivable only in certain limited circumstances."

These concerns have pressing salience for access to and control of medical information. One of the core elements in property law's classic bundle of rights is full alienability--allowing property owners to permanently relinquish all of their rights to a purchaser. Although actual commercial practices embrace many less absolute transactional forms such as leasing and licensing, property law disfavors prohibitions of full alienation. Yet it is unlikely our legal regime would ever allow patients to forever relinquish rights to access and control their private medical information because full alienability conflicts with the values we associate with personal medical information. In general, medical-information law should have a strong normative content--specifying permissible and impermissible uses and modes of obtaining consent. Privacy law does this to a considerable extent, but most of property law is adamantly neutral.

This clash between property and privacy regimes could be avoided by constructing a more limited bundle of property rights, as intellectual property law usually does, for example, by limiting the length of those rights, or as patent law specially does to take account of the importance of medical

uses. For instance, “property 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.” But, the more sticks that are removed or shortened, the less compelling the argument is for pursuing a bundling approach at all. As Mark Lemley observes, “a properly designed right would look rather more like a system of regulation than a system of property rights.”

An information system's architecture could be designed creatively to reduce the complexity of a nonbundled regulatory regime. The detailed limits required by regulators or desired by contracting parties could be specified and enforced efficiently by embedding them in the software that operates I-EMRs [interconnected electronic medical records]. The technological sophistication of electronic systems makes it possible to protect individual rights at a much more granular level than traditional regulatory or contracting systems. Thus, according to Jonathan Zittrain, using a “trusted system may allow for ‘baby-splitting’ among interests that is not feasible in more traditional regimes.” For example, “in place of the stalemate over who should ‘own’ a record, a well-defined self-enforcing rights architecture could allow information sharing without having to ultimately resolve matters in as coarse a way as ‘owner’ or ‘nonowner.”

Still, if any kind of property regime were adopted for medical information, additional lines would need to be drawn between medical information and other personal information, over which there are no property rights. The balance of opinion among property- and privacy-law scholars opposes propertizing personal information generally. For medical information, there are good reasons to find the propertization arguments more compelling, but if we accepted those arguments we would then need to differentiate the two realms of personal information, which adds an additional element of complexity.

However, much the same is true for any type of intellectual property regime. Because property rights are not inherent in information, it is always necessary when creating intellectual property to define and justify what is protected from what is not. In part, we have undertaken this chore already for medical information by defining special privacy protections. Similar definitions could also describe the scope of patients' property rights. However, property law definitions would likely differ from those in existing privacy law because, as noted above, the latter arise from special fiduciary responsibilities of health care providers and they have somewhat different aims. Excavating these additional layers is another reason to pause before leaping into a property regime.

Finally, property rights might frustrate the very goals they seek by inhibiting the public-goods value of medical information. Creating more legal rights may not be the best solution to an anticommons problem that was created in part by too many legal rights in the first place. “An intellectual property law governing personal data would result in the creation of literally billions of new intellectual property rights every day; economics wisely counsels us not to expect frictionless licensing in this circumstance.” The Internet, for instance, owes its spectacular success to the fact that its basic structure and elements are all in the public domain. Imagine how its development might have stalled or been severely stunted if key elements were protected by copyrights or patents that owners refused to license or provide for free.

For medical information, Professor Marc Rodwin makes an impressive argument that conferring property rights would interfere with important public goods, such as assembling research databases

and engaging in public health monitoring. His focus is primarily on de-identified data rather than the personalized medical records we consider here, but his objections must be considered carefully. If patients had property rights in their personal medical data, would the government have to pay them "just compensation" for any "taking" of medical information for public purposes? Not if the information is not identifiable to the patient, since any property interest resides in patient-specific information. Government presumably would not take identifiable information except for public health purposes under its police power, as now happens without constitutional objection. Any newly created or expanded property rights would be against the backdrop of these long-standing government practices and policies and therefore could be made subject to them. Still, creating new property rights might give patients more legal power than they currently possess to refuse uses or demand payments for either public or private purposes.

C. Common Ground

Whichever route is pursued, it will not lead to a pure legal regime. As with any other type of intellectual property, because these legal rules are specially constructed to serve an instrumental purpose, we cannot avoid a fairly sui generis set of rules, especially considering the unique importance attached to medical information. Therefore, in the end it may not matter a great deal whether the bundle of rights in medical information is built stick by stick, starting with simple contract and privacy rights, or winnowed and reconstructed from a larger standard set of property rights. This gravitational pull toward a common ground can be seen in the broader debate over personal information generally. Some scholars favor a special bundle of property rights, others favor a special set of tort rules, and still others feel that contract rights are sufficient if properly enforced. Despite these differences, what is common (albeit far from identical) among them is a set of shared concerns about the following important interests that require legal protection and facilitation. By more finely mapping this common ground, the following principles can guide construction of patients' rights to license access to their own medical information.

1. People should be able themselves, or through their agents, to authorize access to and use of their medical information for financial rewards, and these licenses should be transferable.

Without clear recognition of the core entitlement to commercialize access rights, network benefits will not be sufficiently captured, or "internalized" to give anyone in the health care finance and delivery system (as it is currently structured) enough incentive to invest in the construction of I-EMRs. Conferring rights of access and use should not be demandable as an absolute condition of providing or insuring health care services. However, positive or negative incentives can be offered as long as they are not unconscionable--for instance, providing a modest discount to patients who allow their data to be warehoused.

2. Default rules should be set with some degree of paternalism toward protecting patients' interests, in order to take account of the cognitive and other limitations on consent involving vital medical information.

For instance, default rules can be set in a way that forces more choice and more information. Usually, to minimize transaction costs legal default rules are set in an "opt-out" fashion, so that these rules apply unless otherwise specified, according to what most parties would accept when fully informed. However, if a substantial minority strongly dislikes the majority option, there may

be good reason to adopt a more protective default rule that requires parties to affirmatively opt in to the majority position. Otherwise, the net social condition might be suboptimal if the default position is offered only on a take-it-or-leave-it basis, with no real choice or with a technical "choice" but inadequate notice.

3. Some rights or protections should be nonwaivable (or inalienable) and should follow the information regardless of agreement or provenance.

For instance, patients should always retain their basic rights to inspect, copy, and correct medical records, and patients should have a nonwaivable right to revoke any permissions they give for access or use. Enabling patients to back out of an improvident bargain helps correct market flaws by preventing initial mistakes from having long-term consequences. This power also gives market participants a strong incentive to conform their behavior to patients' expectations. Further protections are available by overseeing the "infomediaries" that assemble and process medical information and by embedding safeguards in the software architecture of the system. These protective mechanisms can originate either from regulators or entrepreneurs.

4. Patients' rights to control or sell access to their medical information should be limited to data that can be linked to them personally.

If information is anonymized (or "deidentified") so that it cannot reasonably be connected to anyone in particular, the individual's claim to "ownership" of the information should cease, along with the need for strong legal protections. Recognizing this limit will foster more public goods derived from medical research and public health monitoring.

Much Ado About Data Ownership

Barbara J. Evans

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I. Introduction

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Rule, a major federal regulation affecting health information privacy, is criticized both for hindering access to health data and for allowing too much data access. . . . Regulatory approaches that have worked fairly well in clinical research "are not easily exported and applied to the very different challenges of [informational] research." As the Department of Health and Human Services ("HHS") was developing the HIPAA Privacy Rule in 2000, multiple public commenters, including several members of Congress, voiced this same concern. Research with data and tissues has grown in importance, making these problems more apparent and fueling calls for reform. In 2009, the Institute of Medicine ("IOM") called for changes to the HIPAA Privacy Rule. The IOM recommended replacing the Privacy Rule with an unspecified "new approach" for regulating privacy and access to data for use in health research. HHS recently published an advance notice of proposed rulemaking ("ANPRM"), which called for changes to the Common Rule but offered few specifics, instead posing seventy-four broad questions for public comment.

Rather than reforming the regulations, other proposals seek legislation to clarify data ownership. Ownership of the data held in administrative and clinical databases is a matter of state law and, in most states, data ownership is not clearly defined. Patient data ownership is touted by some observers as a way to enhance patient privacy and by others as a way to make data more widely available for research. Still others call for public (governmental) ownership to enhance researchers' access to data. While differing in details, data propertization proposals seem to agree that property rights in data are important and that clarifying them should be high on the legislative agenda. Ominously, this view is starting to infect policymakers, raising a real risk that what began as an abstract scholarly debate may end in ill-advised legislation.

The urge to propertize health data needs to be weighed skeptically and with a clear understanding of how property rights actually work. If pursued, data ownership may disappoint many of its proponents because of a surprising truth: the framework of patient entitlements and protections afforded by the HIPAA Privacy Rule and the Common Rule is strikingly similar to what patients would enjoy if they owned their data. Part II challenges the claim that private data ownership would improve privacy protection. It finds that both regimes -- patient ownership of data, on the one hand, and the federal regulatory protections, on the other -- provide pliability-rule protection32 that strikes a balance between patient control and the public's need for data access. Both regimes allow some unconsented uses of patients' data, and the grounds for nonconsensual data use are substantively similar under either regime. This similarity suggests that property rights may not be the right locus for reform. Creating property rights in data would produce a new scheme of entitlements that is substantively similar to what already exists, thus perpetuating the same frustrations all sides have felt with the existing federal regulations.

Part III challenges the claim that clarifying data ownership would improve access to useful data resources for clinical care, public health, and research. This claim was central to the recent debate between Professors Hall and Schulman and Professor Rodwin, who disagreed whether private or public ownership of patients' data would better promote data access. Data propertization proposals fail because patients' raw health information is not in itself a valuable data resource, in the sense of being able to support useful, new applications. Creating useful data resources requires significant inputs of human and infrastructure services, and owning data is fruitless unless there is a way to acquire the necessary services. . . .

Despite this progress, important problems remain unresolved. A major challenge in twenty-first century privacy law and research ethics will be to come to terms with the inherently collective nature of knowledge generation in a world where large-scale informational research is set to play a more prominent role.42 Informational research differs starkly from interventional research, exemplified by randomized, controlled clinical trials, which were the major workhorse of late twentieth-century biomedical discovery. A person's refusal to participate in a clinical trial does not jeopardize the broader clinical research enterprise, which can move forward using other willing

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[32] *See* Abraham Bell & Gideon Parchomovsky, *Pliability Rules*, 101 Mich. L. Rev. 1 (2002). The important feature of pliability rule protection, for purposes of this discussion, is that it offers a dynamic scheme of entitlements in which a baseline rule of consensual ordering of data access can shift to nonconsensual access under specified circumstances. *See id.* at 5 ("Pliability, or pliable, rules are contingent rules that provide an entitlement owner with property rule or liability rule protection as long as some specified condition obtains; however, once the relevant condition changes, a different rule protects the entitlement -- either liability or property, as the circumstances dictate. Pliability rules, in other words, are dynamic rules, while property and liability rules are static.").

research subjects; only 600-3000 people are needed for a typical clinical drug trial. In contrast, a person's refusal to participate in informational research may bias the dataset and reduce its statistical power for everyone. Many important types of informational research must be done collectively with large, inclusive datasets. An individual's wish not to participate, perhaps motivated by privacy concerns, potentially places other human beings at risk and undermines broader public interests -- for example, in public health or medical discovery -- in which the individual shares.48 Existing regulations lack tools to resolve this complex dilemma.. . .

II. Why Data Ownership Would Not Protect Patients' Privacy

A. Nonconsensual Access to Patient Data Under a Property Regime

Data propertization proposals fall into two broad categories: pro-privacy proposals that portray private ownership as a way to bolster patients' power to block unwanted uses of their data and pro-access proposals that aim to promote wider availability of data for clinical, research, and public health uses. The pro-privacy proposals rest on a mythical view of private property. Three centuries ago, Sir William Blackstone noted how the human imagination is drawn to the idea of property as "that sole and despotic dominion which one man claims and exercises over external things of the world in total exclusion of the right of any other individual in the universe." This idea resonates with the "autonomy über alles" strand of privacy advocacy that asserts that a patient's right to control access to health data should trump all other interests, even society's interest in conducting studies that might save or improve other people's lives. Blackstone, however, was merely describing how people imagine property. He himself did not espouse this view, nor has American law ever done so.

Different assets call for different forms of ownership, and proponents of patient data ownership do not always specify what they have in mind. Data ownership might, for example, need to look something like the nonexclusive rights riparian owners have in a river that runs by their land -- a right to use the river oneself but not to interfere with others' simultaneous uses for fishing and navigation -- or like a copyright, which expires after a fixed term of years and allows fair use by others even during that term. Pro-privacy proposals seem to draw on the ideal of property reflected in the saying, "one's home is one's castle." In the usual course of events, access to a person's home requires a consensual transaction with the owner, and unconsented uses can be enjoined. This package of rights and remedies corresponds to property-rule protection, and it is what privacy proponents seem to be seeking in their calls for data ownership: consensual ordering of data access and the power to stop unconsented uses.

The fatal flaw in pro-privacy proposals is this: having a property right does not ensure property-rule protection. Law recognizes that there are many situations where consensual transactions cannot be relied on as a way of ordering an owner's relations with the larger community. In many circumstances, a property owner only receives liability-rule protection, which means the owner can be forced to give up her property in return for compensation that is externally set, often by a court, legislature, or administrative agency. That compensation may be zero. The government -- when acting under its police power to protect the public's health, safety, morals, or welfare -- has broad power to confiscate or interfere with property without compensating the owner. Dating back to colonial times, the state's police power has been used not just to prevent property owners from injuring others, but also to pursue broader public welfare objectives for the benefit of the

community. “[T]here was no single paradigm of public welfare that confined what we now call the police power. Then, as now, lawmakers pursued a shifting amalgam of goals .... Legislation coercively promoted uses of private land that were viewed as conducive to the community's well-being.” Consistent with this tradition, the government can require nonconsensual access to data for use in public health activities, which long have been viewed as a legitimate exercise of the state's police power. This would remain true even if data were patient-owned.

The state also has eminent domain power to take property for “public use” without the owner's consent, subject to payment of just compensation. The public uses that can support a taking are quite broad and could include private, commercial research uses of data, if data were patient-owned. Takings require “some showing of ‘publicness”’ of the intended use, and takings that lack the requisite public quality can be enjoined. Public uses traditionally involved placing the property under public ownership or transferring it to a private company, such as a utility or railroad, that is obligated to serve the public, often but not always for a regulated price. There was never a requirement that the fruits of a taking be made freely available to the public: railroads and stadiums built on taken land routinely require users to buy tickets. Modern courts, somewhat controversially, allow takings that transfer property to new private owners for commercial projects that need not be open to the general public and for projects that offer only indirect public benefits, such as boosting local tax revenues or aiding urban renewal or land reform.

The possibility of eminent domain appears to have been lost on privacy advocates who view data ownership as a way to halt unconsented, private-sector research use of data. Modern takings doctrine would allow privately owned health data to be taken for use in academic and commercial research that offers a prospect of developing a beneficial therapy. This is true even if the new therapy, when successfully developed, would be available only to patients who can pay for it. It seems doubtful that patients would be entitled to compensation when their data were taken for use in research. Courts construe “just compensation” to mean payment of market value -- what the property would fetch in an alternative, consensual sale on the open market. There is no compensation for subjective value, such as the emotional attachment an owner has to a particular home, or for undeveloped use rights -- what the undeveloped property might have been worth if the current owner had chosen to develop it. There also is no compensation for consequential costs of the taking, such as an owner's moving expenses. These same limitations presumably would apply if patient-owned data were taken for public use in research. When patients wish to have their data “lie fallow” because of privacy concerns, the fair market value of the data arguably is zero: if patients oppose having their data used in research at all, there is no alternative consensual use by which to gauge the data's market value. The value of unused data is largely subjective, reflecting an emotional attachment to the data and a wish to keep it secret. This is not compensable under modern takings doctrine.

B. Nonconsensual Data Access Under the Existing Federal Regulations

The HIPAA Privacy Rule and the Common Rule offer a framework of patient entitlements and protections that is strikingly similar to what patients would enjoy if they owned their data. Under ordinary circumstances, both regulations require consensual ordering of data access: they require a privacy authorization or informed consent before data can be used. However, both regulations contain exemptions, exceptions, and definitional nuances that shift to a regime of liability-rule protection under certain circumstances. . . .

Under the current regulations, certain activities that are considered to have high social value -- such as using data for judicial, law enforcement, and public health purposes -- are not subject to the usual consent and authorization requirements. Nonconsensual research use of data is allowed under conditions aimed at reducing privacy risks to the data subjects. Such use is allowed if the data have been deidentified, coded in compliance with specified standards, or converted to a limited data set. Nonconsensual research uses are also allowed if an Institutional Review Board or privacy board (collectively, "IRB") approves a waiver of the usual consent or authorization requirements. Data supplied to researchers under a HIPAA waiver must meet "minimum necessary" requirements -- i.e., no more information can be disclosed than is necessary to accomplish the intended research purpose. However, there is no requirement that the data be de-identified or even coded to qualify for a waiver. In theory, it is possible to disclose fully identified data under a waiver, if the research requires the use of identified data and if an IRB deems the other waiver conditions to be met.

While some people object to any nonconsensual use of their data, there is fairly solid public support for police power uses of data -- such as monitoring the spread of epidemics -- that protect public health, safety, and welfare. The public also has some degree of comfort with the use of de-identified and other "masked" forms of data despite ongoing concerns about the potential for such data to be reidentified. Waivers do not inspire similar levels of public understanding. They are subject to ongoing critique from research institutions and IRBs that find the waiver provisions cumbersome to apply and from scholars and privacy advocates who view them as an abuse-prone bypass to consent requirements….

"President Weighs in on Data from Genes"
By Julie Hirschfield Davis
New York Times, Feb. 25, 2016

President Obama on Thursday waded into the complex and high-stakes debate over whether patients own their genetic information, saying that he believes that his tissues and any discoveries that stem from his DNA belong to him.

"I would like to think that if somebody does a test on me or my genes, that that's mine, but that's not always how we define these issues," Mr. Obama said during a White House forum on a major biomedical research initiative he began last year.

The president said that the success of his Precision Medicine Initiative, which aims to collect genetic data on one million American volunteers so scientists can develop drugs and treatments tailored to individual patients, hinged at least in part on "understanding who owns the data."

Many researchers and the universities and medical centers that back them regard genetic material and the results from tests they conduct on it as their intellectual property and are reluctant to share it. But consumer groups and some health advocacy organizations believe that individuals are the rightful owners of the data and the discoveries that emanate from them.

Advances in genetics and cell biology and the use of electronic medical records have paved the way for more sophisticated research into genes that may increase the risk of developing certain diseases. The debate over such research has broad implications for privacy and the success of precision medicine efforts, which depend on access to troves of genetic data.

Mr. Obama's comments on Thursday seemed to place him in the camp of individual patients.

"Right now, what happens is the best researchers and the best universities, oftentimes they're kind of hoarding their samples," Mr. Obama said, essentially for fear of losing their grants if they do not keep control of them.

The president's remarks elated some health advocates who have long argued that participants in genetic testing should be partners in the research that their cells enable.

"I had chills and a few tears, because I had not heard this before from the president or anyone high-up at the White House," said Sharon F. Terry, the chief executive of the Genetic Alliance, who was in the auditorium, across from the White House, as Mr. Obama spoke.

"The Precision Medicine Initiative has been trying to shift the conversation toward the idea that participants should be partners," Ms. Terry said. "But this is a really, really hard issue."

The Obama administration has been working to address it. On Thursday, the Department of Health and Human Services issued new guidance to clarify that patients should have access to their medical records, including genomic testing results.

Dr. Francis S. Collins, the director of the National Institutes of Health, has said participants in the Precision Medicine Initiative should be treated as "partners in research, not subjects." The program's principles include finding "innovative, responsible and consumer-friendly ways of sharing research data with participants."

The N.I.H. announced on Thursday that Vanderbilt University would team with Verily, formerly known as Google Life Sciences, to begin building the group of one million American volunteers who will participate in the individualized medicine effort.

Mr. Obama signed legislation in December providing about $200 million for the program.

"The president says patients should own their genetic data. He's wrong"

By Jorge Contreras

34 Nature Biotechnology 585 (2016)

As reported by the *New York Times*, US President Obama recently told a gathering of scientists, policymakers and patient advocates that individuals should own the data that comes from studying their DNA. He observed that "if somebody does a test on me or my genes...that's mine." Although, at first blush, the idea that we should own our data has an intuitive appeal, it contradicts a century of US legal precedent and, if put into effect, could have serious ramifications for biomedical research.

The President's comments were made during a White House briefing on the Precision Medicine Initiative (PMI), an ambitious new federal program that will fund the analysis of DNA from more than a million American volunteers. If the PMI gets off the ground, it will be the largest study of its kind ever conducted, and it could revolutionize our understanding of human disease and physiology.

To achieve its goals, the PMI will need to overcome significant fiscal, scientific and data-management hurdles. But perhaps the greatest challenge for this and other population-wide genetic studies will be persuading large numbers of individuals to contribute their DNA to the cause. Unlike drug trials and other experimental medical procedures, the cheek swabs and other minimally invasive techniques used to collect this DNA present no physical risk or harm. Nevertheless, there is a general public unease surrounding research using human DNA.

Some of this unease may arise from accounts of past research abuses, including the notorious Tuskegee syphilis experiments and the commercial exploitation of a poor black patient's cells, as recounted in Rebecca Skloot's *The Immortal Life of Henrietta Lacks*. Stories like these have made it clear that the public will need to be engaged in the research enterprise if large-scale research projects like PMI are to succeed.

But claiming that individuals 'own' the data derived from their DNA is not the right way to achieve this goal. Information cannot be 'owned' in the same way as land, tangible goods or even intangibles like money and securities. Pure data, once known, is, as Justice Louis Brandeis wrote nearly a century ago, as “free as the air to common use”.

Since then, US courts have repeatedly denied individuals' ownership claims over data derived from their cells and tissue3. Just imagine the chaos that would ensue if each of the million participants in the PMI could claim ownership over discoveries that were made after large pools of DNA were analyzed. If a drug or a vaccine were developed years after the study ended, should that person be entitled to compensation? Should everyone whose DNA was analyzed? What if one person's DNA were simply part of a control group, or of a trial that yielded no meaningful results? As one federal court cautioned, in *Greenberg* v. *Miami Childrens' Hospital*, the recognition of personal property rights in such data “would cripple medical research”.

Yet the temptation to give individuals such ownership rights is strong. Several states have already passed legislation granting individuals ownership of the data derived from their DNA. And several recent lawsuits have objected to research based on claims seeking property-like control over genetic data. Among these was a 2009 Texas suit seeking to prevent the use of stored infant blood spots for a range of public health purposes.[52] To settle that suit, the state of Texas agreed to destroy over 5 million existing blood samples, resulting in the loss of an irreplaceable research resource.

In another highly publicized case, members of the Havasupai Indian tribe sued Arizona State University (ASU; Phoenix, AZ) for $50 million, arguing that DNA samples allegedly collected to investigate diabetes were impermissibly being used to investigate other things, such as schizophrenia and human migratory patterns.[53] To settle the case, ASU agreed to discontinue the

[52] *Beleno v. Lakey*, Order, Civ. Action No. SA-09-CA-188-FB (W.D. Tex. 17 September 2009).

[53] *Havasupai Tribe v. Ariz. Bd. of Regents*, 220 Ariz. 214, 217 (2008).

research and return all samples, even though broad consent forms had been signed by the individual donors.

Admittedly, individuals have legitimate concerns regarding how their donated DNA will be used. But giving them ownership of the resulting data is not the best way to address those concerns, nor is the complex set of exceptions and exclusions currently proposed in an amended version of the federal Common Rule.[54] Instead, federal and state legislation should be enacted to prevent the types of research abuses that have occurred in the past. In 2008, the US Congress took a first step when it passed the Genetic Information Nondiscrimination Act (GINA) to outlaw discrimination by health insurers and employers on the basis of genetic information. That legislation could be expanded to cover more: life and disability insurance, education, loan applications and so on.

Other rules could be put in place to ensure that an individual's health information will not be used for direct marketing purposes and that anonymized data will not be 'reverse engineered' to identify specific individuals. And existing federal research regulations, such as the Common Rule and HIPAA Privacy Rule, which today cover mostly government-funded research, could be expanded to cover private sector initiatives as well.

If large-scale genetic research studies like the PMI are to succeed, the US Administration should think carefully about the best way to achieve its goals. Ample legal measures are available to protect the public from research abuses, but giving individuals ownership of research data is not one of them.

Oregon Senate Bill 703

Whereas the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects the privacy and security of the protected health information of an individual and affords the individual the right to access, amend and obtain an accounting of disclosures of the individual's protected health information; and

Whereas HIPAA balances these protections and individual rights with the need to avoid the creation of unnecessary barriers to the access of quality health care; and
Whereas, notwithstanding individuals' expectations that protected health information will be used and disclosed as necessary to treat them, to bill for treatment and, to some extent, to operate a covered entity's health care business, protected health information is often used for purposes unrelated to treatment, payment or health care operations of the covered entity; and

Whereas companies that provide services on behalf of covered entities that give them and their contractors access to protected health information, routinely de-identify individuals' protected health information in order to sell the information in de-identified form to third parties for remuneration; and

Whereas after protected health information has been de-identified, it is no longer protected by or subject to HIPAA; however, the de-identification process itself is a use of protected health in-

[54] US Department of Homeland Security et al. *Fed. Reg.* 80, 53933 (8 September 2015).

formation that may only be performed under limited circumstances and for limited purposes under HIPAA; and

Whereas an individual may authorize a use or disclosure of the individual's protected health information that is not otherwise permitted by HIPAA, such as for the de-identification of protected health information for the purpose of commercial sale; and

Whereas the individual who authorizes the de-identification of the individual's protected health information for the purpose of commercial sale should have the right to assert a property interest in the health information such that the individual may receive remuneration in connection with the commercial sale; now, therefore,

Be It Enacted by the People of the State of Oregon:…

SECTION 2. (1) A covered entity, business associate, subcontractor or other third party doing business in this state may not engage in the commercial sale of protected health information, health information or de-identified data without first obtaining a signed authorization from the individual.

(2) A covered entity, business associate, subcontractor or other third party doing business in this state may not discriminate against or penalize an individual who declines to sign an authorization or who elects to receive remuneration in exchange for signing an authorization.

(3) A covered entity, business associate, subcontractor or other third party shall provide a share of any remuneration received by the covered entity, business associate, subcontractor or other third party to an individual who elects to receive remuneration in exchange for signing an authorization.

(4) A third party that has not obtained a signed authorization from the individual may not engage in the commercial sale of any protected health information, health information or de-identified data purchased or otherwise obtained from a covered entity, business associate or subcontractor without first documenting that a signed authorization has been obtained by the covered entity, business associate or subcontractor in accordance with subsection (1) of this section.

(5) This section does not apply to a public body, a federal agency or the business associates or subcontractors of a public body or federal agency with respect to health information created, received, transmitted or maintained by the business associate or subcontractor on behalf of the public body or federal agency.

(6) Violation of subsection (1), (2), (3) or (4) of this section is an unlawful practice under ORS 646.608.