PREVENTING THE CORRUPTION OF HEALTHCARE ALGORITHMS

Philip M. Nichols

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The intersection of technology and healthcare will radically change the provision of healthcare services. The full extent of the changes cannot be known now, but the direction is clear: collection of voluminous data and tools powerful enough to analyze that data will facilitate the design of algorithms that will enable machines to make important decisions regarding diagnoses and treatments. In addition to the possible benefits, policymakers and scholars have focused on issues of privacy and potential bias. The potential for corruption of the design of healthcare algorithms has been ignored, but the potential for corruption is real and dangerous. This article shows how healthcare algorithms could be corrupted by pharmaceutical and medical device firms and examines the possibility that such corruption will occur. The article concludes that the likelihood, verging on certainty, of corruption requires transparent public review of healthcare algorithms. Privacy and bias are more comfortable subjects, but new technologies require new thinking if the benefits of algorithmic healthcare are to be enjoyed.

INTRODUCTION

Corruption poses a clear danger to the benefits that could flow from the application of large-scale data analytics to healthcare. Whether called the "big data revolution," the "digital revolution," the "fourth industrial revolution," or simply large-scale data analytics, changes in technology now enable machines to make decisions in ways never before thought possible. The decision-making capacities of machines "are transforming the way that business is conducted in all sectors of the economy."[1] Healthcare, in particular, is experiencing "a major transformation fueled by regulatory shifts and technological advances."[2] This transformation is in its nascence; even though almost a third of the stored data in the world relates to healthcare, the tools of large-scale data analysis have barely dented this extraordinary

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[1] Max N. Helveston, *Consumer Protection in the Age of Big Data*, 93 WASH. U. L. REV. 859, 861 (2016).

[2] Ritu Agarwal et al., *Emerging Technologies and Analytics for a New Era of Value-Centered Marketing in Healthcare*, 48 J. ACAD. MARKETING SCI. 9, 9 (2019), https://doi.org/10.1007/s11747-019-00692-4.

mass of data.[3] The potential could be extraordinary.

The extent to which machine-made healthcare decisions will replace human-made decisions engenders vigorous debate. Some predict that humans will merely consult machines but continue to make all decisions; others predict that machines will make most decisions.[4] Most agree that machines will make a significant amount of decisions regarding diagnoses and treatment and that those decisions will be increasingly personalized to individual patients.[5] The full extent to which technology will change healthcare is unknown–the integration of machine-made decisions into the provision of healthcare has only begun.[6]

Large-scale data analytics relies on voluminous data, and much commentary focuses on privacy issues associated with accumulating and using health-related data.[7] Somewhat less commentary focuses on bias built into these decisions.[8] This article examines a hitherto unexplored danger presented by these changes: the deliberate manipulation of algorithms to benefit the interests of third parties rather than the patient.

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[3] Ziawasch Abedjan et al., *Data Science in Healthcare: Benefits, Challenges and Opportunities*, *in* DATA SCIENCE FOR HEALTHCARE: METHODOLOGIES AND APPLICATIONS 3, 6 (Sergio Consoli et al., eds. 2019); *see also id.* (suggesting that the application of analytical tools to this body of data could "change the world itself.").

[4] *See infra* notes 82-87 and accompanying text.

[5] *See* Thomas Davenport & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 94, 97-98 (2019) (suggesting it is "increasingly clear" that machines will play a large role in diagnosis and prescription).

[6] *See id.* at 95-97 (describing the current state and predicting the future of algorithmic healthcare).

[7] *E.g.*, Fred H. Cate, *Protecting Privacy in Health Research: The Limits of Individual Choice*, 98 CALIF. L. REV. 1765 (2010); Liane Colonna, *Legal and Regulatory Challenges to Utilizing Lifelogging Technologies for the Frail and Sick*, 27 INT'L J.L. INFO. TECH. 50 (2019); Mary F.E. Ebeling, *Uncanny Commodities: Policy and Compliance Implications for the Trade in Debt and Health Data*, 27 ANNALS. HEALTH L. 125 (2018); Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69 (2011); Deven McGraw, *Privacy and Health Information Technology*, 37 J.L. MED. & ETHICS 121 (2009); Amy L. McGuire et al., *Importance of Participant-Centricity and Trust for a Sustainable Medical Information Commons*, 47 J.L. MED. & ETHICS 12 (2019); Laird A. Pisto, *The Need for Privacy-Centric Role-Based Access Controls to Electronic Health Records*, 7 J. HEALTH & LIFE SCI. L. 79 (2013); Marc A. Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 AM. J.L. & MED. 586 (2010); Elaine M. Sedenberg & Deirdre K. Mulligan, *Public Health as a Model for Cybersecurity Information Sharing*, 30 BERKELEY TECH. L.J. 1687 (2015); Effy Vayena & Alessandro Blasimme, *Health Research with Big Data: Time for Systemic Oversight*, 46 J.L. MED. & ETHICS 119 (2018); W. Gregory Voss & Kimberly A. Houser, *Personal Data and the GDPR: Providing a Competitive Advantage for U.S. Companies*, 56 AM. BUS. L.J. 287, 316-20 (2019).

[8] *E.g.*, Franklin G. Miller, *Research on Medical Records Without Informed Consent*, 36 J.L. MED. & ETHICS 560 (2008); John R. Stone, *Elderly and Older Racial/Ethnic Minority Healthcare Inequalities*, 21 CAMB. Q. HEALTHCARE ETHICS 342 (2012).

Algorithms, whether used by humans or machines, are steps and processes used to process data to achieve an outcome. Arguably, humans and very simple machines can make decisions without an algorithm; computers, however, always use algorithms to arrive at a decision.[9] The design of healthcare algorithms, therefore, will determine the quality of machine-made decisions regarding diagnosis and treatment. Pharmaceutical and medical device firms will almost certainly attempt to corrupt the design of those algorithms.[10] As this article will show, pharmaceutical and medical devices have a long and deep history of corrupting research and prescription, which maps closely on the steps involved in designing an algorithm.[11] Their attempts to corrupt the design of healthcare algorithms seem inevitable unless action to prevent the corruption of algorithms is taken now.

This article outlines the necessary action, of which transparency is the most important part. Before outlining the necessary response to the threat of corruption, this article first discusses how algorithms are developed and how pharmaceutical and medical device firms are likely to corrupt their development.

I. ALGORITHMIC HEALTHCARE

An algorithm is not itself a machine; indeed, algorithms preceded machines.[12] "[A]n algorithm is any well-defined computational procedure that takes some value, or set of values, as input and produces some value, or set of values, as output. An algorithm is thus a sequence of computational steps that transform the input into the output."[13] Algorithms themselves are not machines but instead enable machines to make decisions. "Before there were computers, there were algorithms. But now that there are computers, there are even more algorithms, and algorithms lie at the heart of computing."[14]

It is important to understand that even though algorithms are not ma-

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[9] *See infra* notes 12-14 and accompanying text.

[10] This assertion is offered factually rather than as a provocation. The author readily acknowledges that most individual people in the pharmaceutical and medical devices industries act with integrity. The author has worked with the pharmaceutical and medical devices industries, for example, in the context of helping to negotiate APEC's Kuala Lumpur Principles Medical Device Sector Code of Ethics and does not claim that every actor is corrupt. However, as this article will discuss, pharmaceutical and medical devices firms have consistently acted corruptly.

[11] *See infra* notes 99-165 and accompanying text.

[12] THOMAS H. CORMEN ET AL., INTRODUCTION TO ALGORITHMS xiii (3d ed. 2009).

[13] *Id.* at 5.

[14] *Id.* at xiii.

chines, they also are not natural phenomenon that are discovered by scientists. Algorithms instead are technology that are created like any other iteration of technology. Moreover, there will almost always be more than one version of algorithm that can work with any given set of data to achieve any given goal.[15] A "correct" algorithm is nothing more than an algorithm that always produces an answer related to the question that is asked of it.[16]

The Federal Trade Commission, in parsing the functionality of algorithmic decision making from the perspective of bias, identified four stages in the "life cycle" of data-driven algorithms: data collection, consolidation, analysis, and use.[17] Healthcare has experienced revolutionary change in each, and reviewing these four stages allows a finer-grained understanding of the corrupt activities of pharmaceutical and medical device firms. Discussing these changes in a scholarly publication, however, presents a Sisyphean task–generational changes in technology outpace the publication timeline. This article, therefore, will attempt only to convey the nature of change rather than report on the most current state of technology. The nature of the change has been profound: "Smartphones already are replacing stethoscopes and pagers as the most ubiquitous physician accessory."[18]

A. Data Collection

The collection of data has become universal.[19] This is especially true with respect to data related to health. In the past, most data about a person's health was collected either through self-reporting or through infrequent observations made by a healthcare professional, usually in a clinic. Information was limited by whatever observational tools were available and to the time periods of the clinical visits. Statements regarding baseline health conditions of healthy populations, such as "the average normal blood pressure" or "the average normal heartbeat," were based on research studies that conducted brief measurements of a few hundred or thousand healthy persons.[20] Instruments used to collect data, with the exception of

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[15] *Id.* at 12.

[16] *Id.* at 6; *see also* STEVEN S. SKIENA, THE ALGORITHM DESIGN MANUAL 3 (2d ed. 2008) ("An algorithm is a procedure to accomplish a specified task.").

[17] FED. TRADE COMM'N, BIG DATA: A TOOL FOR INCLUSION OR EXCLUSION? UNDERSTANDING THE ISSUES 3-5 (Jan. 2016), https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf.

[18] Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1177 (2014).

[19] Sonia K. Katyal, *Private Accountability in the Age of Artificial Intelligence*, 66 UCLA L. REV. 54, 59 (2019).

[20] *See* Greg Samsa et al., *Determining Clinically Important Differences in Health Status Measures: A General Approach with Illustration to the Health Utilities Index Mark II*,

instruments such as thermometers, tended to be far too large, expensive, and complicated for widespread use.

That has changed. Instruments that collect information on the state of individual health are widespread and widely used. The vanguards of these instruments were mobile health apps and wearable fitness monitors.[21] A recent survey in the United States found that more than half of the respondents had downloaded health apps and that of those almost two-thirds opened a health app at least once a day.[22] At least one out of every ten people in the United States also wears a fitness monitor.[23] Hundreds of thousands of fitness-monitor-apps already exist and that number is growing.[24] Each of these monitors, as well as associated applications, collects data.

Improvements to mobile technologies that measure and observe health conditions are just as impressive as the increase in the number and sophistication of apps. A slew of diagnostic applications, plug-ins, and dongles allow for sophisticated observations, including sensors that can identify pathogens and plug-ins that can administer x-rays.[25] The development of new materials and fibers also enables monitoring and observation of health through everyday items such as clothing, shoes, bedsheets, and even toilets.[26] Small scale magnetic resonance imagers will, in the near future, be widely available and easily connected to digital interfaces.[27]

These devices and programs can already collect a great deal of information. At the time this is written, mobile devices available to consumers can constantly collect information on aspects of health such as blood flow, blood pressure, blood sugar, body chemistry, changes in autonomous nervous system, heart rate variability, exposure to ultraviolet light, hemoglobin levels, lactic acid levels, muscle exertion, oxygenation, sleep habits,

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15 PHARMACOECONOMICS 141, 143 (1999) ("[Clinically Important Differences] may be estimated using direct, cross-sectional, longitudinal or standardised approaches. . . . None of the above methods has been universally acknowledged to be superior to the others . . . .").

[21] Janine S. Hiller, *Healthy Predictions? Questions for Data Analytics in Health Care*, 53 AM. BUS. L.J. 251, 276 (2016).

[22] Paul Krebs & Dustin T. Duncan, *Health App Use Among US Mobile Phone Owners: A National Survey*, 3 JMIR MHEALTH & UHEALTH 1, 5 (2015), http://mhealth.jmir.org/2015/4/e101.

[23] Elizabeth A. Brown, *The Fitbit Fault Line: Two Proposals to Protect Health and Fitness Data at Work*, 16 YALE J. HEALTH POL'Y L. & ETHICS 1, 8 (2016).

[24] *Id.* at 9.

[25] Robert F. Service, *The Cyborg Era Begins*, 340 SCI. 1162, 1162-64 (2013).

[26] Araya Abrha Medhanyie et al., *Mobile Health Data Collection at Primary Health Care in Ethiopia: A Feasible Challenge*, 68 J. CLINICAL EPIDEMIOLOGY 80, 80-85 (2015); Service, *supra* note 25, at 1162-65; Toshiyo Tamura et al., *Fully Automated Health Monitoring System in the Home*, 20 MED. ENGINEERING & PHYSICS 573, 575 (1998).

[27] Service, *supra* note 25, at 1162-64.

and temperature.[28] These and other technologies used to gather data on everyday health conditions–technologies that barely existed a decade ago–have become widely available and may soon be ubiquitous. Health data collection will be an almost invisible part of daily life.[29] Devices, barely contemplated today, will collect and transmit voluminous flows of health data.[30] Data collection will be constant, instantaneous, and automatic and no longer limited to clinics and memory.[31]

Genes constitute another aspect of health in which collection has and continues to experience extraordinary change. In 2003, the Human Genome Project announced the completion of the first sequencing of a human genome.[32] That first sequencing took thirteen years, involved two government agencies and numerous private partners, and, at a cost of US$3.8 billion, was "the most expensive and arguably the most significant life science research project undertaken in the history of U.S. science."[33] In less than a decade, the cost of sequencing a genome fell to 0.0014% of the amount spent by the Project, the time required to sequence a genome shrank to a few hours, and hundreds of thousands of genomes were sequenced.[34] Soon, genomes may be sequenced in real time through hand-held connected monitoring devices, and genomes may be sequenced at birth as a matter of course.[35] The technology to cheaply and quickly perform next generation sequencing, such as RNA, cDNA, and mitochondrial sequencing, seems to have a trajectory similar to that of genome sequencing.[36]

The ability to collect these two disparate bodies of data–one dynamic and constantly changing, the other the fundamental and unique blueprint

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[28] Karen E.C. Levy, *Intimate Surveillance*, 51 IDAHO L. REV. 679, 691 (2015); Scott R. Peppet, *Regulating the Internet of Things: First Steps Toward Managing Discrimination, Privacy, Security, and Consent*, 93 TEX. L. REV. 85, 88 (2014); Adam Steele, *An Emergency Room in Your Living Room: Privacy Concerns as Health Information Moves Outside of the Traditional Medical Provider Context*, 19 VA. J.L. & TECH. 389, 403-04 (2015).

[29] *See* Hiller, *supra* note 21, at 269-70.

[30] *See* Service, *supra* note 25, at 1165.

[31] Alex H. Krist, *Electronic Health Record Innovations for Healthier Patients and Happier Doctors*, 28 J. AM. BOARD FAM. MED. 299, 300 (2015).

[32] Kenneth G. Huang & Fiona E. Murray, *Entrepreneurial Experiments in Science Policy: Analyzing the Human Genome Project*, 39 RES. POL'Y 567, 573 (2010).

[33] *Id.* at 569.

[34] Tom Ulrich, *Opinionome: Can DNA Sequencing Get Any Faster and Cheaper?*, BROAD INST.: BROADMINDED BLOG (Sept. 13, 2016), http://www.broadinstitute.org/blog/opinionome-can-dna-sequencing-get-any-faster-and-cheaper.

[35] Eric D. Green et al., *The Future of DNA Sequencing*, 550 NATURE 179, 179-81 (2017).

[36] *See* Fatih Ozsolak & Patrice M. Milos, *RNA Sequencing: Advances, Challenges and Opportunities*, 12 NATURE REV. GENETICS 87, 87, 96 (discussing technologies and speculating on future advances).

of an individual living organism–are unprecedented and herald almost unimaginable changes in the provision of healthcare.[37] Voluminous data, however, is useless unless it can be stored and retrieved in a useful way.

B. Data Consolidation

The Federal Trade Commission describes consolidation of data into usable bodies as the second step in the data-algorithm process. Over the last decade, health data has been usably consolidated at both individual and population levels. Much of this change has occurred as a result of legal requirements imposed on healthcare providers.[38]

With respect to individuals, consolidation has occurred through the use of electronic records that follow each patient regardless of caregiver.[39] The use of electronic records has largely been and will continue to be driven by changes in law. Medical records for most people were once kept on paper, in disparate file drawers, separated by the segments of a person's life, often in the scribbled codes of an individual healthcare provider who no longer even practiced.[40] Electronic record keeping made some inroads into healthcare, but these efforts were primarily intended to streamline billing and therefore focused on the cost aspects of care.[41] The costs of creating electronic records and even greater costs associated with creating a net-

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[37] Erica Bowton et al., *Biobanks and Electronic Medical Records: Enabling Cost-Effective Research*, 6 SCI. TRANSITIONAL MED. 234, 234 (2014); Travis B. Murdoch & Allan S. Detsky, *The Inevitable Application of Big Data to Health Care*, 309 J. AM. MED. ASS'N 1351, 1351 (2013); Griffin M. Weber et al., *Finding the Missing Link for Big Biomedical Data*, 311 J. AM. MED. ASS'N 2479, 2479-80 (2014).

[38] *See* Hiller, *supra* note 21, at 257-59 (describing changes and their effects).

[39] Within the healthcare industry, the terms "electronic health records" and "electronic medical records" are sometimes used interchangeably. The Office of the National Coordinator for Health Information Technology, the Office within the United States Department of Health and Human Services charged with promoting and coordinating a national health information exchange, prefers the use of the term electronic health records as broader and more inclusive. *See* Peter Garrett & Joshua Seidman, *EMR vs EHR - What is the Difference?*, HEALTHITBUZZ (Jan. 4, 2011), https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference.

[40] Ab Bakker, *Access to EHR and Access Control at a Moment in the Past: A Discussion of the Need and an Exploration of the Consequences*, 73 INT'L J. MED. INFORMATICS 267, 267 (2004); Ashish K. Jha, *Meaningful Use of Electronic Health Records: The Road Ahead*, 304 J. AM. MED. ASS'N 1709, 1709-10 (2010).

[41] *See* Tracy D. Gunter & Nicolas P. Terry, *The Emergence of National Electronic Health Record Architectures in the United States and Australia: Models, Costs, and Questions*, 7 J. MED. INTERNET RES. e3 (2005), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550638 (discussing business reasons for adoption of electronic medical records).

work for sharing those records inhibited the growth of electronic recordkeeping.[42]

Several factors led to change. In Europe, the fact that most healthcare is provided through a single entity led to the organic evolution of shared electronic medical records.[43] In the United States, on the other hand, federal legislation forced healthcare providers to adopt electronic recordkeeping. The Health Information Technology for Economic and Clinical Health Act,[44] often called the HITECH Act, provides subsidies and financial incentives for healthcare providers to adopt electronic recordkeeping.[45] Taking advantage of HITECH Act incentives, most hospital systems as well as office-based physicians in the United States have now adopted some form of electronic health record system.[46]

It is difficult to overstate the extraordinary change in information wrought merely by this change in how records are kept.[47] The fact that these records now easily follow a person from place to place and from provider to provider means that these medical histories will be life histories.[48] In the past, technology simply could not support the real time aggregation of multiple points of data on the health of people over long periods of time.[49]

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[42] *See* Mark A. Hall, *Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records*, 95 IOWA L. REV. 631, 638-39 (2010).

[43] *See* Klaus M. Brisch & Claudia E. Haupt, *Information Technology Meets Healthcare: The Present and Future of German and European E-Health Initiatives*, 12 DEPAUL J. HEALTH CARE L. 105, 110-12 (2009) (describing European investment in shared electronic health records).

[44] 42 U.S.C. § 300jj-19 (2012).

[45] Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 251 (2013); *see also* Victoria A. Shaffer, *Nudges for Health Policy: Effectiveness and Limitations*, 82 MO. L. REV. 727, 734-35 (describing the HITECH Act as a "nudge").

[46] Benjamin Shickel et al., *Deep EHR: A Survey of Recent Advances in Deep Learning Techniques for Electronic Health Record (EHR) Analysis*, 22 IEEE J. BIOMED. & HEALTH INFORMATICS 1589, 1589 (2018).

[47] *See* Eric B. Larson, *Building Trust in the Power of "Big Data" Research to Serve the Public Good*, 309 J. AM. MED. ASS'N 2443, 2443-44 (2013) (describing reaction of research community to this database); Weber et al., *supra* note 37, at 2479-80 (describing community reaction to database).

[48] Bakker, *supra* note 40, at 267.

[49] *See* STANFORD MEDICINE, STANFORD MEDICINE 2017 HEALTH TRENDS REPORT: HARNESS THE POWER OF DATA IN HEALTH 3 (2017) (discussing changes to medical research due to changes in data accessibility in last decade); R.S. Evans, *Electronic Health Records: Then, Now, and in the Future*, 2016 Y.B MED. INFORMATICS S48, S50-S53 (2016) (describing the difficulties of transforming paper and early electronic health records into usable research data); Sabyasachi Dash, Sushil Kumar Shakyawar, Mohit Sharma & Sandeep Kaushik, *Big Data in Healthcare: Management, Analysis and Future Prospects*, 6 J. BIG DATA art. 54, at 5-6 (2019), https://doi.org/10.1186/s40537-019-0217-0 (discussing effects of extraordinary changes in data technology).

A few long term studies attempted to follow cohorts of patients over periods of decades, but these studies were expensive and lost track of large numbers of subjects.[50] Most life histories depended on memory and self-reporting.[51] These life histories were extremely valuable but were small in number and sparse in detail.

Electronic health records have changed that. Where once life histories were counted in the hundreds or perhaps thousands, soon they could be counted in the millions.[52] And where once life histories made reference to a few data points, soon they will contain comprehensive data of every second of the conditions of a person's health.[53] Moreover, the standardization of recordkeeping allows for meaningful comparison across tens of thousands, eventually millions, and, in the near future, billions of health histories.[54]

Health-related data also exists in forms other than that obtained through visits to healthcare providers. Data collected through fitness apps, monitoring internet searches, monitoring purchases, and other daily activities also provides valuable information regarding health.[55] This data is stored and distributed by commercial data brokers, who, by their very nature, store data in easily retrievable ways.[56] In the aggregate, extraordinarily rich bodies of data are available for analysis.

C. Data Analysis

Analysis consists of detecting patterns and trends within data.[57] As discussed, people generate substantial amount of data in daily life, and many

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[50] Bowton et al., *supra* note 37, at 234.

[51] Jan Walker et al., *The Value of Health Care Information Exchange and Interoperability*, 24 HEALTH AFFAIRS W5-10, W5-13-W5-14 (2005).

[52] Nitesh V. Chawla & Darcy A. Davis, Bringing Big Data to Personalized Healthcare: A Patient-Centered Framework, 26 J. INTERNAL GENERAL MED. S660, S662 (2013); *see* Mona Lebied, *12 Examples of Big Data Analytics In Healthcare That Can Save People*, DATAPINE (Jul. 18, 2018), https://www.datapine.com/blog/big-data-examples-in-healthcare/ (discussing growth in numbers of life histories).

[53] *See* Service, *supra* note 25, at 1165.

[54] Larson, *supra* note 47, at 2443-44.

[55] *See* Laura Palk & Krishnamurty Muralidhar, *A Free Ride: Data Brokers' Rent-Seeking Behavior and the Future of Data Inequality*, 20 VAND. J. ENT. & TECH. L. 779, 782, 785 (2018) (noting that privacy and other rules have made data from commercial brokers more valuable); Jules Polonetsky & Stacey Gray, *The Internet of Things as a Tool for Inclusion and Equality*, 69 FED. COMM. L.J. 103, 113 (2017) (describing the wide "spectrum" of health data).

[56] *See* Hiller, *supra* note 21, at 276-77 (describing the activities of health data brokers).

[57] *See* Alexander Tsesis, *The Right to Erasure: Privacy, Data Brokers, and the Indefinite Retention of Data*, 49 WAKE FOREST L. REV. 433, 441 n.29 (2014) (defining analysis).

of the general privacy concerns attached to data analysis arise from the capacity of analysis to provide insights into an individual person, particularly insights inferred from but not explicit in the data.[58] As Robert Sprague puts it, "The principal privacy conundrum posed by predictive analytics is that data mining relies to a large extent on 'public' information" but can "reveal[] intimate personal information before it becomes publicly available."[59]

In healthcare, analysis tends to operate differently.[60] Large amounts of private data tend to be analyzed on the basis of populations, rather than at the level of the individual.[61] Healthcare data analytics is, however, in its infancy. After a comprehensive review of data sets and existing projects and a comparison to the trajectory of data analysis in business, Yichuan Wang, LeeAnn Kung, and Terry Byrd suggest four broad areas of potential analysis: finding patterns of care, which once discerned could be further analyzed to evaluate outcomes such as effectiveness or patient satisfaction; finding patterns in unstructured data, which would enable researchers to study relationships previously hidden in the voluminous medical data; prediction, including of disease manifestation; and traceability, the effective unification of patients' disparate medical records in comprehensive and understandable ways.[62]

One of the more ambitious data analytics undertakings, which encompasses several of these broad areas, is the ENCode Project.[63] The ENCode Project sets as its goal an understanding of the function of the full range of the more than 3 billion DNA bases in the human genome.[64] The project uti-

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[58] *See* Daizhuo Chen et al., *Enhancing Transparency and Control When Drawing Data-Driven Inferences About Individuals*, 5 BIG DATA 197, 198 (2017) ("To many, privacy invasions via statistical inferences are at least as troublesome as privacy invasions based on personal data."); James C. Cooper, *Separation Anxiety*, 21 VA. J.L. & TECH. 1, 12-13 (2017) (discussing privacy concerns associated with the increased ability to infer minutia about individuals).

[59] Robert Sprague, *Welcome to the Machine: Privacy and Workplace Implications of Predictive Analytics*, 21 RICH. J.L. & TECH. 13, 13-14 (2015).

[60] *See* Weber et al., *supra* note 37, at 2479-80 (criticizing data analysis in healthcare for not analyzing data at the level of individuals).

[61] *See* Yichuan Wang et al., *Big Data Analytics: Understanding its Capabilities and Potential Benefits for Healthcare Organizations*, 126 TECHNOLOGICAL FORECASTING & SOC. CHANGE 3, 4 (2018) (noting the disparity analytics between healthcare and commercial business in the use of large-scale data).

[62] *Id.* at 5-9.

[63] *See ENCODE: Encyclopedia of DNA Elements*, https://www.encodeproject.org (last visited Apr. 20, 2020) (introducing the project).

[64] Elizabeth Pennisi, *ENCODE Project Writes Eulogy for Junk DNA*, 337 SCI. 1159, 1159 (2012).

lizes more than four hundred researchers in more than thirty teams analyzing more than 1600 distinct data sets.[65] The project is far from concluded but has already revolutionized the understanding of the operation of genes and of RNA and the interaction between genes and the environment and has led to better understandings of and treatments for conditions such as lupus, Crohn's disease, metabolic diseases, high cholesterol, and rheumatoid arthritis.[66]

To list all of the phenomena that can be understood through the analysis of large-scale data would again overwhelm this article. A multitude of possible analyses exist. Analysis of data collected at a fine level could detect whether there is a relationship between health and actual physical activity rather than self-reported activity.[67] Analysis of data collected from tens of thousands of inhalers fitted with location and time sensors could provide deep insights into environmental triggers of asthma.[68] Analysis of data gleaned from social media and news reports could assist in the important task of mapping of incidents of infectious diseases, something conventional analysis has not done.[69] As human activity continues to affect the environment, analysis of both environmental and health data can detect spillover effects on human populations.[70]

These are only illustrative of possible analyses of healthcare data. Each of these analytical projects, and thousands more, could enhance understandings of the health and overall well-being of large swaths of the world's peoples. Criticism of an algorithmic future for humankind tends to focus on possible infringements on autonomy and privacy. In the realm of healthcare, however, algorithmic analysis portends true benefits.[71]

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[65] *Id.* at 1159, 1161.

[66] *See id.* at 1159-60; Ian Dunham et al., *An Integrated Encyclopedia of DNA Elements in the Human Genome*, 489 NATURE 57, 57-58 (2012); National Institute of Health, *The Encode Project: Encyclopedia of DNA Elements* (Sept. 17, 2018), https://www.genome.gov/10005107 (last updated Jan. 3, 2020); Mapping a Genetic World Beyond Genes, BROAD INST. (Sept. 5, 2012), https://www.broadinstitute.org/news/mapping-genetic-world-beyond-genes.

[67] Meredith A. Barrett et al., *Big Data and Disease Prevention: From Quantified Self to Quantified Communities*, 1 BIG DATA 168, 171-72 (2013).

[68] *Id.* at 172.

[69] Simon I. Hay et al., *Big Data Opportunities for Global Infectious Disease Surveillance*, 10 PLOS MED. 1, 2-3 (2013). Conventional analysis has mapped only two percent of the incidents of such diseases. *Id.* at 1.

[70] Xiaoyu Chen et al., *Impacts of Air Pollution and its Spatial Spillover Effect on Public Health Based on China's Big Data Sample*, 142 J. CLEANER PROD. 915, 916-17 (2017).

[71] W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 424 (2015).

D. Use of Data Analytics

Only the outline of these benefits has emerged. Algorithmic healthcare is in its infancy. Machines do make decisions, but for the most part, these decisions focus on a single disease or symptom. Algorithmic medicine allows users outside of traditional medical facilities to test for exposure to HIV, to test for strep throat and the flu, to evaluate whether a person has suffered a heart attack, to detect leukocoria in newborns, to make eyeglass prescriptions, to detect diabetes and kidney failure as well as urinary diseases, to quantify the numbers of parasites in blood, and even to perform ultrasounds.[72] These applications maintain high standards. Field studies conducted in Africa, for example, indicate that diagnostic applications attached to mobile phones equal or surpass the accuracy of blood workups conducted in laboratories.[73]

The future of data-driven healthcare almost certainly lies in machine-driven personalized medicine.[74] Personalized medicine utilizes each of the life stages of an algorithm. The analysis of vast stores of collected data will find trends and patterns based on highly differentiated biological aspects of persons as well as environmental factors.[75] These patterns and trends will enable the creation of diagnostic algorithms.[76] Recall that an algorithm is a

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[72] *See* Alireza Abdolvahabi et al., *Colorimetric and Longitudinal Analysis of Leukocoria in Recreational Photographs of Children with Retinoblastoma*, 8 PLOS ONE 1, 11 (2013) (discussing detection of leukocoria); A. Bastawrous et al., *iPhones for Eye Surgeons*, 26 EYE 343, 344-49 (discussing great number of mobile visual diagnostic tools); Michael V. D'Ambrosio et al., *Point-of-Care Quantification of Blood-Borne Filarial Parasites with a Mobile Phone Microscope*, 7 SCI. TRANSLATIONAL MED. 1, 1 (2015) (discussing mobile phone microscope that automatically counts parasites); Tassaneewan Laksanasopin et al., *A Smartphone Dongle for Diagnosis of Infectious Diseases at the Point of Care*, 7 SCI. TRANSLATIONAL MED. 1, 1 (2015) (describing "full laboratory-quality immunoassay . . . on a smartphone accessory"); Service, *supra* note 25, at 1163 (discussing heart rate and blood pressure monitors); Steven R. Steinhubl et al., *The Emerging Field of Mobile Health*, 7 SCI. TRANSLATIONAL MED. 1, 2 (2015) (discussing a number of monitors); Navdeep Tangri et al., *A Predictive Model for Progression of Chronic Kidney Disease to Kidney Failure*, 305 J. AM. MED. ASS'N 1553, 1554 (2011) (discussing renal diagnostic tools).

[73] Medhanyie et al., *supra* note 26, at 84-85 (2015).

[74] *See, e.g.*, Leland L. Black, *Patenting and Protecting Personalized Medicine Innovation Post-*Mayo*,* Myriad, *and* Limelight, 95 N.C. L. REV. 493, 493 (2017); Price, *supra* note 71, at 425; Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1881 (2015).

[75] Nilesh Jain, *How Precision Medicine will Change the Future of Healthcare*, WORLD ECON. F. (Jan. 1, 2019), https://www.weforum.org/agenda/2019/01/why-precision-medicine-is-the-future-of-healthcare; *see* NATIONAL RESEARCH COUNCIL, TOWARD PRECISION MEDICINE 41-50 (2011) (describing the complex sources of information that can be used in precision medicine).

[76] Akram Alyass et al., *From Big Data Analysis to Personalized Medicine for All: Challenges and Opportunities*, 8 BMC MED. GENOMICS 1, 1 (2015).

set of rules applied to inputs to yield an outcome: inputs when diagnosing an individual person might include factors such as age, weight, height, genome, diet, sleep cycle, exercise, background health conditions, exposure to pollutants, exposure to stress, and, of course, symptoms or complaints.[77] Many of these inputs could themselves be retrieved from data collected and stored by detectors embedded in everyday items and wearables.[78] A machine would then sort through the data and, using rules based on trends and patterns discerned from analyses of tens of millions of other cases, diagnose probable ailments.[79]

Personalized medicine will also encompass prescription. Analysis of vast quantities of data will not just discern patterns and trends in the manifestation of ailments but will also discern patterns and trends in effective treatment, and these patterns and trends will enable the creation of prescriptive algorithms.[80] Thus, machines will not only makes decisions regarding the diagnosis of diseases or ailments, but will also make recommendations on customized treatment at the level of specific individuals.[81] Machines will prescribe drugs and medical devices.

The extent to which a human doctor is involved in the process engenders substantial dispute.[82] Vinod Khosla, a venture capitalist who has successfully predicted the trajectory of other technologies, argues that "[h]ealthcare today often results in suboptimal patient outcomes despite doctors doing the best they can within the current system" because the current system is constrained by an acute lack of knowledge and objective testing.[83] Khosla predicts that "[t]echnology will reinvent healthcare as we know it. It is inevitable that, in the future, the majority of physicians' diagnostic, prescription and monitoring, which over time may approach 80-percent of total doctors'/internists' time spent on medicine, will be replaced by smart hardware, software, and testing."[84] Lloyd Minor, the Dean

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[77] *See* Doran Satanove, Note, *The Challenging Economics of the Companion Diagnostics Industry: A Compelling Case for Invigorated Patent Protection*, 6 N.Y.U. J. INTELL. PROP. & ENT. L. 142, 145-46 (2016) (describing possible inputs).

[78] *See supra* notes 25-27 and accompanying text (describing sensors).

[79] W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 423 (2017).

[80] Wang et al., *supra* note 61, at 7-8.

[81] *See* Price, *supra* note 71, at 420-21.

[82] In discussions with medical school faculty in the United States, this issue generated by far the strongest negative reactions. By contrast, health administrators in emerging economies took the likelihood of automated medicine as a welcome given.

[83] Vinod Khosla, *"20 Percent Doctor Included" & Dr. Algorithm: Speculations and Musings of a Technology Optimist*, KHOSLA VENTURES (Sept. 30, 2016), https://www.khoslaventures.com/20-percent-doctor-included-speculations-and-musings-of-a-technology-optimist.

[84] *Id.*

of Stanford Medical School, on the other hand, observes that "[w]e are just beginning to understand the degree to which patient healing can be positively influenced by the patient-doctor bond."[85] He argues that:

> in the current AI debate, there is a tendency to underestimate the importance of relationships and to oversimplify the dynamics of good health care. A diagnosis, even if dispatched with breathtaking speed, isn't enough. It is just one point in a constellation of relationships, conversations, decisions, and actions involving care teams and patients that, in sum, lead a patient to improved health.[86]

He advises fellow physicians "that we needn't lose sleep over our job security any time soon."[87]

The argument between the two seems to take place in the context of healthcare in the United States. It is worth noting that the United States Food and Drug Administration has approved diagnostic algorithms that explicitly work without the aid of a human doctor.[88] Within the context of the United States, therefore, it would seem that machine-dispensed medicine has already established a beachhead.

It is even more important to understand that in resource-poor polities, the lack of doctors and healthcare clinics might render the debate moot. Whereas algorithmic healthcare offers improvements to diagnoses and treatment in resource-rich countries, in resource-poor countries, machine-driven medicine may bring medical care to people who have had none before.[89] Algorithmic healthcare will bring new healthcare tools and technologies to these countries.[90] Algorithmic healthcare offers these countries the possibility of leapfrogging from low-quality, low-coverage

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[85] Lloyd Minor, *Will Doctors be Replaced by Algorithms?*, SCOPE (Sept. 11, 2018), https://scopeblog.stanford.edu/2018/09/11/will-doctors-be-replaced-by-algorithms.

[86] *Id.*

[87] *Id.*

[88] *See* Ike Swetlitz, *FDA Approves First AI Software That Can Identify Disease, No Specialists Needed*, STAT (Apr. 11, 2018), https://www.statnews.com/2018/04/11/fda-ai-software-interpret-images (describing algorithm that can detect diabetic retinopathy without the intervention of a human doctor).

[89] *See* Aminuddin Rizal et al., *Contactless Vital Signs Measurement for Self-Service Healthcare Kiosk in Intelligent Building*, *in* IEEE 2018 3rd Int'l Conference on Intelligent Green Building and Smart Grid (Apr. 22-25, 2018) (observing that the benefits of algorithmic healthcare will be relatively greater in developing countries).

[90] *See* Antoine Bagula et al., *A Framework for Healthcare Support in the Rural and Low Income Areas of the Developing World*, 120 J. NETWORK & COMP. APPLICATIONS 17 (2018) (discussing the benefits of new healthcare technologies); Daniel Richard Leff & Guang-Zhong Yang, *Big Data for Precision Medicine*, 1 ENGINEERING 277, 278 (2015) (discussing targeted interventions made possible in developing countries by large-scale data analytics).

care to high coverage, sophisticated healthcare services.[91] It is fair to say that algorithmic healthcare will improve the quality of many millions of lives.

Personalized medicine, relying on algorithms, seems to constitute the future of healthcare. To those who grew up on a steady diet of visits to human doctors it probably sounds outlandish, the stuff of bad science fiction movies, but the world is on the verge of a healthcare transformation that will transfer much of the work of evaluating patients, diagnosing ailments, and prescribing courses of treatments, to machines. A future in which a machine, rather than a human doctor, advises a patient to take two aspirin and come back in the morning.

II. CORRUPTING HEALTHCARE ALGORITHMS

But perhaps the machine will tell that patient to take three aspirin. Overprescribing aspirin would not be in the patient's interest. Over-prescription would impose small but unnecessary costs on the patient and would expose that patient to small but real health risks.[92] Manufacturers and distributors of aspirin, on the other hand, would benefit handsomely from over-prescription at the scale of algorithmic healthcare.[93] These firms have a powerful incentive to corruptly influence the design of healthcare algorithms so that the algorithm processes data in a way that favors the firms rather than the patient. This section of this article explains how healthcare algorithms could be corrupted and why it seems almost certain that pharmaceutical and medical device firms will attempt to do so.

A. Corrupting the Underlying Algorithm

As has just been described, algorithms are constructed, not found. Technicians construct algorithms to process data in a manner that achieves a goal. The design of healthcare algorithms could have several legitimate objectives. Healthcare algorithms might be designed to direct the allocation of healthcare resources in a way that maximizes overall health within the general population or in a way that prioritizes provision of services to those in most need or in ways that directs services to those most likely to

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[91] *See* Munyaradzi Mandava et al., *Cyber-Healthcare for Public Healthcare in the Developing World* 1, 1, *in* 2016 IEEE Symposium on Computers and Communication (June 27-30, 2016) (describing the possibility of leapfrogging over long periods of developing capacity and resources).

[92] *See* John P. Cunha, *Aspirin*, RXLIST (Feb. 25, 2019), https://www.rxlist.com/aspirin-side-effects-drug-center.htm (discussing potential harms associated with aspirin).

[93] *See infra* note 182 and accompanying text (discussing revenue from the sale of aspirin).

benefit from them.[94] Healthcare algorithms might legitimately be designed to prescribe the most effective course of treatment for each individual patients based on that patient's unique characteristics and symptoms.[95] Any of these goals alone or in combination constitute legitimate objectives. "Health . . . [and] [w]ellbeing . . . provide a shared objective around which to engage to deliver health benefits."[96]

The objectives of pharmaceutical and medical device firms, however, differ from these legitimate social goals. Pharmaceutical and medical device firms desire to sell as much product as possible, and thus increase their profits.[97] When acting within the boundaries of social and legal norms, there is nothing inherently wrong with firms seeking profit. Pharmaceutical and medical device firms, however, will face a strong temptation to act in anti-social ways. These firms would benefit by subverting algorithmic design so that healthcare algorithms operated to overprescribe or oversell their products.[98]

There are many ways in which pharmaceutical and medical device firms could subvert the integrity of algorithmic design. Pharmaceutical and medical device firms could distort the collection of data by, for example, withholding data sets, relying only on certain data sets, or even by providing fake data. They could interfere with the storage and retrievability of data in much the same way. They could interfere in the analysis of data by releasing only positive analyses, by making harmful research seem helpful, by faking the credentials of analysts, or through outright falsified analyses. Finally, they could simply bribe the experts or expert firms writing the algorithms to be used by machines in making decisions about healthcare.

It may seem fanciful, perhaps paranoid, to suggest that pharmaceutical

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[94] *See* Theodore R. Marmor & Jan Blustein, *Models of Rationing: Introduction to Rationing*, 140 U. PA. L. REV. 1539, 1540-41 (1992) (describing questions about the allocation of healthcare resources as "central").

[95] *See supra* notes 74-79 and accompanying text (discussing personalized medicine).

[96] DEP'T OF HEALTH, *The Relationship Between Wellbeing and Health* 1-2 (Jan. 2014), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/295474/The_relationship_between_wellbeing_and_health.pdf.

[97] *See* Joel Lexchin, *The Pharmaceutical Industry and the Pursuit of Profit*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL, AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING (Jillian Clare Cohen et al. eds. 2006) (noting that "[p]harmaceutical companies have never denied that they are motivated by profit" and going on to debunk the caveat that profit-seeking does not conflict with serving patients' needs).

[98] In other words, changing the processing rules of an algorithm. If the original algorithm would process inputs A, B and C and produce the answer "take two aspirin," the rules could be changed so that when processing the same inputs, A, B and C, the algorithm would produce the answer "take three aspirin." *See* infra notes 182-84 and accompanying text for a discussion of the benefits to firms of selling additional aspirin.

and medical device firms will subvert the integrity of healthcare algorithms, endangering the health of patients just to make money. A review of the history of the healthcare industry, however, suggests the opposite. Reviewing that history leads to the ineluctable conclusion that pharmaceutical and medical device firms will attempt to corrupt the design of healthcare algorithms.

B. Corruption in the Pharmaceutical and Medical Devices Sector

More than thirty years ago, John Braithwaite described bribery as endemic among large pharmaceutical firms.[99] Braithwaite and his colleagues now find pharmaceutical firms "less ethical, less innovative and less law-abiding than was the case a generation ago."[100] Nika Antonikova observes that "[t]he medical device and pharmaceutical industries have long been considered as exemplifying industries with a high intrinsic level of corruption,"[101] and Marc Rodwin describes the current state as an "epidemic of illegal conduct."[102]

In a comprehensive analysis of corruption in the healthcare industry, the World Health Organization observes that "[c]orruption is a major obstacle to strengthening pharmaceutical systems and increasing access to quality medicines" and notes that "[o]pportunities for corruption occur in every stage of the medicines chain before they reach to patient."[103] The European Commission agrees that "the healthcare sector is one of the areas that is particularly vulnerable to corruption."[104] Bribery appears at almost every critical junction in the lifespan of a drug or device, from obtaining the (mis)representation of recognized researchers to obtaining regulatory ap-

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[99] JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 14-17 (Routledge & Kegan Paul ed.,1984).

[100] GRAHAM DUKES, JON BRAITHWAITE & J.P MOLONEY, PHARMACEUTICALS, CORPORATE CRIME AND PUBLIC HEALTH 272 (2014).

[101] Nika A. Antonikova, *Private Sector Corruption in International Trade: The Need for Heightened Reporting and a Private Right of Action in the Foreign Corrupt Practices Act*, 11 BYU INT'L L. & MGMT. REV. 93, 119 (2015).

[102] Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance By Pharmaceutical Firms?*, 70 FOOD & DRUG L.J. 435, 435 (2015).

[103] Guitelle Baghdadi-Sabeti & Fatima Serhan, *WHO Good Governance for Medicines Programme: An Innovative Approach to Prevent Corruption in The Pharmaceutical Sector* 5-6 (2010), https://www.who.int/healthsystems/topics/financing/healthreport/25GGM.pdf.

[104] EUROPEAN COMMISSION, *Study on Corruption in the Healthcare Sector* 25 (Sept. 2017), https://ec.europa.eu/home-affairs/sites/homeaffairs/files/20170928_study_on_healthcare_corruption_en.pdf.

proval to colluding with healthcare systems and individual healthcare providers in prescribing the drug or device.[105]

One obvious factor that contributes to corruption is the sheer amount of money that flows through the healthcare industry; "greed is often reported as a main cause of corruption" in the pharmaceutical sector.[106] Moreover, many pharmaceutical and medical device firms are publicly traded and consider the earning of as much revenue as possible by whatever means possible to have priority over the provision of the highest quality treatment for patients.[107] The World Health Organization also points to structural factors in the healthcare industry that contribute to high levels of corruption, including the large number of stakeholders involved, little accountability, a lack of transparency, wide imbalances in information, the ability to understand information, and weak enforcement of regulations.[108]

Algorithmic healthcare is in its infancy. Pharmaceutical and medical device firms have not yet had an opportunity to corrupt the creation of healthcare algorithms. Their behavior to this point, however, vividly demonstrates a willingness to engage in corrupt behaviors. Moreover, these behaviors closely map onto the stages in the life cycle of data and algorithms. Examining past behavior in the context of algorithm creation and development leads to a conclusion that corruption is inevitable.

1. Data collection and storage. – Interference with data is endemic, particularly in the process of applying for regulatory approval.[109] In a lengthy study of the Food and Drug Administration's records, Charles Seife found "numerous studies for which the FDA determined there was significant evidence of fraudulent or otherwise problematic data."[110]

One such case involved the drug Ketek (telithromycin), developed by

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[105] *See* Lawrence O. Gostin & Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1, 45 (2013); European Commission, *supra* note 104, at 35 ("Corruption in the medical devices sector occurs throughout all stages of the supply chain.").

[106] Baghdadi-Sabeti & Serhan, *supra* note 103, at 5.

[107] Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, 41 J.L. MED. & ETHICS 571, 571 (2013); Joel Lexchin, *Those Who Have the Gold Make the Evidence: How the Pharmaceutical Industry Biases the Outcomes of Clinical Trials of Medications*, 18 SCI. & ENGINEERING ETHICS 247, 258 (2012).

[108] *See* Baghdadi-Sabeti & Serhan, *supra* note 103, at 5-6 (discussing the pharmaceutical industry); EUROPEAN COMMISSION, *supra* note 104, at 36-37 (finding similar factors in the medical devices industry).

[109] Adam D.K. Abelkop, *Tort Law as an Environmental Policy Instrument*, 92 OR. L. REV. 381, 449 (2013).

[110] Charles Seife, *Research Misconduct Identified by the US Food and Drug Administration: Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature*, 175 J. AM. MED. ASS'N INTERNAL MED. 567, 574 (2015).

the pharmaceutical firm Aventis.[111] The Food and Drug Administration approved Ketek for limited use in treating pneumonia but asked Ketek for more trial data before it awarded final approval to Ketek, largely due to concerns that Ketek might exacerbate liver, heart, or kidney problems.[112] Aventis engaged practicing physicians with little or no research experience to conduct trials, paying them for the number of patients enrolled in the study; somewhat predictably, the vast majority of enrolled "patients" did not actually exist and most of the data was fabricated.[113] The investigating agents who discovered the fraud did not inform the Advisory Committee–the committee that grants approval of drugs–of the fraud and Ketek was approved for wide use.[114] As a result, dozens of people experienced acute liver failure and death.[115]

Pharmaceutical and medical device firms falsify and distort data. Distorted data could severely distort the downstream development of algorithms. In a very simple example, if patients of one particular racial and gender characteristic responded to a particular drug treatment, then misrepresenting data derived only from that group as data from a general population would result in an algorithm that overprescribed that drug. Indeed, inadvertent use of such data has already led to concerns of bias in healthcare algorithms.[116]

2. Research (Analysis of Data). – Pharmaceutical and medical device firms distort and interfere with research. In general, research that is financially supported by pharmaceutical and medical device firms is four times more likely to report positive findings than research that is not funded.[117] A study that involved both observing and interviewing scientists whose research was funded by pharmaceutical firms concluded that:

> Because these private-sector [Principal Investigators (PIs)] are largely motivated by financial gain as opposed to making a contribution to science, we suggest that the professional identity of private-sector PIs may inadvertently offer pharmaceutical companies the ability to exert more control over their

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[111] *See* Julie M. Aultman, *Abuses and Apologies: Irresponsible Conduct of Human Subjects Research in Latin America*, 41 J.L. MED. & ETHICS 353, 355 (2013).

[112] Thomas O. McGarity, *Corporate Accountability for Scientific Fraud: Ketek and the Perils of Aggressive Agency Preemption*, 58 EMORY L.J. 287, 296-97 (2008).

[113] *Id.* at 300-02. The head of one research project was convicted of criminal fraud. *Id.* at 302.

[114] *Id.* at 303. The Advisory Board and the Food and Drug Administration as a whole soon learned of the fraud but failed to take action until Congress intervened. David B. Ross, *The FDA and the Case of Ketek*, 356 NEW ENG. J. MED. 1601, 1602-03 (2007).

[115] Aultman, *supra* note 111, at 355; McGarity, *supra* note 112, at 310; Ross, *supra* note 114, at 1603.

[116] *See* Roger Allan Ford & W. Nicholson Price II, *Privacy and Accountability in Black-Box Medicine*, 23 MICH. TELECOMM. & TECH. L. REV. 1, 34 (2016) (describing bias).

[117] Lexchin, *supra* note 107, at 248.

> proprietary information and clinical trial data. This provides one explanation as to why, despite the participation of physicians as PIs, pharmaceutical companies have been able to suppress negative trial data and selectively publish study results.[118]

Research reports are especially important because they directly affect the care of patients.[119] Practicing physicians and other healthcare providers use published reports to stay current in diagnosis and prescription.[120] Just as importantly, published reports guide "off-label" usage of drugs and devices, which consist of the use of a drug or medical device for a purpose other than that for which it received government approval[121] (for example, the use of aspirin to reduce the risk of heart attacks, the use of therapies approved for one type of cancer to treat a broad range of cancers, or the use of antiretrovirals to prolong the lives of HIV-positive persons[122]).

Pharmaceutical and medical device firms distort the reporting on and dissemination of research in many other ways, including repeatedly publishing positive trials while not publishing negative trials, presenting information in a different way than it was disclosed to regulators, writing introductions and conclusions that are far more positive than the reported study supports, and using weak methodologies or misleading comparators.[123]

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[118] Jill A. Fisher & Corey A. Kalbaugh, *United States Private-Sector Physicians and Pharmaceutical Contract Research: A Qualitative Study*, 9 PLOS MED. e1001271, at 6 (July 24, 2012), https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001271&type=printable.

[119] Jennifer S. Bard, *What to Do When You Can't Hear the Whistleblowing: A Proposal to Protect the Public's Health by Providing Whistleblower Protection for Medical Researchers*, 9 IND. HEALTH L. REV. 1, 37 (2011) (observing that published research can "change[] the standard of practice" and that "[b]y influencing the result of a study which changes the prescribing practices of thousands of physicians, pharmaceutical companies can greatly expand the sale of drugs already on the market").

[120] *See* Andrew D. Oxman et al., *Users' Guides to the Medical Literature: I. How to Get Started*, 270 J. AM. MED. ASS'N 2093, 2093-94 (1993) (describing use of articles in medical journals).

[121] *See* Barbara J. Evans, *The Limits of FDA's Authority to Regulate Clinical Research Involving High-Throughput DNA Sequencing*, 70 FOOD & DRUG L.J. 259, 285 (2015) (describing how practicing physicians obtain information about off-label use); Stephanie M. Greene & Lars Noah, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. ONLINE 239, 239 (2014) (defining off-label use).

[122] Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 HASTINGS L.J. 967, 968 (2007).

[123] Abelkop, *supra* note 109, at 449; Lexchin, *supra* note 107, at 247-53; Simon Stern & Trudo Lemmens, *Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles*, 22 PLOS MED. 264, 264 (2013).

Perhaps most insidiously, these firms employ "ghost writers."[124]

Ghost writing is a practice whereby persons in the employ of a pharmaceutical or medical device firm write scholarly articles or clinical reports (or even create posters for poster sessions at conferences) purporting to analyze clinical data regarding a drug or medical device.[125] Pharmaceutical and medical device firms treat these articles as marketing tools rather than objective reports on science and report on the drug or device in a very favorable light.[126] To give the report the patina of legitimacy, the articles are not attributed to the actual authors; instead, the firms recruit well known researchers to publish the articles under their names even though those researchers may have little or no knowledge of the data presented in the article.[127] These well-known researchers receive financial honoraria and the scholarly accolades that accompany publication.[128] One well-publicized example of ghost writing involved Merck's painkiller Vioxx. Rather than disclose evidence that the painkiller Vioxx substantially increased risks of heart attacks, Merck engaged in an aggressive campaign of promotion and refutation through ghost-written articles in medical journals; tens of thousands of deaths are attributed to the continued prescription of Vioxx after Merck knew of the dangers it presented.[129]

Distortions to research harm patients.[130] The distorted information "give[s] a positive product profile while underestimating the adverse effects and medical risks."[131] The distorted information reaches many thousands of health care providers who base their courses of treatment on what they believe to be authentic research and who, therefore, overprescribe or

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[124] *See* Stern & Lemmens, *supra* note 123, at 264 ("Guest authorship is a disturbing violation of academic integrity standards, which form the basis of scientific reliability."); S.W. Choi et al., *Ghost in the Machine*, 22 HONG KONG MED. J. 292, 293 (2016) (describing ghost writing as "a blight to scientific writing").

[125] *See* Abelkop, *supra* note 109, at 449 (describing ghost writing); Dennis K. Flaherty, *Ghost- and Guest-Authored Pharmaceutical Industry-Sponsored Studies: Abuse of Academic Integrity, the Peer Review System, and Public Trust*, 47 ANNALS OF PHARMACOTHERAPY 1081, 1081 (2013); Lexchin, *supra* note 107, at 254 (defining ghost writing).

[126] *See* Choi et al., *supra* note 124, at 293 (ghost writing enables a "company . . . to embed favourable marketing messages into the medical literature that is read by other clinicians"); Flaherty, *supra* note 125, at 1081 (ghost writing is "a tool to manage medical publications to best suit product marketing").

[127] Abelkop, *supra* note 109, at 449; Bard, *supra* note 119, at 37; Lexchin, *supra* note 107, at 254.

[128] Choi et al., *supra* note 124, at 292.

[129] Howard M. Erichson & Benjamin C. Zipursky, *Consent versus Closure*, 96 CORNELL L. REV. 265, 276-77 (2011); Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 J. AM. MED. ASS'N 1800, 1802-06 (2008).

[130] Flaherty, *supra* note 125, at 1082 (describing harm as "profound").

[131] *Id.* at 1081.

prescribe without knowing the associated risks.[132] The results can be "catastrophic."[133]

Unfortunately, under current conditions, there are few incentives to stop:

> Corruption of the scientific literature through ghostwriting persists in medicine due to the enormous profits for all stakeholders, including the pharmaceutical industry that creates the publication strategy, academic researchers acting as key opinion leaders (KOLs) for industry, universities employing KOLs, medical journals and their proprietors, including medical societies and publishers, and medical communication companies employing ghostwriters.[134]

The problem appears intractable.

Analysis, in the lifecycle of an algorithm, consists of detecting trends and patterns in large amounts of data. Pharmaceutical and medical device firms have demonstrated a willingness to interfere in research and in the analysis of data to arrive at a conclusion. They have demonstrated a willingness to distort research, to misrepresent research, and to present research to other scientists in a false light. They have done so at the cost of the health, and even the lives, of patients receiving their products.

3. Pharmaceutical and Medical Device Firms Pay Bribes to Induce Healthcare Providers to Prescribe their Products. – Pharmaceutical and medical device firms have a long history of bribing healthcare providers so that those providers will prescribe the firms' products. Even when examining only reports from roughly the last decade, the narrative is striking. The tale of the U.S. pharmaceutical firm Pfizer is illustrative. Over a period of at least a decade, subsidiaries of Pfizer paid bribes throughout Bulgaria, Croatia, Italy, Kazakhstan, and Russia.[135] Bribery played such an important

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[132] *Id.* at 1082; Bard, *supra* note 119, at 37; Stern & Lemmens, *supra* note 123, at 264.

[133] Flaherty, *supra* note 125, at 1082. Some scholars have suggested that the harms associated with ghost writing in particular are so severe that researchers who allow their names to be use on ghost written articles can be held liable for fraud, personal injury and wrongful death, False Claims Act violations, and violation(s) of the federal Anti-Kickback statue prohibiting commercial bribery. Xavier Bosch et al., *Challenging Medical Ghostwriting in US Courts*, 9 PLOS MED. (Jan. 24, 2012), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001163; Stern & Lemmens, *supra* note 123, at 265.

[134] Bosch et al., *supra* note 133, at 1.

[135] Alexandra L. Anderson, *Good Grief! Iran Sanctions and the Expansion of American Corporate Liability for Non-U.S. Subsidiary Violations Under the Iran Threat Reduction and Syria Human Rights Act of 2012*, 34 NW. J. INT'L L. & BUS. 125, 141 (2013).

role in Pfizer's sales strategy that it offered what could be called a "frequent-bribee" awards program to its most reliably corrupted clientele.[136] At the beginning of this decade, Pfizer was assessed one of the largest corporate fines in U.S. history for, among other things, bribing U.S. doctors to prescribe its drugs.[137] With the cooperation of the Department of Justice, Pfizer created a shell company, Pharmacia & Upjohn, to plead guilty to criminal charges so that Pfizer would not be blacklisted from future business with the government.[138] Almost immediately after the criminal trial concluded, Pfizer disclosed improper payments amounting to US $20 million made to 4,500 doctors in the United States, as well as improper payments amounting to US $15.3 million made to 250 academic and research medical centers.[139]

Pfizer earned leniency by not only cooperating in the investigation of itself but also by reporting on the corrupt acts of its competitors.[140] There was a substantial amount of corrupt activity to report. The U.S. medical device firm Orthofix International, for example, paid kickbacks to healthcare providers in the United States to induce them to purchase its bone growth stimulator.[141] British pharmaceutical company GlaxoSmithKline pleaded guilty to illegally promoting drugs in the United States, in part by paying bribes to doctors.[142] British pharmaceutical and medical device firm AstraZeneca did not pay bribes to doctors but instead

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[136] Press Release No. 2012-152, Sec. & Exch. Comm'n, SEC Charges Pfizer with FCPA Violations (Aug. 7, 2012), http://www.sec.gov/news/press-release/2012-2012-152htm ("'Pfizer subsidiaries in several countries had bribery so entwined in their sales culture that they offered points and bonus programs to improperly reward foreign officials who proved to be their best customers.'") (quoting Kara Brockmeyer, Chief, Enforcement Division, Foreign Corrupt Practices Act Unit).

[137] *See* Gagnon, *supra* note 107, at 575 (describing transgressions and noting that the penalty was the largest corporate fine at that time); *see also* Rodwin, *supra* note 102, at 436 (stating that the fine represented only 14% of what Pfizer earned from sales of the drugs).

[138] Robert G. Evans, *Tough on Crime? Pfizer and the CIHR*, 5 HEALTH CARE POL'Y 16, 19 (2010).

[139] David Wallechinsky, *Pfizer's Bad Week: Kickbacks, Whistleblowers, and Doctors on the Payroll*, ALLGOV (Apr. 4, 2010), http://www.allgov.com/news/controversies/pfizers-bad-week-kickbacks-whistleblowers-and-doctors-on-the-payroll?news=840610.

[140] William Magnuson, *International Corporate Bribery and Unilateral Enforcement*, 51 COLUM. J. TRANSNAT'L L. 360, 410-11 (2013).

[141] Press Release, Off. of the U.S. Att'y, Dist. Mass., Orthofix, Inc. Sentenced for Illegal Promotion of Bone Growth Stimulators (Dec. 14, 2012), http://www.justice.gov/archive/usao/ma/news/2012/December/OrthofixsentPR.html.

[142] Cindy A. Schipani et al., *Doing Business in a Connected Society: The GSK Bribery Scandal in China*, 2016 U. ILL. L. REV. 63, 66.

paid bribes to U.S. pharmacy management company Medco to secure orders of its heartburn medicine Nexium.[143]

Pharmaceutical and medical device firms have paid bribes in Europe as well. French pharmaceutical firm Sanofi, for example, paid bribes to a German client's consultant in exchange for preferential recommendations of Sanofi to that client.[144] British medical device firm Smith & Nephew funneled money through a shell company that in turn used the money to pay bribes to Greek physicians to induce them to prescribe Smith & Nephew's devices.[145] Johnson & Johnson, a U.S. pharmaceutical and medical device firm, paid millions of dollars in "bribes to Greek doctors who chose the company's surgical implants as well as to doctors in Poland and Romania in return for agreements to prescribe the company's drugs."[146] Johnson & Johnson's subsidiary DePuy International also paid bribes in Greece.[147] Bayer Hellas, the Greek subsidiary of the German pharmaceutical firm Bayer AG, has been criminally charged by Greek prosecutors for bribing more than eight hundred doctors in Greece.[148] U.S. pharmaceutical firm Eli-Lilly made donations to a fund in Poland dedicated to the restoration of a castle as quid pro quo for a government official's placement of Eli-Lilly drugs on the government reimbursement list.[149] The U.S. medical device firm Bio-Rad Laboratories used a French subsidiary to pay millions of dollars in bribes to the Russian Ministry of Health.[150]

Pharmaceutical and medical device firms also pay bribes in Asia. Bio-Rad, for example, which used a French subsidiary to pay bribes in Russia, also used a Singaporean subsidiary to pay millions in bribes to officials in

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[143] Press Release, Dep't of Justice, *AstraZeneca to Pay $7.9 Million to Resolve Kickback Allegations* (Feb. 11, 2015), http://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations.

[144] Jerin Mathew, *Sanofi Fined €28m in Germany as Two Former Employees Convicted of Bribery*, INT'L BUS. TIMES (Mar. 4, 2014, 10:19 AM), http://www.ibtimes.co.uk/sanofi-fined-28m-germany-two-former-employees-convicted-bribery-1438784.

[145] Press Release, Dep't of Justice, *Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation* (Feb. 6, 2012), http://www.justice.gov/opa/pr/medical-device-company-smith-nephew-resolves-foreign-corrupt-practices-act-investigation.

[146] Magnuson, *supra* note 140, at 410.

[147] Alexander Avery, *Foreign Corrupt Practices Act: Pleading Parent-Subsidiary Liability*, 35 J. NAT'L ASS'N ADMIN. L. JUD. 131, 142-43 (2015).

[148] Andy Dabilis, *Bayer Hellas Charged With Bribery*, NAT'L HERALD (June 15, 2015), http://www.thenationalherald.com/88405.

[149] Reagan R. Demas, *Biting the Hands that Feed: Corporate Charity and the U.S. Foreign Corrupt Practices Act*, 29 AM. U. INT'L L. REV. 335, 349-50 (2014).

[150] In re Bio-Rad Laboratories, Inc., SEC No. 3-16231, Cease and Desist Order at 4 (Nov. 3, 2014), http://www.sec.gov/litigation/admin/2014/34-73496.pdf.

Thailand and Vietnam.[151] Much of the reported Asian bribery has occurred in China. U.S. pharmaceutical and medical device firm Baxter International, for example, used a joint venture to make improper payments in China to secure orders of its products.[152] The U.S. pharmaceuticals firm Bristol-Myers-Squib bribed officials in China with cash, jewelry and other gifts, meals, travel, entertainment, and sponsorships for conferences and meetings, and then concealed the illicit payments.[153] Subsidiaries of the Swiss pharmaceutical firm Novartis paid similar bribes to Chinese officials and also took Chinese officials to a strip club in Chicago.[154] SciClone Pharmaceuticals, a U.S. firm that focuses on the Chinese market, not only bribed physicians in charge of healthcare facilities but also bribed Chinese regulators.[155]

Firms do not limit their bribes to particular countries or regions. Orthofix International, which paid bribes in the United States, also paid bribes in the form of laptops, televisions, and cash to induce officials in charge of a Mexican social services agency and its hospitals to purchase spinal and orthopedic devices.[156] U.S. medical device firm Stryker Corporation paid hundreds of bribes over a period of about a decade to government officials in Romania, Mexico, Argentina, Poland, and Greece, to induce those officials to order Stryker's medical devices.[157] Teva Pharmaceuticals, an Israeli firm, has disclosed that it has probably paid bribes in Russia and throughout Eastern Europe and Latin America.[158]

Firms' attitudes towards bribery may be revealed by their complacency when bribe paying is revealed. Eli Lilly, for example, upon learning that a

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[151] *Id.* at 6-8.

[152] Colum Murphy et al., *Baxter Found Expense Violations in China*, WALL ST. J., Aug. 2, 2013, http://www.wsj.com/articles/SB10001424127887324136204578642491655230844.

[153] In re Bristol-Myers-Squibb, SEC No. 3-16881, Cease and Desist Order at 4-5 (Oct. 5, 2015), https://www.sec.gov/litigation/admin/2015/34-76073.pdf.

[154] In re Novartis, AG, SEC No. 3-17177, Cease and Desist Order at 3-4 (Mar. 23, 2016), https://www.sec.gov/litigation/admin/2016/34-77431.pdf.

[155] In re SciClone Pharmaceuticals, SEC No. 3-17101, Cease and Desist Order at 3-4 (Feb. 4, 2016), http://www.sec.gov/litigation/admin/2016/34-77058.pdf.

[156] Sec. and Exchange Comm'n v. Orthofix International N.V., Case No. 4:12-CV-419 (E.D. Tex., July 10, 2012), http://www.sec.gov/litigation/litreleases/2012/lr22412.htm.

[157] In re Stryker Corporation, SEC No. 3-15587, Cease and Desist Order at 3-5 (Oct. 24, 2013), http://www.sec.gov/litigation/admin/2013/34-70751.pdf.

[158] Rachel Louise Ensign, *Teva Finds "Likely" FCPA Violations*, WALL ST. J., Feb. 11, 2015, http://blogs.wsj.com/riskandcompliance/2015/02/11/teva-pharmaceutical-finds-likely-fcpa-violations.

subsidiary was paying bribes to government officials in Russia, took no action and allowed the bribery to continue for five years.[159] Similarly, Johnson & Johnson knew of the extensive bribe scheme used by DePuy when it acquired the firm but did nothing to interfere with that scheme after the acquisition.[160]

More striking, however, is that some firms get caught engaging in corrupt activities soon after resolving prosecution of prior charges of corruption. The corruption charges against GlaxoSmithKline for its bribes in the United States resulted in the largest "combined federal and state healthcare fraud recovery in a single case in the history of the United States."[161] Two years later, GlaxoSmithKline was found guilty of bribery by a Chinese court, which resulted in the largest corporate fine ever imposed by China.[162] And although it is outside of the timeframe of this brief narrative, it is worth noting that only a decade earlier, GlaxoSmithKline was linked to the spending of "millions of dollars for bribing thousands of doctors [in Italy] to induce them to prescribe their products."[163] Almost as incredibly, the U.S. medical device firm Biomet, Inc. (now part of Zimmer Biomet) paid bribes to healthcare officials in Argentina, Brazil, and China, and then, while being monitored by the U.S. Department of Justice, paid bribes to government officials in Mexico and Brazil to secure large purchases of medical devices.[164]

Pharmaceutical and medical device firms may take umbrage at the suggestion that they are likely to pay bribes. Facts, however, support the World Health Organization's conclusion that corruption perpetrated by pharmaceutical and medical device firms constitutes one of the most intractable obstacles to the provision of quality healthcare around the world.[165] Of all the potential ways in which pharmaceutical and medical device firms could corrupt algorithms, bribery is the most straightforward. These firms could simply bribe the experts who create algorithms to alter the processing rules that make up the healthcare algorithm. The algorithm would then overprescribe the products of those firms. Pharmaceutical and medical device firms have a long history of bribing actors who prescribe to dozens or

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[159] Olesya Sidorkina, *Establishing Corporate Parent Liability for FCPA Violations*, 14 U.C. DAVIS BUS. L.J. 89, 97-98 (2013).

[160] Avery, *supra* note 147, at 142-43.

[161] Schipani et al., *supra* note 142, at 66.

[162] *Id.* at 67.

[163] Maria Laura Seguiti, *Anti-Corruption Reforms from a Global View: An Initial Attempt of Comparing Italy to China*, 1 BUS. & PUB. ADMIN. STUD. 83, 101 (2006).

[164] Veronica Root, *Modern-Day Monitorships*, 33 YALE J. ON REG. 109, 122-23 (2016).

[165] *See* World Health Organization, *Good Governance for Medicines: Curbing Corruption in Medicines Regulation and Supply* 1 (2007), https://www.who.int/medicines/areas/policy/goodgovernance/GGM.pdf.

hundreds of patients. By bribing the designer of prescriptive algorithms, pharmaceutical and medical device firms can affect prescriptions to thousands or even millions of afflicted people.

C. Resources and Incentives for Corruption

The Institute for Medicines Informatics estimates that by 2020 the global pharmaceuticals market will be worth 1.4 trillion U.S. dollars.[166] The value of the medical devices market is much more difficult to determine because such a wide variety of technologies could be labelled medical devices.[167] Nonetheless, one industry analyst predicts that by 2020 its value will surpass USD 475 billion.[168] Each individual pharmaceutical and medical device firm will attempt to get as many of these dollars as possible.

One way in which they now do so is by aggressively promoting their products. Pharmaceutical firms spend tens of billions of dollars each year marketing their drugs to human decisionmakers.[169] Interestingly, pharmaceutical firms spend approximately twice as much on marketing products as they do on researching and developing those products.[170] A small portion of this money is spent on promoting drugs directly to consumers;[171] only the United States and New Zealand, however, allow advertising directly to consumers.[172] The vast majority of these tens of billions of dollars, therefore, are spent trying to convince healthcare providers to prescribe a particular drug or device.[173]

The fact that pharmaceutical firms pay substantially more to promote

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[166] INSTITUTE FOR MEDICINES INFORMATICS, GLOBAL MEDICINES USE IN 2020: OUTLOOK AND IMPLICATIONS 3 (2015).

[167] "Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices." U.S. Food & Drug Admin., *Is The Product A Medical Device?* (Nov. 21, 2019), https://www.fda.gov/industry/regulated-products/medical-device-common-entry-errors.

[168] EVALUATE, MEDTECH WORLD PREVIEW 2015, OUTLOOK TO 2020, at 6 (2013).

[169] Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), http://www.bbc.com/news/business-28212223; Ana Swanson, *Big Pharmaceutical Companies are Spending Far More on Marketing than Research*, WASH. POST (Feb. 11, 2015, 11:01 AM), http://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research.

[170] *Id.*; Marc-André Gagnon & Joel Lexchin, T*he Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. (2008), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001.

[171] Gagnon & Lexchin, *supra* note 170.

[172] Jonathan J. Darrow, *Pharmaceutical Efficacy: The Illusory Legal Standard*, 70 WASH. & LEE L. REV. 2073, 2117 (2013).

[173] Gagnon & Lexchin, *supra* note 170; Swanson, *supra* note 169.

the sale of drugs than to develop those drugs punctures two misunderstandings of the pharmaceutical industry. One misunderstanding concerns the drivers of industry behavior. The industry portrays itself as a pioneering innovator, dedicated to saving and improving the quality of lives. There is little doubt that many individuals within pharmaceutical firms possess substantial intellectual curiosity and real concern for the lives of others.[174] Large pharmaceutical firms, however, are publicly traded and feel tremendous pressure to generate revenue and profit.[175] Their formula for generating profit is not to engage in expensive and risky innovation but instead to cheaply modify existing drugs and sell them for as much as the market will allow.[176] Indeed, physician groups have long complained of both the lack of innovation and the prices charged.[177]

The second misunderstanding is the cost to the firms of developing a new drug. The industry claims that bringing a drug to market costs more than two billion U.S. dollars.[178] Careful deconstruction of the claimed costs, however, finds that "costs" include phantom opportunity costs such as (greatly exaggerated) profit a firm could have made by investing in the stock market rather than conducting research on drugs, as well as costs that

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[174] Not all pharmaceutical or medical devices firms act in such socially harmful ways. For example, Merck (headquartered in the United States, not to be confused with the bribe-paying Swiss firm of the same name) is a case study in corporate social responsibility; realizing that there were no profitable means of distributing its new drug Mectazin, Merck continued to develop the drug, created a distribution organization, and provided the drug free to people suffering from river blindness in Africa. *See* James E. Austin et al., *Merck Global Health Initiatives* (A) (Harv. Bus. Sch. Case No. 9-301-088, 2001). Nor are all pharmaceutical firms structured to maximize profit. One World Pharmaceuticals, for example, is a social enterprise firm that is owned by the non-profit organization Rest of World; together, the two organizations develop and distribute medicines, particularly diabetes medications, to markets not served by for-profit pharmaceutical firms. *See One World. One Standard*, ROW FOUNDATION, http://rowpharma.org/faqs (last visited Dec. 10, 2017).

[175] Kristina M. Lybecker, *Social, Ethical, and Legal Issues in Drug Development, Marketing, and Pricing Policies: Setting Priorities: Pharmaceuticals as Private Organizations and the Duty to Make Money/Maximize Profits*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING AND PRICING, 25, 26 (Jillian Clare Cohen et al. eds. 2006).

[176] Lexchin, *supra* note 97, at 20.

[177] MARIANA MAZZUCATO ET AL., THE PEOPLE'S PRESCRIPTIONS: RE-IMAGINING HEALTH INNOVATION TO DELIVER PUBLIC VALUE 19 (2018) (finding that 78% of drug patents correspond to existing drugs). Mazzucato's report discusses and quantifies at length the market incentives that reward producing variants of drugs that already exist and market disincentives that discourage research into new drugs of forms of treatment. *Id.* at 12-20.

[178] PHRMA, 2015 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY i (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

are actually borne by public sources rather than by the firm itself.[179] When reasonable parameters are used and costs not borne by a firm are stripped out, it appears that the cost to a firm of getting a drug to the market is closer to between sixty and eighty million U.S. dollars.[180] Pharmaceutical and medical device firms' continued misrepresentation of these costs speaks to the veracity of those firms and, more importantly, to the resources available for corrupt activities.

There is no reliably exact estimate of the budgets available for those corrupt activities. These firms, however, spend a great deal of money promoting their products to human decisionmakers. If machines make decisions, then spending money spent to influence humans will no longer make sense. That money will then be available to corrupt the designers of algorithms. Interestingly, the amount of money paid to research scientists so that they would "align[] their sense of research ethics with industry" is only US$300,000.[181] Pharmaceutical and medical device firms will have multiples of that amount available to bribe designers of algorithms.

The rewards for doing so could be handsome. Distorting an algorithm so that it prescribed one extra aspirin could result in tremendous, and undeserved, revenue streams. Aspirin is one of the most prescribed drugs in the world;[182] more than thirty-five million metric tons, or between 50 and 120 billion tablets, are consumed each year.[183] An aspirin tablet costs around ten cents in the U.S., around fifteen cents in Germany, and around

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[179] Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 37-43 (2011).

[180] Donald W. Light & Joel R. Lexchin, *Pharmaceutical Research and Development: What Do We Get for all that Money?*, BRIT. MED. J. (May 18, 2012), http://www.bmj.com/content/345/bmj.e4348.

[181] Fisher & Kalbaugh, *supra* note 118, at 6.

[182] *See* Yvette Brazier, *Uses, Benefits, and Risks of Aspirin*, MED. NEWS TODAY (Dec. 18, 2017), https://www.medicalnewstoday.com/articles/161255.php (Aspirin "is still one of the most widely used medications in the world."); *see also* Dawn Connelly, *A History of Aspirin*, PHARMACEUTICAL J. (Sep. 26, 2014), https://www.pharmaceutical-journal.com/news-and-analysis/infographics/a-history-of-aspirin/20066661.article?firstPass=false ("[A]spirin is still one of the most researched drugs in the world, with an estimated 700 to 1,000 clinical trials conducted each year.").

[183] *See* ALAN JONES, CHEMISTRY: AN INTRODUCTION FOR MEDICAL AND HEALTH SCIENCES 5 (2005) (estimating that "[a]bout 50 000 000 000 aspirin tables are consumed each year throughout the world"); Brazier, *supra* note 182, (estimating "that around 35,000 metric tons of aspirin is consumed annually"); Timothy D. Warner & Jane A. Mitchell, *Cyclooxygenase-3 (COX-3): Filling in the Gaps Toward a COX Continuum?*, 99 PROC. NAT'L ACAD. SCI. 13371, 13371 (2002) (estimating aspirin consumption of more than 40,000 metric tons and 120 billion tablets per year).

thirty cents in Japan.[184] If aspirin were prescribed by a diagnostic/prescriptive machine, and if the algorithms used by that machine were changed to include the objective of prescribing three aspirin instead of two, then even at low U.S. prices and low estimates of usage, approximately two and a half billion dollars would move from patients to healthcare.

Aspirin, of course, is relatively inexpensive. Corrupting algorithms to prescribe other drugs promises even more undeserved revenue. In 2017, revenue to pharmaceutical firms from the sale of Humira, a drug that treats rheumatoid arthritis, exceeded US $18 billion; of Eylea, which treats retinal problems, US $8 billion; of Enbrel, which also treats rheumatoid arthritis and inflammation, US $8 billion; of Eliquis, which thins blood, US $7 billion. Distorting algorithms so that they overprescribe even small amounts would accrue hundreds of millions of dollars of revenue for pharmaceutical firms. Unnecessary prescription could result in hundreds of millions more.[185]

Pharmaceutical and medical device firms have billions of dollars available to use to distort data and research and to bribe the designers of healthcare algorithms. The historical patterns of behavior of these firms makes it clear that they will distort and that they will bribe when it is in their interest to do so. The illicit payoffs for corrupting healthcare algorithms are immense; because healthcare algorithms will reach patients on a massive scale, the potential revenue to these firms is incalculable. So too, however, is the damage that corruption of healthcare algorithms will do to patients. Something must be done to protect the integrity of healthcare algorithms.

III. EXISTING MECHANISMS CANNOT PROTECT THE INTEGRITY OF HEALTHCARE ALGORITHMS

Those who study the changes wrought by large-scale data analytics and machine decision-making warn that legal scholars and policymakers must think about the relationship between law and data analytics in new ways.[186] Regardless, it will be tempting to turn to traditional institutions such as

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[184] *Aspirin Tablet Price in Selected Countries*, STATISTA, https://www.statista.com/statistics/ 269944/aspirin-tablet-price-in-selected-countries (listing prices of aspirin tablets) (last visited Jan. 12, 2019).

[185] *See* John G.F. Cleland, *Physicians Addicted to Prescribing Aspirin - A Disorder of Cardiologists (PAPA-DOC) Syndrome*, 6 J. AM. COLL. CARDIOLOGY 168, 168 (2018) (criticizing the over-prescription and unnecessary prescription of aspirin).

[186] Janine S. Hiller & Jordan M. Blanke, *Smart Cities, Big Data, and the Resilience of Privacy*, 68 HASTINGS L.J. 309, 312 (2017); Neil Richards & Woodrow Hartzog, *Privacy's Trust Gap: A Review*, 126 YALE L.J. 1181, 1182 (2017).

markets and government oversight. Neither, however, can effectively protect the integrity of healthcare algorithms.

A. Markets Cannot Protect the Integrity of Healthcare Algorithms

Markets do not discipline healthcare. Much of the world delivers healthcare through basic government services or with the government acting as the single payer, which obviates the concept of vigorous market forces.[187] Even in the United States, however, which purports to create competitive marketplaces for healthcare, the healthcare market exhibits multiple imperfections: "inadequate information, agency, moral hazard, monopoly, and selection in insurance markets that greatly distort markets."[188] Healthcare tends to concentrate; consumers usually have little choice in what provider to use.[189] Regardless, therefore, of the manner in which healthcare is provided or paid for, markets can exert little force.[190]

Even if markets were perfect, "[l]ay persons cannot know everything about an illness, even about frequent illnesses."[191] Consumers of health care generally know little about the nature or causes of ailments[192] and

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[187] *See* THE COMMONWEALTH FUND, *International Profiles of Health Care Systems, 2014: Australia, Canada, Denmark, England, France, Germany, Italy, Japan, The Netherlands, New Zealand, Norway, Singapore, Sweden, Switzerland, and the United States* 6-9 (Elias Mossialos, et al. eds, 2015), https://www.commonwealthfund.org/sites/default/files/documents/__media_files_publications_fund_report_2015_jan_1802_mossialos_intl_profiles_2014_v7.pdf (describing healthcare systems); *see also* Nicholas Bagley, *Medicine as a Public Calling*, 114 MICH. L. REV. 57, 61-62 (2015) (noting that even in the United States, healthcare was once regulated in a manner similar to public utilities).

[188] Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo?*, 89 OR. L. REV. 811, 817 (2011).

[189] *See* Thomas L. Greaney, *The New Health Care Merger Wave: Does the "Vertical, Good" Maxim Apply?*, 46 J.L. MED. & ETHICS 918, 923 (2018) (describing healthcare markets as "highly concentrated and competition [as] anemic at best").

[190] *See* Erin C. Fuse Brown, *Resurrecting Health Care Rate Regulation*, 67 HASTINGS L.J. 85, 112 (2015) (noting that market discipline "fundamentally will not work"); Nicolas Terry & Lindsay Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANN. HEALTH L. 62, 62 (2016) ("Notoriously, health care is relatively immune to traditional market forces").

[191] Lucas M. Bachmann et al., *Do Citizens Have Minimum Medical Knowledge? A Survey*, 5 BMC MED. 1, 1 (2007), https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-5-14.

[192] *See*, *e.g.*, *id.* at 4 ("among Swiss citizens, we found a considerable level of ignorance in relation to the symptoms of and risks for frequently found and important illnesses"); Luis E. Chiesa, *Solving the Riddle of Rape-by-Deception*, 35 YALE L. & POL'Y REV. 407, 451 (2017) ("In run-of-the-mill cases, doctors know exponentially more than patients about the nature and risks of medical treatment.").

equally little about the treatment of ailments.[193] The sources of information used by lay persons are often quite inaccurate.[194] Moreover, consumers of healthcare are often ill or distraught and thus in a poor position to evaluate treatment.[195] It is little wonder, and probably for the better, that lay persons tend to rely on their healthcare providers' suggestions with little critical analysis.[196] Erin Brown colorfully distinguishes making decisions regarding healthcare from other types of market decisions:

> Buying health care is thus unlike shopping for a car, unless one imagines buying a car while being chased by a gunman, when there are only a couple unfamiliar models to choose from, relying upon the guidance of a trusted car salesman who tells you which car is best for your situation and also serves as your driver as you try to get away.[197]

Private scrutiny of algorithmic medicine will also be hampered by the lack of a counterfactual with which to compare the diagnoses and treatments that they receive.[198] Patients will only receive one course of treatment. As consumers, these patients cannot compare the treatment that

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[193] *See, e.g.*, Gianfranco Domenighetti et al., *Women's Perception of the Benefits of Mammography Screening: Population-Based Survey in Four Countries*, 32 INT'L J. EPIDEMIOLOGY 816, 818 (2003) (finding that a high proportion of women misunderstood the purpose of regular screening and overestimated health effects); Ernest Kuchar et al., *Knowledge Regarding Influenza and Influenza Vaccination in General Population: Results of a National Survey in Poland*, *in* CURRENT TRENDS IN IMMUNITY AND RESPIRATORY INFECTIONS 55, 55-56 (Mieczyslaw Pokorski ed., 2018) (finding that people have little understanding of how vaccines work or what constitutes an effective vaccine); Bruce Rosenthal & Bob Thompson, *Awareness of Age-related Macular Degeneration in Adults: The Results of a Large-Scale International Survey*, 74 OPTOMETRY 16, 17 (2003) (finding that three quarters of people surveyed were unaware of treatments for the leading cause of severe vision loss in adults over fifty).

[194] *See* Jun Suh Lee et al., *YouTube as a Source of Patient Information on Gallstone Disease*, 20 WORLD J. GASTROENTEROLOGY 4066, 4068 (2014) (finding that 56.5% of 131 videos were misleading); K. Nason et al., *YouTube as a Patient-Information Source for Root Canal Treatment*, 49 INT'L ENDODONTIC J. 1194, 1197-98 (2016) (finding that "much of the content is missing or irrelevant" but that nonetheless "33% of people believe the health-related information sourced on the most popular websites is accurate").

[195] Nan D. Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL'Y L. & ETHICS 93, 98 (2006).

[196] Thomas L. Greaney, *Economic Regulation of Physicians: A Behavioral Economics Perspective*, 53 ST. LOUIS L.J. 1189, 1200 (2009) ("Empirical research suggests that in making medical decisions with potentially serious consequences, patients prefer to have their physician make the key decisions; this result holds even for patients who want to be fully informed.").

[197] Brown, *supra* note 190, at 113.

[198] *See* A. Philip Dawid et al., *The Probability of Causation*, 16 LAW, PROBABILITY & RISK 163, 166 (2017) (noting that determination of causation requires a counterfactual, using the taking of two aspirin as an example).

they received to a treatment that they did not receive.[199] It will be virtually impossible for a consumer of algorithmic healthcare to discern whether they were prescribed one aspirin too many, or which drugs in a course of treatment actually contributed to their recovery, or whether a medical device that was prescribed could have been replaced with a less expensive model or was even necessary at all.

Market discipline can act as an effective deterrent to corruption.[200] Market discipline, however, requires actual markets and consumer capable of making knowledgeable choices. These markets and these consumers do not exist with respect to healthcare. Market discipline cannot protect the integrity of healthcare algorithms.

B. Regulatory Agencies Cannot Protect the Integrity of Healthcare Algorithms

Regulatory oversight cannot ensure the integrity of healthcare algorithms. Regulatory agencies are susceptible to the same sets of influences that will be deployed to corrupt the creators of those algorithms.

The International Medical Device Regulators Forum, to which the United States belongs, defines the use of algorithms and other computing as software and goes on to treat this software as a medical device.[201] In 2019, the Food and Drug Administration implemented a test pilot program for the streamlined approval of software in healthcare. Streamlined approval is critical because, as this article has noted, algorithmic healthcare is a dynamic and rapidly innovating field.[202] The streamlined approval process differs from traditional approval processes in that it is not based on

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[199] *See* Brown, *supra* note 190, at 113 (noting that "much of health care is not 'shoppable'" and that "[a]cute or urgent health care does not lend itself to comparison").

[200] *See* Chen Lin et al., *Market Reforms Give Anticorruption Reforms More Traction: Evidence from China*, VOX (Dec. 22, 2017), https://voxeu.org/article/market-reforms-give-anticorruption-reforms-more-traction (describing ways that markets discipline corruption); Susan Rose-Ackerman, *Redesigning the State to Fight Corruption: Transparency, Competition, and Privatization* Note No. 75 3, PUB. POL'Y PRIVATE SECTOR (April 1996), https://openknowledge.worldbank.org/bitstream/handle/10986/11627/multi0page.pdf?sequence=1 (discussing market disciplines on corruption and noting that "[i]n general, any reform that increases the competitiveness of the economy helps reduce corrupt incentives").

[201] *See* Int'l Med. Device Regulators Forum Software as a Medical Device Working Group, *Software as a Medical Device*, at 6, (Dec. 9, 2013), http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.

[202] Given the wide variety of types of medical devices and the difficulty in determining the classification of algorithms under the standard classification scheme, it is impos-

clinical trials of the product; instead, approval is based on a determination that the producers of software have demonstrated "a robust culture of quality and organizational excellence and are committed to monitoring real-world performance."[203] Producers of software must demonstrate excellence in five areas: product quality, patient safety, clinical responsibility, cybersecurity responsibility, and proactive culture.[204] How producers are to demonstrate excellence in these five categories is still being determined by the Food and Drug Administration through consultation with the public and the industry.[205]

Evaluating the producer rather than testing the algorithm presents an elegant approach to a very dynamic technology. Evaluating excellence in each of the five categories is, however, subjective and leaves a great deal of discretion to the evaluators. Unfortunately, discretion opens the door for the very type of corrupt behavior for which pharmaceutical and medical device firms have demonstrated a propensity.[206] Indeed, Robert Klitgaard places discretion at the heart of his formula for corruption: "Corruption equals monopoly plus discretion minus accountability."[207] Klitgaard's formula aptly describes the expedited approval process for healthcare algorithms.

Those who observe healthcare regulation already suggest that regulators experience a form of discretionary bias known as "capture."[208] George

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sible to predict an average range of times that approval would take; the time taken for approval of medical devices, however, can be quite lengthy. *See* Spenser F. Powell, *Changing Our Minds: Reforming the FDA Medical Device Reclassification Process*, 73 FOOD & DRUG L.J. 177, 186-91 (2018) (describing classifications and times for approval).

[203] U.S. FOOD & DRUG ADMIN., *Digital Health Software Precertification (Pre-Cert) Program,* (last updated July 18, 2019), https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program; U.S. FOOD & DRUG ADMIN., Software Precertification Program: 2019 Test Plan 2 (2019).

[204] U.S. FOOD & DRUG ADMIN., Developing a Software Precertification Program: A Working Model version 1.0, at 11 (2019), https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program.

[205] *Id.* at 2.

[206] *See* Rosemary Barkett, *"Bringing Human Rights Home"? I Thought They were Already Here! Human Rights and Our Constitution*, 91 N.Y.U.L. REV. 535, 543 ("Unfettered discretion provides the opportunity for arbitrary and corrupt action.").

[207] Robert Klitgaard, *International Cooperation Against Corruption*, 35 FIN. & DEV. 3, 4 (Mar. 1998) (emphasis omitted), https://www.imf.org/external/pubs/ft/fandd/1998/03/pdf/klitgaar.pdf.; *see also* Andrew P. Morriss et al., *Homesteading Rock: A Defense of Free Access Under the General Mining Law of 1872*, 34 ENVTL. L. 745, 789 (2004) (demonstrating that discretion opens the door for corruption).

[208] *See*, *e.g.*, DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATION IMAGE AND PHARMACEUTICAL REGULATION (2010) (discussing regulatory capture in the United States); GOVIN

Stigler presents the public choice theory of regulatory capture: a minority that is significantly affected by a bureaucratic body will expend far more resources to avoid or to elicit that affect than will the majority that is only distantly affected.[209] Thus, a timber harvesting firm will expend thousands of dollars to influence the decisions of an environmental agency while the majority of the public, with values significantly opposed to those of the timber firm, might in the aggregate expend only hundreds. The timber firm will have more influence over the agency even though its values and goals are antithetical to those of the public that the bureaucracy is charged with serving.[210]

Political scientists offer a number of potential causes for regulatory capture. These include benign factors such as repeated interactions with the regulated entity leavened with only occasional interactions with the broader public or shared technocratic views of the world but also include more perverse influences such as political contributions and bribes disguised as lobbying and the promise of lucrative private sector positions in exchange for favorable treatment.[211] These are the same sorts of corrupt practices in which pharmaceutical and medical device firms have long engaged.[212]

Structuring regulation to avoid regulatory capture in the presence of severe asymmetries of interest and resources, such as in the healthcare industry, is difficult. The sheer volume of regulatory action overwhelms oversight by parties representing the public's interests.[213] Limited access to judicial review also hampers oversight and reform efforts.[214] Confidentiality and secrecy often render public oversight nugatory.[215] These factors

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PERMANAND, EU PHARMACEUTICAL REGULATION: THE POLITICS OF POLICY-MAKING (2006) (discussing regulatory capture in the European Union); Daniel T. Ostas, *Deconstructing Corporate Social Responsibility: Insights from Legal and Economic Theory*, 38 AM. BUS. L.J. 261, 269-70 (2001) (illustrating capture in drug approval); James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 978 (2008) (stating that the Food and Drug Administration has been captured "by agents of its regulated industries").

[209] George J. Stigler, *The Economic Theory of Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

[210] *See* Nathaniel O. Keohane et al., *The Choice of Regulatory Instruments in Environmental Policy*, 22 HARV. ENVTL. L. REV. 313, 319-21 (1998) (discussing regulatory capture of environmental agencies).

[211] Melissa F. Wasserman, *Deference Asymmetries: Distortions in the Evolution of Regulatory Law*, 93 TEX. L. REV. 625, 629-30 (2015).

[212] *See supra* notes 135-165 and accompanying text.

[213] Sidney A. Shapiro & Rena I. Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741, 1745 (2008).

[214] *Id.* at 1746.

[215] *Id.* at 1745-46.

are especially pertinent to oversight of the regulation of healthcare.[216]

Regulatory oversight, as currently practiced, will not protect the integrity of healthcare algorithms. Neither will markets. Protection requires new approaches to the regulation and approval of healthcare algorithms, and those new approaches must be taken now.

IV. A PRESCRIPTION: TRANSPARENCY AND ACCOUNTABILITY

Traditional thinking will not protect the integrity of healthcare algorithms. A novel form of healthcare delivery demands new rules of control and regulation, and that new thinking must occur now, at the nascence of the algorithmic healthcare.[217] In particular, healthcare algorithms–and the processes by which they were created–must be subject to public review. Public review requires transparency, an important tool in combatting corruption in general. To augment the effect that transparent review has, every person who participates in the development of a healthcare algorithm must acknowledge and accept responsibility for their contributions to the creation of that algorithm.

A. Transparent Public Review

Algorithms are products of the mind and, in that way, are comparable to other types of research and study. As mentioned in this article, pharmaceutical and medical device firms have actively corrupted research in the biological sciences.[218] Confronted with the reality of corruption of research in their fields, the biological sciences have rethought the manner in which scholarship is evaluated. In the past, a handful of peers evaluated scholarly research.[219] Peer review is not perfectly analogous with regulatory review, but it does share the trait of delegating the scrutiny of a product of the mind

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[216] *See* David S. Egilman et al., *Avoiding the Regulatory Capture of the Food and Drug Administration*, 167 ARCHIVES INTERNAL MED. 732, 732-33 (2007) (advocating reform of the Food and Drug Administration to mitigate regulatory capture).

[217] *See* KLAUS SCHWAB & NICHOLAS DAVIS, SHAPING THE FUTURE OF THE FOURTH INDUSTRIAL REVOLUTION X (2018) ("The social norms and regulations governing emerging technologies are in the process of being developed and written today.").

[218] *See supra* notes 109-134 and accompanying text.

[219] *See* Emily Ford, *Advancing an Open Ethos with Open Peer Review*, 78 COLLEGE & RES. LIBR. 406, 407 (2017) (discussing purpose of peer review); Nancy McCormack, *Peer Review and Legal Publishing: What Law Librarians Need to Know about Open, Single-Blind, and Double-Blind Reviewing*, 101 L. LIBR. J. 59, 60-61 (2009) (discussing the history and extent of peer review). Legal journals are relatively unique in that most are reviewed by students rather than by peers. *See* Phil Nichols, *A Student Defense of Student Edited Journals: In Response to Professor Roger Cramton*, 1987 DUKE L.J. 1122, 1124-28 (describing and defending the selection process).

to a small group of people meant to work on behalf of a broader constituency.[220]

Peer review also shares with regulatory review the existence of substantial limitations. Lutz Bormann summarizes the most frequent criticisms:

> (1) reviewers rarely agree on whether to recommend that a manuscript be published or a research grant be awarded, thus making for poor reliability of the peer review process; (2) reviewers' recommendations are frequently biased, that is, judgments are not based solely on scientific merit, but are also influenced by personal attributes of the authors, applicants, or the reviewers themselves (where the fairness of the process is not a given); (3) the process lacks predictive validity because there is little or no relationship between the reviewers' judgments and the subsequent usefulness of the work to the scientific community, as indicated by the frequency of citations of the work in later scientific papers; (4) reviewing is inefficient because it delays publications; inhibits the publication of new, innovative, and unconventional ideas; and is time consuming and costly; and (5) reviewing can be personally damaging, an experience that is particularly painful and distressing for new authors.[221]

Aside from the hardships and burdens forced on researchers, two important facts stand out: peer review can be coopted and the resource limitations of peer review often constrain its ability to capture flaws in the underlying science.[222] In general, the same is true of regulatory review.

Faced with this crisis of legitimacy, scientific journals have turned to innovative new methods of determining the validity of research.[223] Some journals engage in "open review," meaning the journal publishes the names

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[220] *See* McCormack, *supra* note 219, at 59-60 (discussing purpose of peer review).

[221] Lutz Bornmann, *Scientific Peer Review*, 45 ANN. REV. INFO. SCI. & TECH. 197, 203-04 (2011) (emphasis omitted).

[222] *See* Katherine S. Button et al., *Preventing the Ends From Justifying the Means: Withholding Results to Address Publication Bias in Peer-Review*, 4 BMC PSYCHOL. 1, 1-2 (2016), https://bmcpsychology.biomedcentral.com/articles/10.1186/s40359-016-0167-7 (describing peer review biases that result in the publication of scientifically inaccurate articles); P. Charkhchi et al., *Bias in Neuroradiology Peer Review: Impact of a "Ding" on "Dinging" Others*, 40 AM. J. NEURORADIOLOGY 19, 23 (2019) (finding significant mistakes in peer review); Theodore Eugene Day, *The Big Consequences of Small Biases: A Simulation of Peer Review*, 44 RES. POL'Y 1266, 1266, 1268-69 (2015) (describing studies finding bias and reporting results of experiment that found bias). Richard Horton, editor-in-chief of the prestigious medical journal *The Lancet* describes peer review as "just a crude means of discovering the acceptability–not the validity–of a new finding." Richard Horton, *Genetically Modified Food: Consternation, Confusion, and Crack-Up*, 172 MED. J. AUSTL. 148, 148 (2000).

[223] *See* L.M. DeTora, *The Spectre of Ghostwriting: Eroding Public Trust in Physicians, Clinical Trial Integrity and Biomedical Authorship*, 70 INT'L J. CLINICAL PRAC. 630, 630-33 (2016) (describing crisis of legitimacy and acknowledging that medical researchers and scholarship share responsibility for problems with pharmaceuticals).

and/or reviews of peer reviewers as a means of holding reviewers accountable.[224] This practice has some relevance to regulatory capture and to the holding of regulators accountable.[225] Advocates of open review argue that "[m]ore thorough and constructive reviews will be performed because reviewers will know that their efforts will ultimately end up in the public domain."[226]

Many elite scientific journals, however, have gone farther. These journals adopt a multilayered approach to evaluating the validity of scientific research. They continue to utilize peer review but also make submitted articles, along with supporting data, available for public scrutiny and comment.[227] This process, using many of the same technologies that enable algorithmic decision-making, empowers the entire corpus of scholars to evaluate the validity of claimed findings.[228]

The process used by scientific journals to protect research from corruption is of direct relevance to protecting the integrity of health algorithms. Algorithms that direct the real-world provision of healthcare should be subjected to at least the same standard of review that is used for scholarly publications. In order to protect the general public, any algorithm that is used to enable machines to make decisions regarding diagnoses or prescriptions must be available for public scrutiny, along with the data used to create that algorithm and an explanation of the decisions made in designing the algorithm.[229] Algorithms that direct treatment must be transparent.

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[224] *See Peer-Review Policy*, BMC MED., https://bmcmedicine.biomedcentral.com/submission-guidelines/peer-review-policy (describing policy and noting the benefits of transparency) (last visited Apr. 1, 2019).

[225] *See supra* notes 208-212 and accompanying text (discussing regulatory capture).

[226] John J. Foxe & Paul Bolam, *Open Review and the Quest for Increased Transparency in Neuroscience Publication*, 45 EUR. J. NEUROSCI. 1125, 1125 (2017). Open peer review also enhances objectives related to "transparency and collaboration"; open peer review "supports transparent scholarly conversations, improves and enhances collaboration and research, and exposes and alleviates problems endemic in blinded peer review processes." Ford, *supra* note 219, at 406.

[227] *See* Erik Sandewall, *Systems: Opening Up the Process*, NATURE (June 20, 2006, 12:52 PM), http://blogs.nature.com/peer-to-peer/2006/06/systems_opening_up_the_process.html (describing this process).

[228] *See* Eugene Koonin et al., *Systems: Reviving a Culture of Scientific Debate*, NATURE (June 5, 2006, 2:33 PM), http://blogs.nature.com/peer-to-peer/2006/06/systems_reviving_a_culture_of_1.html. Eugene Volokh deliberates the value of technologies that allow scholars to disseminate scholarship directly to public consumption. Eugene Volokh, *Scholarship, Blogging, and Tradeoffs: On Discovering, Disseminating, and Doing*, 84 WASH. U. L. REV. 1089 (2006).

[229] As Cathy O'Niel points out, no algorithm "can include all of the real world's complexity or the nuances of human communication" and thus in designing algorithms "we make choices about what's important enough to include, simplifying the real world into a

Transparency in general constitutes a powerful tool to combat corruption.[230] Transparency inhibits corruption by making misconduct detectible and thus exposing corrupt actors to punishment and public censure.[231] In the case of healthcare algorithms, transparency also reduces asymmetries of knowledge and empowers affected stakeholders to interact with and make demands of powerful and potentially corrupt actors.[232] Transparency could also help to drive algorithmic decision-making toward socially-oriented and -desired goals and away from the narrow goals of self-interested third parties.[233]

Critics of the proposal might lodge three arguments against transparency: that most affected stakeholders lack sufficient knowledge, that making underlying health data public raises privacy concerns, and that transparency would short-circuit the monetization of algorithms. These arguments have merit, but when examined, none outweigh the need to protect the integrity of healthcare algorithms.

1. Knowledge. – Some scholars of technology and law argue, in the broader context of algorithms rather than the narrower context of only healthcare algorithms, first, that public review is ineffective because the general public lacks sufficient knowledge to perform meaningful evaluations and, second, that even experts sometimes cannot predict how code will act.[234] The first of these observations misses the point. Although transparency operates to empower all stakeholders, holding designers accountable does not require that all stakeholders have the capacity to evaluate algorithms; so long as some persons within the larger group of stakeholders have an understanding of algorithms, then corrupt actors are susceptible

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toy version that can easily be understood." CATHY O'NIEL, WEAPONS OF MATH DESTRUCTION: HOW BIG DATA INCREASES INEQUALITY AND THREATENS DEMOCRACY 20 (2016). Explanation would include describing and defending these choices.

[230] *See* Roger P. Alford, *A Broken Windows Theory of International Corruption*, 73 OHIO ST. L.J. 1253, 1269 (2012) ("One of the best tools to combat corruption is transparency.").

[231] *See* Lynn M. LoPucki, *Court-System Transparency*, 94 IOWA L. REV. 481, 494 (2009) (explaining this process).

[232] *See* Jerry Brito & Drew Perraut, *Transparency and Performance in Government*, 11 N.C. J.L. & TECH. ON. 161, 163 (2010) (explaining how transparency reduces asymmetries of information); David Hess, *Combating Corruption through Corporate Transparency: Using Enforcement Discretion to Improve Disclosure*, 21 MINN. J. INT'L L. 42, 66-67 (2012) (explaining how transparency empowers stakeholders and engenders dialogue).

[233] *See* Bruno Lepri et al., *Fair, Transparent, and Accountable Algorithmic Decision-making Processes: The Premise, the Proposed Solutions, and the Open Challenges*, 31 PHIL. & TECH. 611, 614 (2018) (discussing the need for transparency in what they term "social good decision-making algorithms").

[234] *See* Joshua A. Kroll et al., *Accountable Algorithms*, 165 U. PA. L. REV. 633, 638 (2017) (making these arguments).

to exposure.[235]

The second observation, regarding the difficulty that experts have in understanding code, does not survive real-world experience. Crowdsourcing has proven an effective means of creating and improving software, which involves algorithms.[236] When the objectives and processes are clearly explained–made transparent–strangers can work effectively to design complex algorithms. Participants undertake this activity for a variety of reasons, such as tangible reward, skills enhancement, engagement with a community, or curiosity and pleasure, and bring with them a wide variety of perspectives and techniques.[237] The fact that the general public includes individuals capable of picking up the threads of and communally developing complex software belies any assertion that experts cannot evaluate and opine on healthcare algorithms.

The assertion also ignores the importance of considering the entire life cycle of an algorithm. The data used in the creation of an algorithm will affect the quality and nature of that algorithm. Transparent review will help to expose tampering with or distortion of underlying data.[238]

2. Privacy. – Transparency of the underlying data may, however, raise concerns related to individual privacy. The underlying data that will be exposed by transparent review of healthcare algorithms will usually include data regarding the health of individual persons, which raises serious and legitimate concerns regarding privacy.[239] Individual privacy concerns cluster around the publication of private information, which sometimes could render an individual vulnerable to discrimination or social disapproval.[240]

The pat and unsatisfactory response to these concerns is to mandate the

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[235] Bruno Lepri, Nuria Oliver, Emmanuel Letouzé, Alex Pentland & Patrick Vinck also argue that designers of algorithms that make decisions regarding social goods have a duty to explain those algorithms in terms that affected stakeholders can understand. Lepri et al., *supra* note 233, at 621.

[236] *See* Wenjun Wu et al., *Creative Software Crowdsourcing: From Components and Algorithm Development to Project Concept Formations*, 1 INT'L J. CREATIVE COMPUTING 57, 58-59 (2013) (discussing nature and benefits of crowdsourcing the development of software and algorithms); *see also* Klaas-Jan Stol & Brian Fitzgerald, *Researching Crowdsourcing Software Development: Perspectives and Concerns*, 7, 7, *in* Proceedings of the 1st Int'l Workshop on CrowdSourcing in Software Engineering (June 2014) (stating that "[c]rowdsourcing is an emerging form of 'outsourcing' software development," but noting the need for more research on why crowdsourcing is effective and how to manage it).

[237] *See* Nada Sherief et al., *Crowdsourcing Software Evaluation*, at 1 (2014), doi:10.1145/2601248.2601300.

[238] *See* Lepri et al., *supra* note 233, at 619.

[239] *See* Barbara J. Evans, *Barbarians at the Gate: Consumer-Driven Health Data Commons and the Transformation of Citizen Science*, 42 AM. J.L. & MED. 651, 653 (2016) (identifying these concerns in the context of crowdsourced healthcare science).

[240] *See* Hiller, *supra* note 21, at 271.

data be scrubbed of all identifying characteristics.[241] This answer is unsatisfactory because scrubbing–the search for and removal of identifiers such as names and addresses–leaves behind numerous quasi-identifiers that might still in combination with one another identify a patient.[242] K-level anonymity strategies seem to offer more protection; "k represents the number of peoples' records that must be indistinguishable from another record in the set if it is to pass scrutiny" and identifying information is removed from each data set until it meets that objective.[243] This strategy too, however, is vulnerable to reverse engineering.[244]

Mandated scrubbing is also unsatisfying because as each layer of personal information is stripped out of the data, that data becomes less useful. If, for example, the genders of people are not included in the data, then the resulting algorithm will not take genders into account when diagnosing or prescribing treatment.[245] Data that is richer in identifiers is also richer in information that produces more effective algorithms.

Several scholars have written thoughtfully and sensitively about the inherent tension between protecting individual privacy and enhancing the public good. Janine Hiller, for example, acknowledges the public benefits that can flow from analysis of large amounts of health data that contain personal information but observes that the moral considerations attendant to the public good are obscured by the fact that many private actors profit handsomely in the process.[246] Barbara Evans also recognizes the tensions between the public good and privacy interests in health data; she, however, suggests that the conflation of health data with personal property has obscured the balancing of values.[247] Yianni Lagos suggests that this debate ignores technical realities and that the resolution of the tension between so-

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[241] *See*, *e.g.*, Ronald F. Wright, *Reinventing American Prosecution Systems*, 46 CRIME & JUST. 395, 423 (2017) (arguing that prosecutorial data should be released to the public and blithely suggesting "scrubbing some information to protect legitimate privacy concerns").

[242] *See* Kostas Pantazos et al., *Preserving Medical Correctness, Readability and Consistency in De-Identified Health Records*, 23 HEALTH INFORMATICS J. 291, 294 (2017) (discussing difficulties in removing quasi-identifiers).

[243] Shawn N. Murphy et al., *Strategies for Maintaining Patient Privacy in i2b2*, 18 J. AM. MED. INFORMATICS ASS'N i103, i103 (2011).

[244] *See id.* (describing reverse engineering).

[245] *See* Anita Holdcroft, *Gender Bias in Research: How Does it Affect Evidence Based Medicine?*, 100 J. ROYAL SOC. MED. 2, 2 (2007) (criticizing health studies in the 1970s for not including information about gender, which resulted in poorer treatment of women).

[246] Hiller, *supra* note 21, at 289.

[247] Evans, *supra* note 239, at 678.

cial good and privacy interests needs to take into account that de-identification might not be possible.[248]

Each of these scholars suggests that resolution of this tension lies in some sort of dialogue among stakeholders and the many competing interests.[249] None, however, include protection of the integrity of underlying healthcare algorithms among the interests to be considered. Omission of concerns regarding corruption would constitute a critical failure. Corruption of the integrity of healthcare algorithms would render nugatory an interest that each of these scholars rightly considers fundamental–the public good.

This article cannot resolve the complex tension between the public benefits of analyzing fulsome health data and the rights of individuals to privacy. This article can, however, contribute to that debate an important observation. Preventing corruption of healthcare algorithms must be among the interests that is taken into consideration. And preventing corruption requires transparency.

3. Monetization. – The roots of algorithmic secrecy lie in efforts to extract revenue from those algorithms and their use. The most direct method of extracting revenue is by exercising exclusive control over the use of an algorithm, which, in turn, is most directly accomplished by treating an algorithm as property.[250] In the case of algorithms, however, the full range of legal protections as property is not available.

Algorithms, in general, cannot receive patent protection.[251] Article 52 of the European Patent Convention, for example, explicitly excludes "programs for computers" from patentable discoveries.[252] The United States of-

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[248] Yianni Lagos, *Taking the Personal Out of Data: Making Sense of De-Identification*, 48 IND. L. REV. 187, 199-200 (2014).

[249] Evans, *supra* note 239, at 684; Hiller, *supra* note 21, at 314; Lagos, *supra* note 248, at 194.

[250] *See* Joshua S. Gans & Scott Stern, *Is There a Market for Ideas?*, 19 INDUS. & CORP. CHANGE 805, 808 (2010) ("Specific institutions, most notably formal intellectual property rights such as patents, play a crucial role in addressing the challenges raised by market design.").

[251] *See* Brian J. Love et al., *Determinants of Patent Quality: Evidence from Inter Partes Review Proceedings*, 90 U. COLO. L. REV. 67, 129-30 (2019) (discussing the difficulty in obtaining patents for algorithms); *see also* Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 928 ("Software patents are widely acknowledged as creating a large number of problems for the patent system.").

[252] Convention on the Grant of European Patents, art. 52, Oct. 5, 1973, 1065 U.N.T.S. 255.

fers a murkier picture. A long line of Supreme Court cases generally characterizes algorithms as patent-ineligible abstractions.[253] The Court, however, has approved patent protection for some functional algorithms; the lack of clarity as to what constitutes a patentable functional algorithm and what constitutes a non-patentable abstraction discourages creators of algorithms from attempting to seek patents.[254]

In the absence of patent protection, many healthcare algorithms are treated as proprietary trade secrets.[255] Perfecting a trade secret interest requires making reasonable efforts to keep others from accessing intellectual property.[256] Designers of healthcare algorithms, therefore, usually hide the algorithm and its development and share with healthcare providers only the outcome of the processing of any given set of data–that is, the diagnosis or prescription for a given patient.[257]

Trade secrecy does facilitate the commercialization of ideas and thus may incentivize innovation.[258] On the other hand, "uncritical protection of all secret business information conflicts with effective law enforcement and protection of public health, safety, and welfare."[259] Scholars embrace both sides of this conflict. Some argue that trade secrecy is necessary to promote lifesaving innovation.[260] Other scholars counter that trade secrecy imposes a host of risks to the trustworthiness and efficacy of automated medicine.[261]

Ultimately, arguments regarding the monetization of ideas cannot outweigh the need to protect the integrity of healthcare algorithms. Even the most extreme form of such arguments, that no ideas would be generated

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[253] *See* Joseph Allen Craig, *Deconstructing Wonderland: Making Sense of Software Patents in a Post-*Alice *World*, 32 BERKELEY TECH. L.J. 359, 363-66 (2017) (describing case law).

[254] *See* Michael Xun Liu, *Subject Matter Eligibility and Functional Claiming in Software Patents*, 20 N.C. J.L. & TECH. 227, 272 (2018) (describing the lack of clarity and its effect on creators of algorithms).

[255] Michael Clancy, *Intellectual Property Law–The Future of Patent Eligibility Analysis on Medical Diagnostics and Its Effects on Healthcare Innovation–Ariosa Diagnostics, Inc. v. Sequenom Inc.*, 12 J. HEALTH & BIOMEDICAL L. 319, 333 (2017); *see* David S. Levine & Ted Sichelman, *Why Do Startups Use Trade Secrets*, 94 NOTRE DAME L. REV. 751, 785 (2018) (describing the use of trade secrets by technology firms).

[256] *See* Elizabeth A. Rowe, *RATs, TRAPs, and Trade Secrets*, 57 B.C. L. REV. 381, 408-12 (2016) (explicating the reasonable efforts requirement).

[257] Hiller, *supra* note 21, at 272-73; Price, *supra* note 71, at 423.

[258] *See* Peter S. Menell, *Property, Intellectual Property, and Social Justice: Mapping the Next Frontier*, 5 BRIGHAM-KANNER PROP. RTS. CONF. J. 147, 196 (2016) (discussing the relationship between trade secrecy and innovation).

[259] *Id.* at 172.

[260] *See e.g*, Clancy, *supra* note 255, at 334. It should be noted that Clancy finds trade secrets second best to patents for this purpose.

[261] *See e.g.*, Frank Pasquale, *Restoring Transparency to Automated Authority*, 9 J. ON TELECOMM. & HIGH TECH. L. 235, 243 (2011).

unless the creators of ideas could completely monetize their ideas, cannot outweigh the need to protect the integrity of algorithms because if the implementation of ideas can be corrupted by self-interested third parties, then those ideas do not contribute to the public welfare and in fact may be deleterious to overall health and wellbeing.

This is not to say that monetization has no role in the development of healthcare algorithms. It may, which means there is policy work to be done. At a minimum, legislatures could clarify the extent to which property rights can be perfected in healthcare algorithms.[262] Legislatures could, and arguably should, extend the reach of patent rights to healthcare algorithms.[263] Eventually, as with many other aspects of law, the relationships between social needs, public goods, innovation, and monetization will be re-evaluated in the context of the revolutionary changes wrought by the algorithmic analysis of large-scale data.[264] That evaluation must include concerns regarding the protection of the integrity of healthcare algorithms.

B. Accountability

Tortious liability and other liabilities for the use of healthcare algorithms raise interesting questions not yet fully resolved in the law.[265] Accountability with respect to healthcare algorithms, however, must involve more than issues of mis-practice and malpractice. Accountability must also include responsibility for the safe, effective, and socially conscionable design of healthcare algorithms.

Such accountability requires that all parties who influenced the design and creation of healthcare algorithms must disclose their involvement. They must also make not just the algorithms available for public scrutiny but also their own actions and decisions regarding the design and creation of those algorithms.

Once again, the experience of scientific journals in their efforts to reduce corruption are instructive. Academic journals in the biological disciplines now demand transparency in disclosing research responsibility and

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[262] *See* Ben Hattenbach & Gavin Snyder, *Rethinking the Mental Steps Doctrine and Other Barriers to Patentability of Artificial Intelligence*, 19 COLUM. SCI. & TECH. L. REV. 313, 318 (2018) (criticizing the lack of clarity and suggesting a need for clarification).

[263] *See* Hyunjong Ryan Jin, *Think Big! The Need for Patent Rights in the Era of Big Data and Machine Learning*, 7 N.Y.U. J. INTELL. PROP. & ENT. L. 78 (2017) (making the argument for algorithms in general).

[264] *See* Hattenbach & Snyder, *supra* note 262, at 318 (calling on scholars to re-evaluate intellectual property in light of current technology).

[265] *See* W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, 14 SCITECH LAWYER, 10, 11-12 (discussing liability issues).

conflicts of interest.[266] The International Committee of Medical Journal Editors, for example, prohibits the inclusion of persons who did not contribute in meaningful ways as authors and also requires that each named author indicate their contribution to the research.[267] Authors, as well as reviewers and editors, must reveal all potential conflicts of interest.[268]

In the case of scientific scholarship, disclosure of the roles of all persons involved allows readers to evaluate the likely veracity of the scholarship and also exposes individuals to public censure if they have been involved in conduct that violates the norms of academia. The same would be true of the creation of healthcare algorithms. Norms play an important role in controlling anti-social and criminal behavior.[269] "[T]he real power to gain compliance with society's rules of prescribed conduct lies not in the threat or reality of official criminal sanction, but in . . . [t]he networks of interpersonal relationships in which people find themselves, [and] the social norms and prohibitions shared among those relationships."[270]

Public censure is a valuable tool in combatting corruption.[271] Some evidence suggests, for example, that public disclosure of corrupt business firms in the extractive industries sector affected the share prices of those firms, which may have had a disciplining effect on their behaviors.[272] Fieldwork in Southeast Asia suggests that social norms partially account for differences in the amounts of corruption in Malaysia and Singapore.[273] Experimental evidence demonstrates that public censure deters corruption and

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[266] *See* Adam Jacobs & Elizabeth Wager, *European Medical Writers Association (EMWA) Guidelines on the Role of Medical Writers in Developing Peer-Reviewed Publications*, 21 CURRENT MED. RES. & OPINION 317, 317-18 (2005) (stating that guidelines were developed in response to distrust engendered by the use of ghost writers).

[267] Int'l Committee of Med. J. Editors, *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, at 2 (2018), http://www.icmje.org/icmje-recommendations.pdf.

[268] *Id.* at 3.

[269] *See* Alessandro Balestrino, *It Is a Theft but Not a Crime*, 24 EUR. J. POL. ECON. 455, 456 (2008) (discussing the deterrent effect of social stigma attached to violation of norms); Patrick J. Keenan, *The New Deterrence: Crime and Policy in the Age of Globalization*, 91 IOWA L. REV. 505, 536 (2006) (discussing social costs including shame and social censure).

[270] Paul H. Robinson & John M. Darley, *The Utility of Desert*, 91 NW. U. L. REV. 453, 457 (1997).

[271] *See* Philip M. Nichols, *The Perverse Effect of Campaign Contribution Limits: Reducing the Allowable Amounts Increases the Likelihood of Corruption in the Federal Legislature*, 48 AM. BUS. L.J. 77, 100-02 (2011) (discussing the psychic costs of corruption).

[272] Rose Jacobs, *How to Fight Corruption–and Why We Should*, CHICAGO BOOTH REVIEW (May 20, 2019), https://review.chicagobooth.edu/economics/2019/article/how-fight-corruption-and-why-we-should.

[273] Philip M. Nichols, *The Psychic Costs of Violating Corruption Laws*, 45 VAND. J. TRANSNAT'L L. 145, 199 (2012).

that increasing the amount of detail included in the public reporting of corrupt acts increases the amount of deterrence.[274]

This evidence suggests that public evaluation of the conduct of those who contribute to or influence the design of healthcare algorithms could potentially exert a powerful disciplinary effect on such actors. Accountability, therefore, should play a role in protecting the integrity of healthcare algorithms. As a matter of public policy, actors who influence the design of healthcare algorithms should be required to disclose their roles.

CONCLUSION

Machine-made decisions will occupy a large role in the provision of healthcare and will play a significant role in determining the quality of human lives. The integrity of the algorithms that will enable machines to make decisions about healthcare is at risk. Billions of dollars of revenue are at play. Pharmaceutical and medical device firms have consistently demonstrated that they will undertake to distort research and to bribe prescribers in order to increase sales of their products. Pharmaceutical and medical device firms have done so even though their actions force upon patients extra costs, the ingestion of unneeded or harmful drugs, and risks associated with unneeded surgeries, devices, and treatments. Pharmaceutical and medical device firms have tremendous resources available to corrupt algorithms, and by corrupting those algorithms in ways that result in mis-prescription and over-prescription, accrue billions of dollars in revenue. It seems inevitable that they will do so.

Algorithmic healthcare has generated substantial commentary and debate. Unfortunately, within that commentary and debate, the threat posed by deliberate distortion of underlying algorithms has received no attention. This threat is not, however, a small problem. The corruption of algorithms poses as much of a threat to health, wellbeing, and dignity as do issues of privacy and bias. Protection of the integrity of healthcare algorithms must occupy a prominent place in the deliberations of the rules for the creation and implementation of healthcare algorithms.

Corruption of healthcare algorithms is also not a problem that will just go away or simply resolve itself. Market and regulatory forces cannot resolve this threat, and time will only harden a corrupted status quo. Action must be taken now, at the nascence of algorithmic healthcare. Doing so will help to ensure the potentially revolutionary benefits to be accrued from the application of large-scale data analytics to the provision of healthcare services.

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[274] Dmitry Ryvkin et al., *I Paid a Bribe: An Experiment on Information Sharing and Extortionary Corruption*, 94 EUR. ECON. REV. 1, 4 (2017).