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ARTICLES AND SURVEYS

PATIENTS AS PEERS: BLOCKCHAIN BASED EHR AND MEDICAL INFORMATION COMMONS MODELS FOR HITECH ACT COMPLIANCE

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I. INTRODUCTION

Touted as a revolution in patient health care, existing electronic health records ("EHR") systems have failed to meet Congressional and private aspirations for improving patient outcomes and recognizing operational cost savings.[1] A combination of technological shortcomings and

1. *See* DUSTIN CHARLES ET AL., THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., ADOPTION OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG U.S. NON-FEDERAL ACUTE CARE HOSPITALS: 2008-2014 1 (2015); David Dranove et al., *The Trillion Dollar Conundrum: Complementarities and Health Information Technology* 1, 3, 5 (Nat'l Bureau of Econ. Research, Working Paper No. 18281, 2012), http://www.nber.org/papers/w18281.pdf. The surveyed literature uses EHR and *electronic medical record* ("EMR") interchangeably. CHARLES ET AL., *supra*, at 1; Dranove et al., *supra*, at 1. We follow the usage of the Office of the National Coordinator for Health Information

anticompetitive incentives to engage in information blocking has resulted in a systemic failure of both health care providers and patients to reap the promised beneficial yields of adopting comprehensive EHR systems.[2]

In this Article, we explore how utilization of distributed ledger technologies, such as blockchain ledgers, can better promote interested stakeholder's interests in adoption of comprehensive EHR systems, as blockchain ledgers improve patient outcomes, increase interoperability between health care providers, generate cost operational savings to health care, and simplify compliance with the Health Insurance Portability and Accountability Act ("HIPAA") privacy rule.[3]

In Part II of this Article, we address existing EHR systems.[4] In Section II.A., we develop a working technological framework of EHR.[5] In Section II.B., we explain Congressional efforts to promote comprehensive EHR adoption through the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") incentives program.[6] In Section II.C., we summarize the HITECH Act amendments to HIPAA Privacy Rule as they relate to the implementation of comprehensive EHR systems.[7] In Section II.D., we review the empirical literature, which demonstrates how the adoption of existing EHR systems has led to marginal gains in patient outcomes and generated significant operational costs to health care providers.[8]

In Part III, we argue that blockchain ledgers, a nascent technological system can remedy the technological and social failings of existing EHR

Technology and Congressional enactments, though there is no operative difference between one nomenclature over the other. CHARLES ET AL., *supra*, at 1; Dranove et al., *supra*, at 1.

2. *See* Dranove et al., *supra* note 1, at 3.

3. *See* Tsung-Ting Kuo et al., *Blockchain Distributed Ledger Technologies for Biomedical and Health Care Applications*, 24 J. AM. MED. INFORMATICS ASS'N 1211, 1213–14 (2017).

4. *See* Swati Yanamadala et al., *Electronic Health Records and Quality of Care: An Observational Study Modeling Impact on Mortality, Readmissions, and Complications*, MED., May 2016, at 1, 1; discussion *infra* Part II.

5. *See* Dranove et al., *supra* note 1, at 6; discussion *infra* Section II.A.

6. *See* Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, § 13001, 123 Stat. 226, 246 (2009) (codified as amended in scattered sections of 42 U.S.C.); discussion *infra* Section II.B.

7. *See* 42 U.S.C. § 17935(e) (2018); 45 C.F.R. § 164.524(a) (2019); discussion *infra* Section II.C.

8. *See* NAT'L RESEARCH COUNCIL, TOWARD PRECISION MEDICINE: BUILDING A KNOWLEDGE NETWORK FOR BIOMEDICAL RESEARCH AND A NEW TAXONOMY OF DISEASE 29–31 (2011); discussion *infra* Section II.D.

systems.[9] In Part IV, we explore a number of blockchain-based EHR use cases supporting our arguments in Part III.[10]

II. THE PARADOX OF PRODUCTIVITY: CONTEMPORARY EHR SYSTEMS

A. *What Is EHR?*

EHR is a broad term referring to all integrated aspects of clinical information systems management.[11] There is no consensus as to what constitutes an EHR system.[12] A health care provider may employ EHR systems to handle any or all six major categories of functions: (1) physician documentation; (2) clinical repository data, which combines disparate patient information into a single file; (3) clinical decision support systems, which implements diagnosis, treatment, and prevention plans based on clinical data repository data sets; (4) generation of diagnostic and billing codes; (5) order entry systems, which attempt to streamline basic intradepartmental communications for equipment or scheduling purposes; or (6) computerized provider order entry, which allow specialists within larger health provider facilities to communicate with each other regarding a patient's treatment and history.[13]

Physician documentation and clinical repository data can include the acquisition, use, creation, or permitted transmission of any of the following: (1) patient demographics; (2) physician notes; (3) nursing assessments; (4) problem lists; (5) medication lists; (6) discharge summaries; (7) advance directives; (8) powers of attorney; (9) lab reports; (10) radiology tests; (11) medication histories; (12) consultation reports and nursing orders; (13) diagnostic tests; (14) genomic data; (15) institutional guidelines and policies;

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9. *See* Kuo et al., *supra* note 3, at 1214; discussion *infra* Part III.

10. *See Boehringer Ingelheim (Canada) Ltd. and IBM Canada Announce First of Its Kind Collaboration to Integrate Blockchain Technology into Clinical Trials*, IBM (Feb. 12, 2019), http://newsroom.ibm.com/2019-02-12-Boehringer-Ingelheim-Canada-Ltd-and-IBM-Canada-Announce-First-of-its-Kind-Collaboration-to-Integrate-Blockchain-Technology-into-Clinical-Trials; Mike Miliard, *Blockchain Use Case: Electronic Health Records*, HEALTHCARE IT NEWS (Dec. 14, 2018, 2:01 PM), http://www.healthcareitnews.com/news/blockchain-use-case-electronic-health-records; discussion *infra* Part III; discussion *infra* Part IV.

11. *See* Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1630 (2009).

12. *Id.* "[T]here is no consensus on what functionalities constitute the essential elements necessary to define an electronic health record in the hospital setting." *Id.*; *see also* Dranove et al., *supra* note 1, at 6. "[T]here is no single technology associated with EMR, and different EMR technologies may perform overlapping tasks." Dranove et al., *supra* note 1, at 6.

13. Dranove et al., *supra* note 1, at 5–6.

(16) regulatory compliance protocols; (17) drug allergy concerns; (18) drug-drug interactions; (19) drug dosing information and protocols; (20) treatment protocols; (21) patient care protocols; and (22) triage protocols.[14]

Various technological and institutional barriers slowed institutional adoption of EHR even as the Internet saw widespread adoption by the public in the early 2000s.[15] This prompted Congressional action and, in 2009, a federal incentives bill was enacted to incentivize health care providers toward adopting robust EHR systems for forecasted improvements to efficiency and patient outcomes.[16]

CHART 1[17]

BASIC EHR FUNCTIONS FOR ACUTE CARE HOSPITAL ADOPTION OF BASIC OR COMPREHENSIVE EHR SYSTEMS

EHR FUNCTIONS REQUIRED	BASIC EHR	COMPREHENSIVE EHR
Patient Demographics	✔	✔
Physician Notes		✔
Nursing Assessments		✔
Problem Lists	✔	✔
Medication Lists	✔	✔
Discharge Summaries	✔	✔

14. CHARLES ET AL., *supra* note 1, at 9. Federal guidelines define *Basic EHR* systems as computerized functions relating to: "[P]atient demographics, patient problem lists, electronic lists of medications taken by patients, clinician notes, orders for medications, viewing laboratory results, and viewing imaging results." *Office-Based Physician Electronic Health Record Adoption*, OFFICE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (Jan. 2019), http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php; *see also* Julia Adler-Milstein et al., *Electronic Health Record Adoption in US Hospitals: Progress Continues, but Challenges Persist*, 34 HEALTH AFF. 2174, 2175 (2015).

> A hospital with at least a basic EHR system reported full implementation of the following ten computerized functions in at least one clinical unit of the hospital: patient demographics, physician notes, nursing assessments, patient problem lists, patient medication lists, discharge summaries, laboratory reports, radiologic reports, diagnostic test results, and order entry for medications.

Adler-Milstein et al., *supra*, at 2175.

15. *See id.* at 2174.

16. *See id.*; American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 1, 123 Stat. 115, 115 (2009) (codified as amended at 16 U.S.C. §§ 2601–2645).

17. *See* CHARLES ET AL., *supra* note 1, at 9; *Office-Based Physician Electronic Health Record Adoption*, *supra* note 14.

Advance Directives		✔
Lab Reports		✔
Radiology Tests		✔
Medications	✔	✔
Consultation Requests		✔
Nursing Orders		✔
View Lab Reports	✔	✔
View Radiology Reports	✔	✔
View Radiology Images		✔
View Diagnostic Test Results	✔	✔
View Diagnostic Test Images		✔
View Consultant Report		✔
Clinical Guidelines		✔
Clinical Reminders		✔
Drug Allergy Results		✔
Drug-Drug Interactions		✔
Drug Dosing Support		✔

B. *The HITECH Act EHR Incentives Program*

The American Recovery and Reinvestment Act of 2009 ("ARRA") contained monetary grants to incentivize the implementation of EHR systems by physicians and hospitals called the HITECH Act.[18] Since 2011, $30.8 billion in incentive payments have been made to promote EHR adoption in the United States.[19] At the time of the HITECH Act's enactment, adoption

18. American Recovery and Reinvestment Act of 2009 § 1; Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, § 13001, 123 Stat. 226, 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

19. *Data and Program Reports: Regulations & Guidance*, CENTERS FOR MEDICARE & MEDICAID SERVICES: REGULATIONS & GUIDANCE (May 14, 2019, 11:51 AM), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html. "More than $24.8 billion in Medicare [Promoting Interoperability Programs ("PI Program")] payments have been made between May 2011 and October 2018. More than [six] billion [dollars] in Medicaid [PI Program] payments have been made between January 2011 (when the first set of states launched their programs) and October 2018." *Id.*

rates of basic EHR systems among acute care hospitals in the United States was a dismal 12.2%.[20] By 2012, adoption rates had risen to 44.4%.[21]

The HITECH Act contains enabling provisions for prompting the adoption of EHR systems through subsidies programs targeting demonstrated *meaningful use* of certified EHR systems.[22] The HITECH Act established the Office of the National Coordinator for Health Information Technologies and its functions in establishing the HITECH Act.[23] In 2011, the Centers for Medicare & Medicaid Services ("CMS") established Medicare and Medicaid EHR Incentive Programs (now called the PI Program) to "encourage clinicians, eligible hospitals, and [critical access hospitals] to adopt, implement, upgrade . . . and demonstrate meaningful use of" certified EHR systems.[24] The CMS rules define meaningful use and establish the incentives payment program's guidelines, defining meaningful as "providers . . . using certified EHR technology in ways that can be measured significantly in quality and quantity."[25] CMS has advanced the incentives program for certified EHR implementation in an ongoing, three stage implementation:

- Stage 1 established "requirements for the electronic capture of clinical data," and required provisions for "providing patients with electronic copies of health information;"[26]

- Stage 2 established additional quality of review at point of care and required exchange of certain clinical information between providers;[27] and

- Stage 3 simplified reporting requirements and added new flexibilities for providers to make electronic health information available

20. CHARLES ET AL., *supra* note 1, at 1; Health Information Technology for Economic and Clinical Health Act § 13001.

21. *See* CHARLES ET AL., *supra* note 1, at 1.

22. *Meaningful Use: Qualify for EHR Incentive Programs*, NUEMD, http://www.nuemd.com/white-papers/qualify-ehr-incentive-programs (last visited May 1, 2020); *see also* Health Information Technology for Economic and Clinical Health Act § 13001.

23. Health Information Technology for Economic and Clinical Health Act § 13001(a).

24. *Promoting Interoperability*, CENTERS FOR MEDICARE & MEDICAID SERVICES: REGULATIONS & GUIDANCE, http://www.cms.gov/regulations-and-guidance/Legislation/EHRincentiveprograms/index (last visited May 1, 2020).

25. *Meaningful Use: Qualify for EHR Incentive Programs*, *supra* note 22; *see also* 42 C.F.R. § 495.4 (2019); *Promoting Interoperability*, *supra* note 24.

26. *Promoting Interoperability*, *supra* note 24; *see also* 42 C.F.R. § 495.2.

27. *Promoting Interoperability*, *supra* note 24; *see also* 42 C.F.R. § 495.22.

when and where it matters most and for health care providers and consumers to be able to readily, safely, and securely exchange that information.[28]

1. Stage 1 Benchmarks

To qualify under Stage 1 of the PI Program, hospitals and eligible professionals ("EP") must demonstrate objectives established by the HITECH Act.[29] To achieve minimum meaningful use, hospitals and EP's must meet fourteen and fifteen core objectives respectively and five out of ten menu objectives.[30] Additionally, EP's must meet a total of three Clinical Quality Measures from an additional set of thirty-eight Clinical Quality Measures, and hospitals must complete fifteen Clinical Quality Measures, as follows:[31]

- **Chart II – STAGE 1 OBJECTIVE SUMMARIES**[32]

- **EP Stage 1 Core Objectives**: (1) Computerized provider order entry (CPOE); (2) E-Prescribing (eRx); (3) Report ambulatory clinical quality measures to CMS/States; (4) Implement one clinical decision support rule; (5) Provide patients with an electronic copy of their health information, upon request; (6) Provide clinical summaries for patients for each office visit; (7) Drug-drug and drug-allergy interaction checks; (8) Record demographics; (9) Maintain an up-to-date problem list of current and active diagnoses; (10) Maintain active medication list; (11) Maintain active medication allergy list; (12) Record and chart changes in vital signs; (13) Record smoking status for patients [thirteen] years or older; (14) Capability to exchange key clinical information among providers of care and patient-authorized entities electronically; [and] (15) Protect electronic health information.[33]

- **EP Stage 1 Menu Objectives**: (1) Drug-formulary checks; (2) Incorporate clinical lab test results as structured data;

28. *See* 42 C.F.R. § 412.1 (2019); 42 C.F.R. § 495.24; *Promoting Interoperability*, *supra* note 24.

29. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE & MEDICAID EHR INCENTIVE PROGRAM: MEANINGFUL USE STAGE 1 REQUIREMENTS OVERVIEW (2010); *see also* Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, § 13001, 123 Stat. 226, 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

30. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 29.

31. *Id.*

32. *Id.*

33. *Id.*

(3) Generate lists of patients by specific conditions; (4) Send reminders to patients per patient preference for preventive/follow up care; (5) Provide patients with timely electronic access to their health information; (6) Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate; (7) Medication reconciliation; (8) Summary of care record for each transition of care/referrals; (9) Capability to submit electronic data to immunization registries/systems*; (10) Capability to provide electronic syndromic surveillance data to public health agencies.* *At least [one] public health objective must be selected.[34]

- **Hospital Stage 1 Menu Objectives**: (1) Drug-formulary checks; (2) Record advanced directives for patients [sixty-five] years or older; (3) Incorporate clinical lab test results as structured data; (4) Generate lists of patients by specific conditions; (5) Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate; (6) Medication reconciliation; (7) Summary of care record for each transition of care/referrals; (8) Capability to submit electronic data to immunization registries/systems*; (9) Capability to provide electronic submission of reportable lab results to public health agencies*; (10) Capability to provide electronic syndromic surveillance data to public health agencies.* *At least [one] public health objective must be selected.[35]

- **EP Stage 1 Clinical Quality Measures**: (1) Diabetes: Hemoglobin A1c Poor Control; (2) Diabetes: Low Density Lipoprotein (LDL) Management and Control; (3) Diabetes: Blood Pressure Management; (4) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD); (5) Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI); (6) Pneumonia Vaccination Status for Older Adults; (7) Breast Cancer Screening; (8) Colorectal Cancer Screening; (9) Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD; (10) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD); (11) Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment; (12) Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation; (13) Diabetic Retinopathy: Documentation of Presence or

34. *Id.*
35. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 29.

Absence of Macular Edema and Level of Severity of Retinopathy; (14) Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care; (15) Asthma Pharmacologic Therapy; (16) Asthma Assessment; (17) Appropriate Testing for Children with Pharyngitis; (18) Oncology Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer; (19) Oncology Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients; [20] Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients; [21] Smoking and Tobacco Use Cessation, Medical Assistance: (a) Advising Smokers and Tobacco Users to Quit, (b) Discussing Smoking and Tobacco Use Cessation Medications, (c) Discussing Smoking and Tobacco Use Cessation Strategies; [22] Diabetes: Eye Exam; [23] Diabetes: Urine Screening; (24) Diabetes: Foot Exam; (25) Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol; (26) Heart Failure (HF): Warfarin Therapy Patients with Atrial Fibrillation; (27) Ischemic Vascular Disease (IVD): Blood Pressure Management; (28) Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic; (29) Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement; (30) Prenatal Care: Screening for Human Immunodeficiency Virus (HIV); (31) Prenatal Care: Anti-D Immune Globulin; (32) Controlling High Blood Pressure; (33) Cervical Cancer Screening; (34) Chlamydia Screening for Women; (35) Use of Appropriate Medications for Asthma; (36) Low Back Pain: Use of Imaging Studies; (37) Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control; (38) Diabetes: Hemoglobin A1c Control (<8.0%).[36]

- **Hospital Stage 1 Clinical Quality Measures**: (1) Emergency Department Throughput—admitted patients Median time from ED arrival to ED departure for admitted patients; (2) Emergency Department Throughput—admitted patients—Admission decision time to ED departure time for admitted patients; (3) Ischemic stroke—Discharge on anti-thrombotics; (4) Ischemic stroke—Anticoagulation for A-fib/flutter; (5) Ischemic stroke—Thrombolytic therapy for patients arriving within [two] hours of symptom onset; (6) Ischemic or hemorrhagic stroke—Antithrombotic therapy by day [two]; (7) Ischemic stroke—Discharge on statins; (8) Ischemic or hemorrhagic stroke—Stroke education; (9) Ischemic or hemorrhagic stroke—Rehabilitation assessment; (10) VTE prophylaxis within [twenty-four] hours of

36. *Id.*

> arrival; (11) Intensive Care Unit VTE prophylaxis; (12) Anticoagulation overlap therapy; (13) Platelet monitoring on unfractionated heparin; (14) VTE discharge instructions; (15) Incidence of potentially preventable VTE.[37]

2. Stage 2 Benchmarks

In 2014, Stage 2 guidelines and requirements to obtain certified EHR status were implemented.[38] Stage 2 compliant EHR systems include all Stage 1 objectives and increase the requirements to twenty clinical functions, as follows: Three optional functions, nine care coordination functions including one optional function, three clinical quality measures, nine privacy and security functions including one optional function, seven patient engagement functions, four utilization functions, and three optional transport methods for electronic data, as follows:[39]

Chart III—STAGE 2 OBJECTIVE SUMMARIES[40]

- **EP Stage 2 Core Objectives**:

> (1) Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders; (2) Generate and transmit permissible prescriptions electronically (eRx); (3) Record demographic information; (4) Record and chart changes in vital signs; (5) Record smoking status for patients [thirteen] years old or older; (6) Use clinical decision support to improve performance on high-priority health conditions; (7) Provide patients the ability to view online, download and transmit their health information; (8) Provide clinical summaries for patients for each office visit; (9) Protect electronic health information created or maintained by the Certified EHR Technology; (10) Incorporate clinical lab-test results into Certified EHR Technology; (11) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach; (12) Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care; (13) Use certified EHR technology to identify patient-specific education resources; (14) Perform medication reconciliation; (15) Provide summary of care record for each transition of care or referral; (16) Submit electronic data to immunization registries; (17) Use secure electronic

37. *Id.*
38. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., STAGE 2 OVERVIEW TIPSHEET 1 (2012).
39. *See id.* at 8–9.
40. *Id.* at 8.

messaging to communicate with patients on relevant health information.[41]

- **EP Stage 2 Menu Objectives**: (1) Submit electronic syndromic surveillance data to public health agencies; (2) Record electronic notes in patient records; (3) Imaging results accessible through CEHRT; (4) Record patient family health history; (5) Identify and report cancer cases to a State cancer registry; (6) Identify and report specific cases to a specialized registry (other than a cancer registry).[42]

- **Hospital Stage 2 Core Objectives**: (1) Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders; (2) Record demographic information; (3) Record and chart changes in vital signs; (4) Record smoking status for patients [thirteen] years old or older; (5) Use clinical decision support to improve performance on high-priority health conditions; (6) Provide patients the ability to view online, download and transmit their health information within 36 hours after discharge; (7) Protect electronic health information created or maintained by the Certified EHR Technology; (8) Incorporate clinical lab-test results into Certified EHR Technology; (9) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach; (10) Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate; (11) Perform medication reconciliation; (12) Provide summary of care record for each transition of care or referral; (13) Submit electronic data to immunization registries; (14) Submit electronic data on reportable lab results to public health agencies; (15) Submit electronic syndromic surveillance data to public health agencies; (16) Automatically track medications with an electronic medication administration record (eMAR).[43]

- **Hospital Stage 2 Menu Objectives**: (1) Record whether a patient [sixty-five] years old or older has an advance directive; (2) Record electronic notes in patient records; (3) Imaging results accessible through CEHRT; (4) Record patient family health history; (5) Generate and transmit permissible discharge

41. *Id.*
42. *Id.*
43. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 38, at 9.

prescriptions electronically (eRx); (6) Provide structured electronic lab results to ambulatory providers.[44]

3. Stage 3 Benchmarks

Stage 3's main goal is to promote interoperability among various care providers within the health care industry.[45] Beginning with the 2019 calendar year, all EHR technology must comply with the 2015 Edition Certified EHR Criteria.[46] This stage seeks to improve interoperability by adopting new and updated vocabulary and content standards for the structured capture and exchange of health information.[47] Additionally, the new stage adopts a Common Clinical Data Set and a Consolidated Clinical Document Architecture to ensure that data is consistently available immediately when needed.[48] Patients are also provided with enhanced abilities to choose how they access and share their electronic health information.[49] The goal of these additional requirements is to make interactions between multiple care providers and patients run more efficiently.[50] All necessary personnel need to be able to access important health records to treat patients.[51] A professional's ability to quickly share and view up-to-date patient records through this interoperability and advanced technology should result in higher quality of care and better patient outcomes.[52] Stage 3 implementation also made a number of changes to the HIPAA Privacy Rule in the context of Comprehensive EHR systems, which we consider in the next Section.[53]

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44. *Id.*

45. *See* ELISE SWEENEY ANTHONY & MICHAEL L. LIPINSKI, THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., 2015 EDITION FINAL RULE: OVERVIEW OF THE 2015 EDITION HEALTH IT CERTIFICATION CRITERIA & ONC HEALTH IT CERTIFICATION PROGRAM PROVISIONS 2 (2015).

46. 45 C.F.R. § 170.315 (2019); CTRS. FOR MEDICARE & MEDICAID SERVS., 2019 PROMOTING INTEROPERABILITY PROGRAMS: 2015 EDITION CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY FACT SHEET 1 (2019).

47. Bekah Witten, *The HITECH Act and Electronic Health Records*, USF HEALTH (Feb. 13, 2018), http://www.health.usf.edu/is/blog/2018/02/13/the-hitech-act-and-electronic-health-records.

48. *Id.*

49. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 46, at 1.

50. *See* Witten, *supra* note 47.

51. *See id.*

52. *See id.*

53. *See id.*; Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. 5565, 5566 (Jan. 25, 2013) (codified as amended at 45 C.F.R. § 164.524); discussion *infra* I.C.

C. *HITECH Revisions to EHR and HIPAA Compliance*

Since 1996, the HIPAA has regulated the flow and access to health care information.[54] Stage 3 of the HITECH Act imposed four changes to the HIPAA, including: (1) revisions to the HIPAA Privacy Rule for individual's access to EHR; (2) modification to the Breach Notification Rules; (3) modification of the Privacy, Security, and Enforcement Rules to improve enforcement and strengthen privacy and security protections; and (4) other changes to Department of Health's general authority under HIPAA.[55] These rule changes were designed to "increase workability and flexibility, decrease burden, and better harmonize [compliance] requirements with . . . other Departmental regulations."[56] The first three of these rule changes have the most direct impact on EHR adoption, and we consider each in turn.[57]

1. Privacy Rule Modifications for Individual Access

Section 164.524 of the Privacy Rule was modified to incorporate "[a]ccess of individuals to protected health information."[58] Section 13405(e) of the HITECH Act strengthened the privacy right of access for individuals with respect to entities that incorporate EHR technology.[59] Patients now have the right to obtain a copy of their patient health information in an electronic format, and direct its transmission to any designated third party.[60] The EHR entity may direct the health information electronically to the individual's designee, "provided that [the individual's] choice [of designee]

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54. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5567.

55. *Id.* at 5566; Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, §§ 13401–13411, 123 Stat. 226, 246 (2009) (codified as amended in scattered sections of 42 U.S.C.).

56. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5566.

57. *Id.* at 5566, 5631.

58. 45 C.F.R. § 164.524 (2019); *see also* 42 U.S.C. § 17935(e) (2018); Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5566, 5631.

59. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5631; Health Information Technology for Economic and Clinical Health Act § 13405(e); *see also* 42 U.S.C. § 17935(e).

60. 42 U.S.C. § 17935(e); 45 C.F.R. § 164.524; Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5634. When an individual requests EHR, the request must formally be made in writing, signed by the individual. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5634–35. The Privacy Rule already permits electronic signatures to qualify as written documents. *Id.*

is clear, conspicuous, and specific."[61] Section 13405(e) of the HITECH Act also specifies that the fee to provide the electronic health information shall not exceed the cost of labor in responding to the individual's request.[62] The EHR entity must provide the individual with access to electronic information in a format that is readily produced and accessible, or an agreed-upon format between the entity and the individual.[63] The readily produced format is not specified, but HIPAA provides examples such as PDF, MS Word, Excel, text, and HTML.[64]

2. Breach Notification Modifications

In the event of a breach, the HITECH Act requires EHR entities to notify the affected individuals and the Secretary of the United States Department of Health & Human Services ("HHS").[65] The HITECH Act increased the standard for notifying individuals of security and privacy compromises of their protected health information.[66] The new standard requires notification of "significant risk of financial, reputational, or other harm to the individual."[67] The prior standard was a general unauthorized disclosure of information.[68]

3. Security Standards

To ensure that an EHR system is secure, the HHS suggests three measures to include: Access control, encryption, and an audit trail.[69] HHS recommends limiting access through the use of passwords and pin numbers

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61. 42 U.S.C. § 17935(e); 45 C.F.R. § 164.524.

62. Health Information Technology for Economic and Clinical Health Act § 13405(e); *see also* 42 U.S.C. § 17935(e).

63. Health Information Technology for Economic and Clinical Health Act § 13405(e).

64. *Id.*; Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5631.

65. 42 U.S.C. § 17932 (2018); Health Information Technology for Economic and Clinical Health Act § 13407; Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5638.

66. Health Information Technology for Economic and Clinical Health Act § 13407; Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5638–39.

67. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5639.

68. *See id.*

69. U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE FOR CIVIL RIGHTS, PRIVACY, SECURITY, AND ELECTRONIC HEALTH RECORDS 2. As we established in Part II, Blockchain readily satisfies all of these operant conditions. *See* Miliard, *supra* note 10; discussion *supra* Part II.

so only authorized personnel can access the protected health information.[70] EHR data should be maintained in an encrypted state so that access is limited to authorized personnel with a decryption key.[71] Active monitoring of persons accessing, altering or modifying the records, provides an audit trail.[72]

D. *The Medical Information Commons*

In 2011, the National Academy of Sciences and the National Research Council produced a detailed report titled, *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease* (the "Report").[73] In response to the United States and other international efforts to incentivize adoptions of EHR systems to improve clinical care and patient outcomes, the Report outlines goals and guidelines to create and implement a medical information commons and knowledge network for biomedical research.[74] The information commons will provide significant cost advantages by reducing research time, advancing clinical care, and accelerating the implementation of EHR, increasing EHR functionality, and providing a more expansive database of genomic information.[75] A database of such complexity would provide physicians with an immense network of easily accessible and expansive research.[76]

The Report outlines the proposed structure of the medical information commons within the Report.[77] The information commons would create a unified system of biomedical research accessible through EHR.[78] The information commons structure should be: (1) multilayered; (2) patient-centric; (3) highly interconnected; (4) flexible; and (5) widely accessible.[79] One of the key features the information commons must incorporate is a continuous validation system, which means that the system must be able to identify if clinical data, results, and hypotheses have been confirmed successfully by other sources.[80] The presence of a continuous validation system will enable physicians to learn about successful studies that relate to

70. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 69, at 2.
71. *Id.*
72. *Id.*
73. NAT'L RESEARCH COUNCIL, *supra* note 8, at 1.
74. *Id.* at 29–30.
75. *Id.* at 30–32.
76. *Id.* at 30–31.
77. *Id.* at 50.
78. *See* NAT'L RESEARCH COUNCIL, *supra* note 8, at 50.
79. *Id.* at 50–53.
80. *See id.* at 56.

their patients' symptoms and provide immediate possible treatment plans and predictive outcomes.[81]

The practicality of implementing an information commons is not without certain limitations.[82] As we address in the next Section, there is institutional resistance toward nascent, advanced technologies, and the information compiled would be on a massive scale and timely to compile.[83] The complexity and accessibility of centralized patient health information poses serious privacy and HIPAA risks.[84] Given recent data security breaches at Equifax and Facebook, public concern over information security is increasing.[85] Privacy information regarding patients' personal, financial, and health information is of the utmost importance, and should remain confidentially secured.[86] A medical information commons system should incorporate systems of accountability, in addition to the sanctions imposed by HIPAA for the misuse of protected health information.[87] The large amounts of data collected and stored in a medical information commons are ripe for abuse, consisting primarily of valuable aggregated clinical data and results from patients who have claims in ownership rights to their protected health and genomic information and privacy rights in protecting that information.[88]

E. *Socioeconomic Failings of Existing EHR Systems*

While EHR adoption should translate directly into tangible cost savings to institutions and better patient outcomes, these predictions have failed in practice.[89] Many EHR adopting care providers experienced

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81. *See id.*

82. *See id.* at 78.

83. *See* NAT'L RESEARCH COUNCIL, *supra* note 8, at 60, 69; discussion *infra* Section II.E.

84. *See* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. 5565, 5570, 5581–82 (Jan. 25, 2013) (codified as amended at 45 C.F.R. § 164.524); NAT'L RESEARCH COUNCIL, *supra* note 8, at 67–68.

85. Amy L. McGuire et al., *Importance of Participant-Centricity and Trust for a Sustainable Medical Information Commons*, 47 J.L. MED. & ETHICS 12, 18 (2019).

86. *Id.*; Amy L. McGuire et al., *Who Owns the Data in a Medical Information Commons*, 47 J.L. MED. & ETHICS 62, 67 (2019).

87. *See* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5582; McGuire et al., *supra* note 85, at 18.

88. *See* McGuire et al., *supra* note 86, at 64 (expanding on the legal perspectives on data ownership of medical records and genetic and genomic data).

89. Dranove et al., *supra* note 1, at 6, 8. As explained in a 2012 National Bureau of Economic Research report:

> Nearly all of the information collected by EMR already resides in hospital billing and medical records departments and in physicians' offices. EMR automates the collection and reporting of this information, including all diagnostic information,

increases in information management costs, decreases in patient satisfaction, and marginal gains in patient outcomes post-implementation.[90] These failures are caused by a number of factors, including: Technological barriers, institutional resistance to investments, limited capital for investments, and the skill and supply of the local information technology labor market.[91]

The implementation of a robust EHR system also raises a number of other public policy considerations recognized as important by Congress, such as:

> [F]urthering the availability of electronic health information as needed for authorized and important purposes; protecting and promoting patient safety; maintaining the privacy and security of electronic health information; and protecting the legitimate economic interests and incentives of providers, developers, and other market participants to innovate and compete in ways that ultimately enhance technology, [health care], and consumer health and welfare.[92]

It is important, however, to distinguish between economic or technical barriers to interoperability and concerted *information blocking*.[93] Firms may capture monopolistic or oligopolistic rents in the provision or utilization of

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> test results, and services and medications received by the patient. EMR can also link this information to administrative data such as insurance information, billing, and basic demographics. EMR can reduce the costs and improve the accuracy of this data collection. Two components of EMR, Clinical Decision Support Systems and Computerized Provider Order Entry, use clinical data to support clinical decision making . . . . If implemented in ideal conditions and executed according to the highest standards, EMR can reduce personnel costs while facilitating more accurate diagnoses, fewer unnecessary and duplicative tests, and superior outcomes with fewer costly complications.

Id.

90. *Id.* at 3, 12. "We find that hospitals that adopted EMR between 1996 and 2009 did not experience a statistically significant decrease in costs on average. In fact, under many specifications, costs rose after EMR adoption, particularly for the more advanced EMR systems." *Id.* at 3.

91. *Id.* at 2. "EMR adoption is not correlated with unobservable cost factors that are differentially trending in hospitals with locally available complementary inputs relative to hospitals that lack these inputs." Dranove et al., *supra* note 1, at 2.

92. OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH & DEP'T OF HEALTH & HUMAN SERVS., 2015 REPORT TO CONGRESS ON HEALTH INFORMATION BLOCKING 11–12 (2015).

93. *Id.* at 11–12. "Information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information." *Id.* at 11. Improper or unlawful information blocking requires a knowing act of interference with an authorized persons access to information without a reasonable justification for doing so. *Id.*

EHR systems.[94] To that extent, we focus on overcoming economic and technical barriers, empowering patient's participation, and improving patient outcomes through technological solutions, and not on solving systemic failures in polity, or correcting or punishing rent-seeking behavior by entrenched market participants.[95]

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94. *Id.* at 13; *see also* Adam Hayes, *Economic Rent*, INVESTOPEDIA (Aug. 12, 2019), http://www.investopedia.com/terms/e/economicrent.asp. "Monopoly rent refers to the situation wherein a monopoly producer lacks competition and thus can sell its goods and services at a price far above the otherwise competitive market price would be — at the expense of consumers." Hayes, *supra*. A 2015 report by the Office of the National Coordinator for Health Information Technology on Health Information Blocking identified a number of economic practices that may exploit interoperability failings to reap anticompetitive profits, such as:

> ▪ Contract terms, policies, or other business or organizational practices that restrict individuals' access to their electronic health information or restrict the exchange or use of that information for treatment and other permitted purposes.
>
> ▪ Charging prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.
>
> ▪ Developing or implementing health IT in non-standard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially when relevant interoperability standards have been adopted by the Secretary.
>
> ▪ Developing or implementing health IT in ways that are likely to *lock in* users or electronic health information; lead to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health IT-enabled care delivery.

OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. & DEP'T OF HEALTH & HUMAN SERVS., *supra* note 92, at 13. Ultimately, market failures created by concerted information blocking in EHR systems provision may require regulatory or enforcement action. *See* Lucia Savage et al., *Digital Health Data and Information Sharing: A New Frontier for Health Care Competition?*, 82 ANTITRUST L.J. 593, 595 (2019).

> [I]f firms perceive that control of these data confer competitive advantage, they will be reluctant to share the data with rivals, even if sharing the data likely enables better care to be delivered to patients. Holding on to data may allow market participants to maintain, and in some cases enhance, their market position. *[D]ata blocking* is already a barrier to choose and competition and can make it difficult for new innovative organizations to successfully enter health care markets and compete.

Id.

95. *See id.* at 595; OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. & DEP'T OF HEALTH & HUMAN SERVS., *supra* note 92, at 11; Hayes, *supra* note 94. While we propose several ways blockchain technologies may overcome some anticompetitive information behavior problems, an in-depth discussion of antitrust law and its relations to these topics are beyond the scope of this Article. *See* OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO TECH. & DEPT. OF HEALTH & HUMAN SERVS., *supra* note 92, at 11; Savage et al., *supra* note 94, at 615–19 (suggesting FTC, DOJ, and OHS market interventions to disincentivize health care providers from engaging in anticompetitive information blocking); Hayes, *supra* note 94.

Existing EHR systems are technologically cumbersome and institutionally segregated, depriving health care professionals and patients access to an integrated and universal system of patient records.[96] EHR systems were originally built for billing purposes, not for research, quality of care, or patient outcomes.[97] As a result, competing institutions are reluctant or disincentivized to engage in information sharing with each other due to technological constraints or anticompetitive information blocking.[98] Coordination problems arise as a result of anticompetitive incentives and technological barriers created by existing systems designed to maintain patient data in centralized repositories.[99] Further, many of the inflexible certified EHR requirements found in ARRA impose heavy administrative burdens on care providers in that they provide little discretion in implementation of data inputs that may have little to no relevancy to patient outcome.[100] As one commentator notes, "EHR vendors will be creating features that will most likely benefit the non-EHR user. For instance, a complex immunization system for a nephrologist who most likely only administers a seasonal flu shot. Who benefits from that?"[101]

The lack of a unified lifetime patient medical history often necessitates practitioners reconstruction of medical histories from incomplete data sourced from the patient's imperfect oral recollection and a variety of

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96. *See* Rebecca Angeles, *Blockchain-Based Healthcare: Three Successful Proof-of-Concept Pilots Worth Considering*, J. INT'L TECH. OF INFO. MGMT., Jan. 1, 2019, at 47, 50. Nearly half of reporting United States clinicians have no access to complete patient histories, and patients report difficulty to have an integrated summary of their medical histories. *Id.* Institutional segregation of access to records can also result in concerted information blocking for intentional or unintentional anticompetitive purposes. *Id.*; Yanamadala et al., *supra* note 4, at 5.

97. Yanamadala et al., *supra* note 4, at 5; *see also* William R. Hersh et al., *Caveats for the Use of Operational Electronic Health Record Data in Comparative Effectiveness Research*, 51 MED. CARE S30, S31 (2013).

98. OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. & DEP'T OF HEALTH & HUMAN SERVS., *supra* note 92, at 11–12.

99. *Id.*

100. *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §1, 123 Stat. 115, 115 (2009) (codified as amended at 16 U.S.C. §§ 2601–2645); Diana Strubler, *Regulation vs Innovation: The Battles of a Certified EHR in a Meaningful Use World*, ACUMEN PHYSICIAN SOLUTIONS: BLOG (May 11, 2015), http://www.acumenmd.com/blog/regulation-vs-innovation-the-battles-of-a-certified-ehr-in-a-meaningful-use-world/.

> [T]he heavy burden may 'stifle innovation in our country and reduce the global competitiveness for the entire United States Health IT industry by over-regulating features and functions with complicated *requirements* that only apply to CMS and [United States] special interests. And that the criteria are only designed to 'accrue benefits to people who aren't feeling the opportunity cost.

Strubler, *supra*.

101. *Id.*

previous treating facilities (usually reliant upon the patient's memory of their various historical primary health care providers, treating hospitals, and specialty providers).[102] Existing EHR platforms were not designed with management of interoperable, multi-institutional, lifetime medical records in mind.[103] Accuracy of redundant EHR is further complicated by the HIPAA Privacy Rule, which allows providers sixty days to respond to requests to update or remove erroneous delays.[104] This two month lag time in data correction can cause cascading problems in resolving errors in patient health information accuracy.[105]

Further problems arise in exploiting patient health information for clinical research.[106] An estimated half of all clinical trials are unreported, stunting the growth of aggregated knowledge capital, which in turn dampens the progression of potentially life-saving scientific research utilizing advanced data mining techniques.[107] Even upon updating patient health information, there are little to no technological systems that maintain or seek additional updates to the data set beyond the recreation of the file on a specific date or provide mechanisms for detecting and correcting data errors within existing systems.[108] As a result, most patient histories quickly become fully or partially outdated without constant reevaluation of voluminous amounts of diagnostic, treatment, preventative, curative, or genomic updates to the patient's medical history.[109]

The economic costs of implementing and maintaining existing EHR systems are staggering.[110] Industry studies suggest that existing EHR systems have generally struggled to realize significant cost savings for practitioners and health care providers.[111] A 2015 study by the Center for

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102. Lise Poissant et al., *The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review*, 12 JAMIA 505, 505–06 (2005).

103. Hersh et al., *supra* note 97, at S30–S37; Yanamadala et al., *supra* note 4, at 1.

104. ARIEL EKBLAW ET AL., A CASE STUDY FOR BLOCKCHAIN IN HEALTHCARE: "MEDREC" PROTOTYPE FOR ELECTRONIC HEALTH RECORDS AND MEDICAL RESEARCH DATA 2 (2016); *see also* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. 5565, 5565 (Jan. 25, 2013) (codified as amended at 45 C.F.R. § 164.524).

105. EKBLAW ET AL., *supra* note 104, at 2.

106. *Id.*

107. Angeles, *supra* note 96, at 52.

108. *Id.* at 60.

109. *Id.* at 50–51.

110. *Id.*

111. *See* Dranove et al., *supra* note 1, at 29.

> After three years, hospitals in IT-intensive locations experience a (significant) 3.4 [%] decrease in costs after adopting basic EMR, and a marginally significant 2.2 [%] decrease in costs after adopting advanced EMR. These benefits are greatest in locations with a large number of HIT workers, though the benefits of

Medicare and Medicaid services found that implementation of basic EHR systems costs a single physician approximately $163,765.[112] The average cost of adoption of a new EHR system for an urban hospital has been estimated in the 3 to 9 million dollar range, with estimates of $700,000 to $1,000,000 in annual maintenance costs and nearly 70,000 hours in information technology labor.[113] Many early adopters of EHR systems did not experience statistically significant decreases in costs on average, and in some cases, costs rose after early EHR adoption.[114] It has also been estimated that EHR data breaches have cost the health care industry $50.6 billion between 2009 and 2015.[115]

Existing EHR systems have also, at times, negatively impacted patient treatment and physician quality of life as well.[116] EHR usage has been found to adversely affect time allocation for patient visits, lower overall patient satisfaction with their health care providers, and increase physician error risk.[117] A 2017 survey of family physicians found that 44.6% thought they spent an excessive or moderately high amount of time working on EHR files at home.[118] A survey of ophthalmologists reported spending a mean time of four hours, or twenty-seven percent of their day, inputting data into their practice's EHR system, reducing their patient interaction time.[119] The

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> IT-intensive locations likely extend beyond local expertise in hospital IT. In contrast, hospitals in other locations experience an increase in costs, even after several years.

Id.

112. Tara O'Neill Hayes, *Are Electronic Medical Records Worth the Costs of Implementation?*, AM. ACTION F. (Aug. 6, 2015), http://www.americanactionforum.org/research/are-electronic-medical-records-worth-the-costs-of-implementation/.

113. Dranove et al., *supra* note 1, at 7; Strubler, *supra* note 100.

114. Dranove et al., *supra* note 1, at 3. The authors of this survey suggest that these implementation costs are often abated by the strength of the local information technology markets. *Id.*

> [H]ospitals in IT-intensive markets enjoyed a statistically significant 3.4 [%] decrease in costs from three years after adoption of basic EHR and a marginally significant 2.2 [%] decrease in costs from three years after adoption of advanced EHR. These results are significantly better than the up to 4 percent *increase* in costs after adoption by hospitals in other markets.

Id.

115. Hayes, *supra* note 112.

116. *See id.*

117. Neda Ratanawongsa et al., *Multitasking and Silent Electronic Health Record Use in Ambulatory Visits*, 177 JAMA INTERNAL MED. 1382, 1382 (2017).

118. Monee Rassolian et al., *Workplace Factors Associated with Burnout of Family Physicians*, 177 JAMA INTERNAL MED. 1036, 1037 (2017).

119. *See* Sarah Read-Brown et al., *Time Requirements for Electronic Health Record Use in an Academic Ophthalmology Center*, 135 JAMA OPHTHALMOLOGY 1250, 1254 (2017); *see also* Poissant et al., *supra* note 102, at 505 (finding an increase of 98.1% to

billing and compliance focus of existing EHR systems has resulted in physicians reporting widespread dissatisfaction with existing EHR systems from burnout and a lack of patient first focus in existing architectures.[120]

Worse, existing EHR systems have had either little or negative effects on improving patient outcomes.[121] A 2016 survey published in the Baltimore Journal of Medicine analyzed "patient outcomes, across six large [and] diverse states for . . . medical and surgical care."[122] The survey focused on "inpatient mortality, thirty-day all cause readmission rates, [patient safety indicators], and length of stay."[123] The survey failed to find improvements in patient outcomes based on EHR implementation, concluding that:

> Although EHRs have been extremely helpful for billing and physician compliance measurements, direct improvement of important patient outcomes have yet to be seen. A possible reason for this is that EHRs thus far have largely served as a recording mechanism after a patient care intervention rather than as an effective checking mechanism during the actual execution phase of patient care interventions. It has also been shown that while basic EHRs are associated with gains in quality measures, less benefit is associated with implementing advanced EHRs, suggesting that initial adoption of EHRs may actually be counterproductive by adding additional complexity into clinical settings. Additionally, such improvements have yet to be translated to improvements in mortality. Lack of improvement in other patient outcome measures has also been demonstrated. For example, [one] study demonstrated that although EHRs were associated with better rates of cholesterol testing, this did not translate to improvements in patients' actual cholesterol levels. In another study of ambulatory diabetes care in clinics with and without EHRs, patients at EHR enabled clinics actually did worse in rates of meeting [two] year hemoglobin A1c, cholesterol, and blood pressure goals.

328.6% of physicians time per working shift in data entry into an EHR computerized provider order entry system).

120. *Cost Is Biggest Barrier to Electronic Medical Records Implementation, Study Finds*, COMMONWEALTH FUND, (Sept. 19, 2005), http://www.commonwealthfund.org/publications/newsletter-article/cost-biggest-barrier-electronic-medical-records-implementation.

121. *See* Yanamadala et al., *supra* note 4, at 2.

122. *Id.* at 3. The survey "utilized discharge data from the 2011 State Inpatient Databases (SID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality from Arkansas, California, Florida, Massachusetts, Mississippi, and New York." *Id.* at 2; Donna P. Manca, *Do Electronic Medical Records Improve Quality of Care?*, 61 CANADIAN FAM. PHYSICIAN, 846, 846 (2015).

123. Yanamadala et al., *supra* note 4, at 2.

> Furthermore, data suggest that EHR implementation may actually increase the amount of time spent by patients during clinic visits. These studies suggest that EHRs, with their increased documentation requirements, can have unintended consequences, including clinic inefficacy.[124]

Other barriers to interoperability dampen effective EHR implementation.[125] Existing EHR systems segregate data on competing platforms, often resulting in fragmented or overlapping and redundant data sets and thereby reducing interoperability between providers on different systems.[126] Other data fragmentation may result from the institutional learning curve experienced in adoption of nascent technologies.[127] Implementing EHR platforms require changes in policy, personnel, employee discretion, institutional knowledge and training, information support systems and management, and communications systems between employees and departments.[128] New EHR systems may include gaps in input or output systems, limiting or changing the availability of data sets once available to providers.[129] Adoption requires hardware or software systems changes, which introduce noneconomic costs in the form of delays, lag times in platform conversion, breaks or loss of interoperability, and additional administrative concerns into ongoing treatment and preventative care, the cost of which is ultimately borne by patients.[130] Further, rural areas or areas with undercapitalized labor markets in information technologies may lack necessary technological knowledge to support adoption of new systems, thereby increasing socioeconomic barriers to implementation.[131]

A new technological advancement, blockchain ledgers, offers a solution to these technological and socioeconomic problems, which we consider in the next part of this Article.[132]

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124. *Id.* at 5. The survey notes that "changes in quality of care after the implementation of EHRs may be attributable in part to non-EHR factors, which cannot be fully accounted for in our analysis." *Id.*

125. *See* Dranove et al., *supra* note 1, at 7.

126. *Id.* at 6–7.

127. *Id.* at 13.

128. *Id.* at 9–10.

129. *See id.* "[A]t one ophthalmology unit at a teaching hospital, the physicians could not find a way to put their traditional *hand-drawings* into the new formats. They found that the new electronic formats sometimes reduced the richness of the information they could record." Dranove et al., *supra* note 1, at 10–11.

130. *See id.* at 11, 13.

131. *See id.* at 12.

132. *See* Allison Berke, *How Safe Are Blockchains? It Depends*, HARV. BUS. REV. (Mar. 7, 2017), http://www.hbr.org/2017/03/how-safe-are-blockchains-it-depends.

III. A NEW MODEL: PATIENTS AS PEERS

A. *Blockchain Basics*

There is no agreement as to what constitutes a blockchain, as blockchain ledgers have multiple optional functionalities.[133] Broadly speaking, blockchain is a type of distributed ledger that has certain definable technological components.[134] A distributed ledger is a computerized record that is stored on a peer-to-peer computer network.[135] What is novel about blockchain ledgers are the technological components that maintain, input, update, and utilize the ledger data.[136]

These technological components include: A distributed and decentralized digital ledger or database in which blocks of data are shared between a network of peer-to-peer computers; the digital ledger or database data is distributed on a public or private computer network; the chain of blocks are uniformly ordered and chronological in nature; the records are either immutable or substantially immutable; the records are redundantly maintained and processed by a consensus of the networked public or private computers in the chain to guarantee the consistency and nonrepudiation of the recorded transactions or other data; and the ledger's immutability is maintained by cryptographically policing the ability to alter informational content in the blockchain.[137]

Access to a blockchain requires a public key, which is shared by users (those uploading data and those accessing data) on the network, and a private key which is used by the patient.[138] These keys may be passwords, two-factor authentication access, or decryption controls.[139]

Blockchain is a novel general-purpose database system, with applications beyond commonly known applications like cryptocurrency.[140] The technological operations of a blockchain-based record system offer

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133. HEALTHCARE INFO. & MGMT. SYS. SOC'Y, CONSIDERATIONS FOR POLICYMAKERS: THE APPLICATION OF BLOCKCHAIN TECHNOLOGY IN HEALTHCARE 1 (2019); *see also* WILLIAM BIBLE ET AL., BLOCKCHAIN TECHNOLOGY AND ITS POTENTIAL IMPACT ON THE AUDIT AND ASSURANCE PROFESSION 8 (2017).

134. HEALTHCARE INFO. & MGMT. SYS. SOC'Y, *supra* note 133, at 1; Kuo et al., *supra* note 3, at 1212–15.

135. Kuo et al., *supra* note 3, at 1212–13; Berke, *supra* note 132.

136. *See* Kuo et al., *supra* note 3, at 1212; Berke, *supra* note 132.

137. *See* Kuo et al., *supra* note 3, at 1212; Berke, *supra* note 132.

138. *See* Tanya, *Public and Private Keys*, BLOCKCHAIN SUPPORT CTR. (Jan. 6, 2020, 2:27 PM), http://support.blockchain.com/hc/en-us/articles/360000951966-Public-and-private-keys. "[P]ublic keys . . . are publicly known and essential for identification, and private keys . . . are kept secret and are used for authentication and encryption." *Id.*

139. *See id.*

140. BIBLE ET AL., *supra* note 133, at 8.

several benefits over traditional database management systems.[141] These benefits, in turn, incentivize interested stakeholders to behave differently in their interactions with the data stored on the blockchain ledger.[142] Data on a blockchain ledger is not stored in a centralized location but, rather, is distributed on a peer-to-peer network of individual nodes.[143] Each node must reach agreement at a certain level of predefined consensus before changes can be appended to the blockchain ledger.[144] This agreement is reached through advanced mathematical calculations utilizing encryption protocols which confirm that a record is what a particular node says it is.[145]

A blockchain ledger stores a permanent, unalterable, and indelible historical record of every transaction recorded on the blockchain.[146] This immutability reduces the ability for single actors to commit fraud against the ledger, and automates the creation of an audit trail.[147] Trust in a blockchain ledger is disintermediated and distributed among the nodes that maintain the ledger records.[148] Put differently, trust in a traditional database is inherent in the institution that maintains the database.[149] Blockchain ledgers however, incentivize independent nodes to maintain the accuracy of the ledger for the node operator's benefit.[150] Finally, the records stored on a blockchain ledger are *pseudo-anonymous*, in that the identity of private keys is kept anonymous from the other nodes on the ledger.[151]

It is important to distinguish the decentralized structure of a blockchain ledger, and the centralized structure of a traditional database platform from social, and institutional controls over a blockchain ledger.[152] We are not arguing that health care records should never be stored on a publicly accessible blockchain ledger.[153] Rather, we propose that vetted and qualified institutions can be granted permissioned access to a blockchain-based EHR system, or medical information commons.[154]

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141. *See id.*
142. Berke, *supra* note 132.
143. *Id.*
144. *Id.*
145. *See* Emily Kotow, *What Is Blockchain Hashing?*, HEDGETRADE (Feb. 26, 2019), http://www.hedgetrade.com/what-is-blockchain-hashing/.
146. Kurt Yaeger et al., *Emerging Blockchain Technology Solutions for Modern Healthcare Infrastructure*, J. SCI. INNOVATION MED., Jan. 24, 2019, at 1, 4.
147. *Id.* at 2–4.
148. *Id.* at 4.
149. *See id.*
150. *See id.*
151. Yaeger et al., *supra* note 146, at 2–5.
152. *See* Kotow, *supra* note 145.
153. *See* Yaeger et al., *supra* note 146, at 2–3.
154. *See id.*

B. *Beneficial Modalities of Blockchain Based EHR*

1. Security, Privacy, HITECH, and HIPAA Compliance

Blockchain based EHR offers five key benefits over traditional database management systems, such as Structured Query Language ("SQL") systems like Oracle, and open source NoSQL databases systems like Apache Cassandra.[155] First, decentralizing management of the database from a single institution or entity disincentives information blocking and anticompetitive rent-seeking behavior, as we discussed in Section II.D.[156] Second, the creation of an immutable audit trail eliminates the risk of institutional or individualized fraud against the ledger's records.[157] Third, data provenance allows ownership and control of records to be altered only by the exact authorized person to do so, either the patient or the treating physician, while automatically maintaining a record trail of the author of the change.[158] Fourth, blockchain-based EHR offers robustness and availability, in that the underlying distributed ledger eliminates virtually all single-points-of-failure inherent in traditional database systems, either in the form of data loss at the sole storage point, breach in access to the patient's EHR, or in abuse of the authorization to make alterations to the patient's EHR.[159] Finally, there are significant security gains realized by implementing 256-bit SHA asymmetrical encryption over traditional security architecture to protect access, and verify permission to any blockchain-based EHR system.[160]

Blockchain, by virtue of its technological nature, already complies with the HITECH incentives reporting requirements, HHS's certified EHR security standards, and HIPAA in most respects.[161] The immutable nature of a blockchain ledger provides a consistent and redundant audit trail for reporting compliance.[162] Blockchain systems generally rely on asymmetric

155. Kuo et al., *supra* note 3, at 1214.

156. *See id.* at 1214; discussion *supra* Section II.D.

157. Kuo et al., *supra* note 3, at 1214.

158. *Id.*

159. *Id.* at 1211–12, 1214.

160. Kotow, *supra* note 145.

161. Howard Burde, *The HITECH ACT — an Overview*, 13 AMA J. ETHICS 172, 172–73 (2011); *Certified EHR Technology*, CENTERS FOR MEDICARE & MEDICAID SERVICES: REGULATIONS & GUIDANCE, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification (last updated Mar. 22, 2020); *Summary of the HIPAA Security Rule*, U.S. DEP'T HEALTH & HUM. SERVICES (July 26, 2013), http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html.

162. *See* BIBLE ET AL., *supra* note 133, at 9–10. "[A] transaction recorded in a blockchain may still be: unauthorized, fraudulent or illegal; executed between related parties; linked to a side agreement that is *off-chain*; [or] incorrectly classified in the financial statements." *Id.* at 10.

encryption based on SHA-256 hash functions designed by the National Security Agency, which is *considerably* harder to compromise than traditional computer passwords.[163]

These technological components offer a way for care providers to comply with the Stage 3 objectives of the HITECH Act and the privacy, security, and reporting requirements of the amended HIPAA EHR rules.[164] However, as with every secured data platform, human interaction creates fail points in blockchain security, in terms of lost, forgotten, or stolen access to the blockchain ledger.[165] As a result, a number of objections have been raised to blockchain-based EHR, which we address each in Section III.C.[166]

2. Permissioned Patient Consent and Clinical Data Mining

Additionally, there are significant potentials for improvements in patient outcome, patient satisfaction, and interoperability realized from the use of a patient permissioned EHR blockchain system.[167] An EHR blockchain system can send out auto-generated updates to individual patients about their medications and individual problems.[168] A blockchain-based EHR system offers a unique way for patients to consent to permissioned access to all or portions of their medical histories on a provider-by-provider basis.[169] An "open-source, community-wide trusted ledger" could be used such that additions and subtractions to the EHR are "well understood and auditable across [health care] organizations."[170] Since blockchain can be configured as a smart contract operable between multiple

163. *See* Kotow, *supra* note 145. "This function expresses the possible combinations or values that results from the given input data. SHA stands for *Secure Hashing Function*, and 256 expresses the numerical quantity of the fixed bit length." *Id.* For valuable blockchains, such as cryptocurrency, 2048 RSA encryption is used. *Id.*; EMERGING TECH. FROM THE ARXIV, *How a Quantum Computer Could Break 2048-bit RSA Encryption in 8 hours*, MIT TECH. REV.: TOPICS (May 30, 2019), http://www.technologyreview.com/s/613596/how-a-quantum-computer-could-break-2048-bit-rsa-encryption-in-8-hours/.

164. HITECH Act, 42 U.S.C. §§ 300jj–300jj-52 (2018); ANTHONY & LIPINSKI, *supra* note 45, at 36; *see also* Codrin Arsene, *The Global* Blockchain in Healthcare *Report: The 2019 Ultimate Guide for Every Executive*, HEALTHCARE WKLY. (Jan. 10, 2020), http://www.healthcareweekly.com/blockchain-in-healthcare-guide/.

165. *See* Berke, *supra* note 132.

166. *See* Kuo et al., *supra* note 3, at 1217; David Gerard, *Medical Records, but on the Blockchain — the History of a Bad Idea*, DAVID GERARD: BLOCKCHAIN BLOG (Apr. 20, 2019), http://www.davidgerard.co.uk/blockchain/2019/04/20/medical-records-on-the-blockchain-the-history-of-a-bad-idea/; discussion *infra* Section III.C.

167. *See* Miliard, *supra* note 10; Witten, *supra* note 47.

168. Miliard, *supra* note 10.

169. *Id.*

170. *Id.*

health care providers, the collection and integration of EHR from different databases into a single accessible database provides significant interoperability to the existing distributed and distinct EHR databases.[171] These smart contracts are implemented in the blockchain as "lines of code that define self-executing and/or self-enforcing clauses, running only if certain conditions are met" and are used to link a patient's private key to the EHR system.[172] Further, diagnostic tools and machines can be coordinated to automatically append and transmit diagnostic records and images to a patient's blockchain record.[173] Thus, the presence of smart contracts in the blockchain increases the efficiency of any patient-focused EHR blockchain system.[174]

Advancements in predictive analytics and artificial intelligence offer another developing use case for maintenance of a universal, lifetime EHR file for patients.[175] Machine learning and analytics can be added to data-mine anonymized blockchain-based EHR repositories for disease surveillance, genomic and epidemiological monitoring, prescription abuse access or other long-term treatment based on forecasting of known or unknown trending and other statistically significant data points.[176] These predictive algorithms can also be utilized to track patient outcomes across treatment groups, population demographics, treating providers or other clinical controls in real time.[177] Blockchain-based EHR, by virtue of its technological safeguards, can be utilized to anonymize portions or all of a patient's health information, at the patient's decision, so that clinicians can be limited only to relevant portions of a patient's history for mining purposes.[178]

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171. *See* Yaeger et al., *supra* note 146, at 2–3.

172. *Id.*

173. *See id.* at 5; Miliard, *supra* note 10.

174. *See* Yaeger et al., *supra* note 146, at 2; Arsene, *supra* note 164.

175. *See* Yaeger et al., *supra* note 146, at 5; Arsene, *supra* note 164; Fred Donovan, *Rensselaer Researchers Use Blockchain to Boost Medical Image Sharing*, HIT INFRASTRUCTURE (June 25, 2019), http://www.hitinfrastructure.com/news/rensselaer-researchers-use-blockchain-to-boost-medical-image-sharing.

176. *See* EKBLAW ET AL., *supra* note 104, at 10.

177. *See id.*

178. *See id.* at 8; Yaeger et al., *supra* note 146, at 5. The statistical impact on data relevancy created by patient consent to access relevant health information on clinical data mining, fragmentation caused by gaps in given consent, or transparency in the consent process is beyond the scope of this Article. *See* Shomona Gracia Jacob & R. Geetha Ramani, *Data Mining in Clinical Data Sets: A Review*, INT'L J. APPLIED INFO. SYSTEMS, Dec. 2012, at 15, 21; Miliard, *supra* note 10.

> Cios and Moore have posed a dispute that data problems in [health care] are the result of the dimensionality, intricacy and assorted nature of medical data and their low mathematical characterization and nonconformance to a certain protocol. Moreover ethical, legal and social issues encountered in CDM also have

3. Autonomous Algorithmic Fraud Accounting

Medical billing fraud can be curtailed by a system-wide, patient-centric EHR blockchain system.[179] A pharmaceutical supply blockchain can reduce counterfeit drugs introduced in the supply line because genuine drugs can be tracked from their origin to the end-user with a blockchain that lists every entity handling the pill bottles, the entity's location, and a date code.[180] Medical fraud often occurs when paper records or EHR are stolen and these medical records are used to bill for services that were never rendered, or the records are altered and fabricated medical claims are submitted to insurers using patient data as the backdrop.[181] The United States "based National Healthcare Anti-Fraud Association estimates the loss owing to [health care] fraud [is] about $80 billion annually."[182] These losses occur notwithstanding that the United States spends about twenty-percent of its GDP on health care.[183]

Basic blockchain ledgers used to track inventory in supply chains are currently used for tracking international shipments of goods, such as mangos.[184] These supply chain blockchain ledgers automatically track sourcing, shipping, and other detailed logistics data, without the need of human input.[185] A similar blockchain ledger constructed to track drugs from their point of origin to the end user and through all the transportation and warehousing points, the retail chain and ultimately to the end-user would reduce counterfeiting, diversion, and the opportunity for fraudulent billings.[186] Counterfeit drugs cost the American public around $200 billion

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> to be appropriately handled. The issue of obtaining patterns of diverse nature on exhaustive mining of data needs to be deliberated upon. Extensive research may reveal many interesting patterns and relationships not necessarily valuable.

Jacob & Ramani, *supra* at 22 (internal citations omitted).

179. *See* Yaeger et al., *supra* note 146, at 2; Miliard, *supra* note 10.

180. Yaeger et al., *supra* note 146, at 5; Matt Leonard, *SAP Debuts Blockchain Solution for Counterfeit Drugs*, SUPPLY CHAIN DIVE (Jan. 23, 2019), http://www.supplychaindive.com/news/blockchain-curtail-counterfeit-medicine.

181. *The Challenge of Health Care Fraud*, NAT'L HEALTH CARE ANTI-FRAUD ASS'N, http://www.nhcaa.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud.aspx (last visited May 1, 2020).

182. Sukant Khurana, *Blockchain for Medical Records*, MEDIUM (Apr. 22, 2018), http://www.medium.com/@sukantkhurana/blockchain-for-medical-records-4efbf625b6d4.

183. Arsene, *supra* note 164.

184. Reshma Kamath, *Food Traceability on Blockchain: Walmart's Pork and Mango Pilots with IBM*, J. BRIT. BLOCKCHAIN ASS'N, June 12, 2018, at 47, 48–49.

185. *Id.* at 49.

186. John Tilton, *What's in the Bottle? FDA Announces New Blockchain Pilot Program for Tracking Drug Distribution*, SHEPPARD MULLIN (Aug. 12, 2019),

each year.[187] A drug supply blockchain ledger would provide visibility and transparency throughout the drug supply chain which could result in reduced revenue losses by up to an estimated $43 billion annually.[188] Likewise, drug theft enabled by poor supply chain logistics or corrupt officials continues to plague under-developed nations.[189] A study by non-profit, Global Fund to Fight Aids, Tuberculosis, and Malaria revealed that between 2009 and 2011, more than $2.5 million worth of drugs had been stolen or diverted from African countries.[190] Information Communication and Technology consultant Rashid Kami, explained that "[w]e are therefore grappling with issues of people dying of Malaria not because we do not have medicine, but because of the fraud within the supply chain."[191]

Medical records could "be stored on a distributed ledger or blockchain" using Hyperledger Composer tools.[192] The patient-centric "blockchain is shared with the patient, health care provider, insurer, and the [G]overnment."[193] The Government acts as a trusted party regulator holding the EMR blockchain.[194] "When information is required, the health care provider or insurer" sends a request to the patient with "details of information to be viewed" on the EMR blockchain.[195] The patient authorizes access using his or her private key permitting the health care provider or the insurer access to the information.[196]

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http://www.sheppardhealthlaw.com/2019/08/articles/healthcare/dscsa-tracking-drug-distribution-2/.

187. Arsene, *supra* note 164.

188. *Id.*

189. *See* Tim K. Mackey et al., *The Disease of Corruption: Views on How to Fight Corruption to Advance 21st Century Global Health Goals*, BMC MED., Sept. 29, 2016, at 1, 1.

190. *AP Reports on Global Fund Malaria Drug Thefts, Issues Correction*, KAISER FAM. FOUND.: TOPICS (Apr. 21, 2011), http://www.kff.org/news-summary/ap-reports-on-global-fund-malaria-drug-thefts-issues-correction/.

191. Bob Koigi, *Tanzania's First Blockchain Baby Rubberstamps Power of Tech in Medical Care*, FAIR PLANET (June 25, 2019), http://www.fairplanet.org/story/tanzania's-first-blockchain-baby-rubberstamps-power-of-tech-in-medical-care/; *What Is an ICT Consultant?*, E2E CONSULTING, http://www.e2econsulting.co.za/faq/what-is-an-ict-consultant/ (last visited May 1, 2020).

192. Khurana, *supra* note 182.

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

4. A Blockchain Medical Information Commons

As previously addressed, patient records are often fragmented at various health care providers.[197] A patient may receive care at multiple institutions, whether in a series of treatments for a unified purpose, or for a variety of health care treatment provisions.[198] By appending these records to a unified blockchain ledger, health care providers can centralize and aggregate these records into a single, uniform medical information commons.[199]

Patients would no longer need to rely on their own memory nor coordinate and gather records from various treatment providers, but rather could give providers (and clinical data miners) an as needed, permissioned access to relevant portions of their single unified medical record.[200] A unified system would also reduce or eliminate incentives for health care providers to engage in anti-competitive information blockchain, as all would have access to the same sets of patient health information.[201]

5. Smart Contracts and Autonomous Data Collection

In 1994, Nick Szabo, a legal scholar and cryptographer, argued that decentralized ledgers could be utilized for the performance of what he termed *smart contracts*.[202] The term smart contract is a bit of a misnomer, as it is often used interchangeably to conceptualize the use of smart contracts as binding legal contracts.[203] A smart contract is any self-executing computer code that can act as a digital manifestation of a transaction between two or more parties.[204]

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197. *See* Angeles, *supra* note 96, at 50.

198. *See id.*

199. *See id.*

200. *See* Khurana, *supra* note 182.

201. *See id.*

202. *See* Jake Frankenfield, *Smart Contracts*, INVESTOPEDIA (Oct. 8, 2019), http://www.investopedia.com/terms/s/smart-contracts.asp; Nick Szabo, *Smart Contracts: Building Blocks for Digital Markets*, EXTROPY, 1996, at 50; Stefan Stankovic, *Who Is Nick Szabo, the Mysterious Blockchain Titan*, UNBLOCK (July 13, 2018), http://www.unblock.net/nick-szabo. Szabo also proposed Bit gold around this time, the conceptual predecessor to Bitcoin. Philip Moskov, *What Is Bit Gold? The Brainchild of Blockchain Pioneer Nick Szabo*, COIN CENTRAL: GUIDES (May 22, 2018), http://www.coincentral.com/what-is-bit-gold-the-brainchild-of-blockchain-pioneer-nick-szabo/. Bit gold is credited as presenting the theory of the first disintermediated digital currency. *See id.* Bit gold was never implemented. *Id.*

203. *See* Szabo, *supra* note 202.

204. Mauro Conti et al., *A Survey on Security and Privacy Issues of Bitcoin*, 20 IEEE COMM. SURVEYS & TUTORIALS 3416, 3447 (2018).

Another way to conceptualize smart contracts is that of a digital *vending machine*.[205] A vending machine is a self-contained machine that offers to enter into a certain contract with its users.[206] A group of products and prices are displayed, and, if a purchaser inserts money into the machine, the machine will automatically vend the product to the purchaser.[207] Vending machines are an existing form of an autonomous contract and have existed in one form or another since Hero of Alexandria's first century holy water vending machine.[208] In the 1980s, stock traders started utilizing automated day trading programs for securities investing.[209] By 2014, nearly seventy-five percent of all securities traded on exchanges utilized some form of automated trading system orders.[210]

By linking diagnostic technologies with a blockchain smart contract, a diagnostic smart contract can automate the appending of diagnostic data to a blockchain ledger.[211] For example, instead of having to manually enter a patient's vitals for each visit, a primary care physician's office equipped with smart-contract-enabled diagnostic equipment can rely on that equipment to automatically record a patient's weight, temperature, blood pressure, and other important but routine diagnostic information into the patient's health records.[212] Lab diagnostic and testing machines can automatically record and upload results onto the patient's history, drastically reducing physician data entry times, thereby increasing patient interaction, patient satisfaction, and physician care time.[213]

C. *Addressing Objections to Blockchain EHR*

A number of objections have been raised to utilizing a blockchain ledger to store sensitive EHR.[214] The five major ones identified or suggested by the surveyed literature include: (1) the patient's key creating a security

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205. Giulia Castellani, *Smart Contracts, Legal-Tech Professions and Civil Law Issues*, *in* LEGAL ISSUES IN THE DIGITAL ECON. 141, 142 (Valeria Fili & Federico Costantini eds., 2019).

206. *See id.*

207. *Id.*

208. *Id.*

209. JAMES W. CORTADA, THE DIGITAL HAND: VOLUME II: HOW COMPUTERS CHANGED THE WORK OF AMERICAN FINANCIAL, TELECOMMUNICATIONS, MEDIA, AND ENTERTAINMENT INDUSTRIES 173 (2005).

210. Jean Folger, *Automated Trading Systems: The Pros and Cons*, INVESTOPEDIA (May 12, 2019), http://www.investopedia.com/articles/trading/11/automated-trading-systems.asp.

211. *See* Gerard, *supra* note 166; Miliard, *supra* note 10.

212. *See* Miliard, *supra* note 10.

213. *See id.*

214. *See id.*; Gerard, *supra* note 166.

point of failure; (2) exponential data growth in a blockchain ledger could render it unusable; (3) HIPAA compliance is harder (and therefore, more expensive) when records are not centralized in a single institutional repository; (4) scalability and transactions speeds slow as more records are added to the blockchain ledger; (5) brute force attacks and other data issues pose a security threat to blockchain-based EHR.[215]

1. The Patient's Key

In an EHR blockchain system, each patient maintains their private key to operate their data stored on the blockchain.[216] There are a number of risks in traditional computer controls over the patient's key, as found in a password log in system.[217] A patient might forget his or her key.[218] They could inadvertently reset the key to an unknown key (necessitating customer support to reset the private key, representing another security risk).[219] They could become incapacitated or unable to consent to their use of the key, and the private key is forever lost, resulting in a complete loss of access to the EHR.[220] They could also unwittingly provide sensitive information to a third party through social engineering.[221] This objection is reductionist, as the problem with these types of security weaknesses, focused on single points of failure, is *not* caused by blockchain technology itself, but rather represents a long-standing problem in computer system and database management.[222]

A pending United States patent application by Walmart offers a solution to this problem in EHR systems.[223] The Walmart patent application utilizes a wearable device on the user, such as a bracelet, to capture a biometric from an unresponsive or incapacitated patient to obtain access to the patient's private key.[224] The patient's medical record is then stored on a limited access blockchain.[225] The system receives an encrypted private key and a public key associated with the patient stored on a wearable device.[226]

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215. *See* Kuo et al., *supra* note 3, at 1211–17; Gerard, *supra* note 166.
216. *See* Gerard, *supra* note 166.
217. *See id.*
218. William J. Gordon & Christian Catalini, *Blockchain Technology for Healthcare: Facilitating the Transition to Patient-Driven Interoperability*, 16 COMPUTATIONAL & STRUCTURAL BIOTECHNOLOGY J. 224, 228 (2018).
219. *See id.*
220. Gerard, *supra* note 166.
221. *See id.*
222. *See* Gerard, *supra* note 166; Miliard, *supra* note 10.
223. U.S. Pat. App. Pub. No. 2018/0167200 to High et al.
224. *Id.* at [0023], [0024].
225. *Id.* at [0028].
226. *Id.* at [0005].

The wearable device is scanned, for example, at the scene of an emergency to obtain the encrypted private key which is decrypted by a biometric signature obtained from the patient (such as a retina scan, fingerprint or other bodily feature of the patient).[227] The biometric signature is used to decrypt the encrypted private key.[228] The patient's health information is accessed using the private key and the public key obtained from the wearable device.[229] The biometric data input overcomes the human single-point of failure found in traditional computer security access systems.[230]

2. Exponential Scaling and Data Growth Externalities

Other commentators have noted that there is an enormous amount of aggregate patient data including genomic data, hospital records, immunization records, and lab results.[231] There has been an exponential explosion in the amount of digital data in the health care industry since EHR adoption began.[232] Experts estimate that each patient will add about eighty megabytes ("MB") of text data and images to the blockchain each year.[233] If a physician has one hundred patients, over a ten year period, this will equate to eighty gigabytes ("GB") of data, not accounting for new patients during the ten years.[234] Given typical patients loads and data growth, doctor groups will generate nearly a terabyte ("TB") of data in a short time period.[235] There are transactional costs which must be accounted for when each block of data is integrated into the patient-centric blockchain which include processing, encryption, data transmission, and data storage over multiple databases

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227. *Id.* at [0006].
228. High at [0006].
229. *Id.*
230. *See id.*
231. *See* Nathan Brown, *Healthcare Data Growth: An Exponential Problem*, NEXTECH: BLOG (Sept. 11, 2015), http://www.nextech.com/blog/healthcare-data-growth-an-exponential-problem; Miliard, *supra* note 10.
232. *See* Brown, *supra* note 231. In economic terms:

> As the unit cost of a good falls, demand for the good increases. Thus, even as the unit cost of computer-related work has fallen (due to productivity improvements), the demand for that work within the corporation has increased. With a price elasticity of demand greater than one, the total amount of information processing work after computerization, and its cost, can be greater than the volume and cost of information work prior to computerization. Thus, even if the unit cost of doing information work falls dramatically due to computerization, the total demand for such work, and the total cost to the corporation may increase.

Stuart Macdonald et al., *Measurement or Management?: Revisiting the Productivity Paradox of Information Technology*, 69 Q. REV. ECON. & FIN. 601, 609 (2000). This is true regardless of the underlying database technology used to store data. *See id.*
233. Brown, *supra* note 231.
234. *Id.*
235. *Id.*

forming the backbone of the blockchain.[236] Each copy of the blockchain must be maintained in a secure storage at multiple database locations.[237] There are also processing costs when various health care providers access that patient-centric blockchain associated with password (a key control), data transmission, and data storage.[238]

3. Public vs. Private Blockchain EHR Systems

Others object to utilizing blockchain for EHR data storage, suggesting that: (a) a blockchain is not designed for such large volumes of data; (b) for medical clinical studies, each patient has a unique identifier, and to access the data in each block a mechanism must be provided to redact or mask the individual's unique identifier; and (c) the anonymity of data on the blockchain does not mean that the blockchain is private only to the patient.[239]

As noted by one commentator,

> identity on blockchain tends to be anonymous but not private. What this means is that while transactions are anonymous (real identity is hidden), they are publicly recorded. Once an individual's identity is linked to a blockchain identifier, their entire history of transactions is available—which could be catastrophic for clinical data. There are mechanisms to mitigate these issues—for example, *private* blockchains that [are not] public, or storing data *off-chain*—these issues need to be addressed more fully before we see widespread EHR data sharing via blockchain.[240]

For this reason, HIPAA compliance is maintained by limiting institutional control over a health care EHR blockchain system by granting access to the underlying ledger to authorized health care providers.[241] We envision a decentralized blockchain EHR system in which each participating hospital, physician, or other authorized entity, maintains a separate computer node to maintain the blockchain ledger, but is required to gain patient permission before accessing the patient's records stored on the ledger.[242] Linking the files to permissioned access by the patient would help ensure

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236. *See* Ryan Hales Hylock & Xiaoming Zeng, *A Blockchain Framework for Patient-Centered Health Records and Exchange (HealthChain): Evaluation and Proof-of-Concept Study*, J. MED. INTERNET RES., Aug. 31, 2019 at 1, 2.

237. *See id.*

238. *Id.* at 1.

239. Miliard, *supra* note 10.

240. *Id.*

241. *See* 45 C.F.R. § 164.310 (2019); BIBLE ET AL., *supra* note 133, at 3–4; *Summary of the HIPAA Security Rule*, *supra* note 161.

242. *See* EKBLAW ET AL., *supra* note 104, at 3–4.

that only the permissioned authorized entities of the patient's choosing could access the data stored onto the blockchain ledger.[243]

4. Maintaining Anonymity and HIPAA Compliance

HIPAA requires both physical and technological safeguards.[244] A health care facility must restrict physical access to its facilities while permitting necessary authorized access.[245] Its policies and procedures must specify proper use of and physical access to workstations and electronic media.[246] HIPAA also imposes technical policies and procedures for control of access, audit, and data integrity and data transmission security.[247] For HIPAA compliance, a blockchain-based EHR can impose immutable technical policies and procedures to allow only authorized persons to access EHR systems.[248] The blockchain incorporates technologic audits monitoring hardware, software, and procedures that record access and other activity in the EHR system.[249] Data integrity controls ensure that the data blocks in the blockchain-based EHR are not improperly altered or destroyed by requiring chronological supplementation to the chain.[250] By design, the chain has built-in electronic measures to confirm that the data has not been improperly altered or destroyed.[251] Data transmission security can be embedded in the blockchain such that data passing through each router on the transmission network generates a log record in the chain.[252] All access points are similarly logged onto the blockchain ledger to guard against unauthorized access to transmitted EHR.[253]

Anonymity of unique patient data or personally identifiable information is maintained by having varying levels of authorized health care

243. *Id.* at 10.

244. *See* 45 C.F.R. § 164.310; *Summary of the HIPAA Security Rule*, *supra* note 161.

245. *See* 45 C.F.R. § 164.310.

246. *Id.* Also, policies and procedures must specify proper use of and physical access to workstations and electronic media. *Id.* These include policies regarding the transfer, removal, disposal, and re-use of electronic media, to ensure appropriate protection of EHR. *Id.*

247. *See id.*; *Summary of the HIPAA Security Rule*, *supra* note 161.

248. *See* 45 C.F.R. § 164.312 (2019); BIBLE ET AL., *supra* note 133, at 3–4; *Summary of the HIPAA Security Rule*, *supra* note 161.

249. *See* 45 C.F.R. § 164.312; BIBLE ET AL., *supra* note 133 at 11.

250. EKBLAW ET AL., *supra* note 104, at 9.

251. *See* BIBLE ET AL., *supra* note 133, at 3.

252. *See* EKBLAW ET AL., *supra* note 104, at 2 (referring to the log record as a *bread crumb* trail).

253. *See* BIBLE ET AL., *supra* note 133 at 6.

user access.[254] A token-based access control can be required in the blockchain-based EHR, similar to systems used by credit card companies.[255] The blockchain-based EHR only permits access to view, upload, or download data based upon each person's or entity's key, and all chain interactions are logged into the chain.[256]

As for the objection that the patient's identity on the blockchain can be ascertained by using the person's social media data and/or generally public data, the risk that the patient's identity will be compromised by comparing the patient's public data with masked patient health information on the EHR blockchain system is less than the risk of that person accessing any financial portal on the internet to facilitate the transfer of funds, because the blockchain-based EHR is end-to-end encrypted and all access is logged into the chain.[257] Hence, the use of a well-designed blockchain-based EHR is relatively safer than other common financial transactions.[258]

5. Transactional Scalability

Scalability is the ability of a blockchain system to integrate continually increasing data and process that data through the blockchain network within an acceptable time frame.[259] As explained above, an EHR blockchain system is a distributed and decentralized digital ledger or database wherein blocks of data—individual EHR data blocks of texts, images, videos, etc.—are shared between a private or a public network of peer-to-peer computers communicating with each other to confirm the authenticity of any proffered block of data.[260] "At its core, there are three key factors affecting the scalability of public blockchain networks": (1) the block size and block creation time; (2) the consensus protocol defining the

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254. *See* 45 C.F.R. § 164.312.

255. NAT'L RESEARCH COUNCIL, FOR THE RECORD: PROTECTING ELECTRONIC HEALTH INFORMATION 91 (1997). Token-based cryptographic authentication and authorization systems for the Mastercard-Visa consortium and CyberCash Inc. can be deployed by health care organizations in EHR systems. *Id.*

256. *See id.* at 91–92.

257. *See id.* at 96.

258. *See id.* at 97.

259. Vijay Raghunathan, *The Scalability Conundrum of Blockchain Networks*, ENTREPRENEUR (Feb. 27, 2019), http://www.entrepreneur.com/article/329084.

> Block size and block creation time: The size of the bitcoin block is fixed at [one] MB. Each [one] MB block can hold between 2000–4000 transactions. The bitcoin protocol is tuned to throttle the creation of blocks — one block created approximately every [ten] minutes. This results in a horrid [three]–[seven] TPS [thousand transactions per second].

Id.

260. *See* BIBLE ET AL., *supra* note 133 at 3–4.

rules and guidelines for participating in the blockchain distributed computer network; and (3) the confirmation time which refers to the time needed to reach a consensus on the computer nodes confirming the creation of a valid block in a permanent place in the blockchain database.[261]

In a blockchain-based EHR, if a full copy of the ledger is presented each time a new transaction is added, this accumulation of information may degrade performance.[262] One commentator has suggested that data sets containing demographics, encounters, diagnosis, and medications be included in the blockchain, but larger data (images, notes, etc.) can be excluded, thereby keeping chain performance stable.[263]

If the blockchain-based EHR is maintained on a private, distributed computer network, consensus protocol may be shortened, thereby increasing confirmation times, while permitting larger data block sizes and increasing access controls to the private network; however, interoperability between different private networks may be degraded.[264] Scalability issues can also be solved by government-imposed data set guidelines; the use of several trusted private networks; and a two-tiered blockchain ledger with one-tier reasonably accessible with important more recent EHR data and a second tier with larger data set blocks, potentially an archival data set.[265] In general, since access to and upload and download times for the EHR system are not critical to its performance (unlike cryptocurrency transactions), the latency and bandwidth of the network is less critical than the block size and consensus protocol.[266]

6. Brute Force Attacks and Other Data Issues

Some commentators raise concerns as to whether the EHR blockchain system can be compromised by a brute force attack to ascertain the patient's private key or to decrypt an encrypted blockchain.[267] In

261. Raghunathan, *supra* note 259.

262. *Blockchain Performance, Throughput and Scalability*, HEALTHCARE INFO. MGMT. SYSTEMS SOC'Y, http://www.himss.org/blockchain-performance-throughput-and-scalability (last visited May 1, 2020).

263. *Id.*

264. *See id.*; BIBLE ET AL., *supra* note 133, at 6.

265. *See* Gerard, *supra* note 166; Raghunathan, *supra* note 259.

266. *See Blockchain Performance, Throughput and Scalability*, *supra* note 262.

267. *Brute Force Attack*, TECHNOPEDIA: DICTIONARY, http://www.techopedia.com/definition/18091/brute-force-attack (last visited May 1, 2020); *see also* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. at 5565, 5639 (Jan. 25, 2013) (codified as amended at 45 C.F.R. § 164.524). "A brute force attack is a trial-and-error method used to obtain information such as a user password . . . ." *Brute Force Attack*, *supra*. Typically, "automated software is used to generate a large number of consecutive guesses as to the value of the desired data." *Id.*

connection with cryptocurrency, brute force attacks on electronic wallets have sometimes been successful, but efforts to decrypt well-designed currency have failed.[268] Bitcoin currency uses a public blockchain and an established consensus protocol, subjecting the coin to a fifty-one percent consensus brute force attack.[269] Given the data block size issue discussed above, the EHR may only use trusted third party computer networks (a private distributed network).[270] The use of permission blockchain networks permits the blockchain provider to limit access to the entire network, which increases security and reduces the probability of a successful brute force attack, but increases access time to the EHR.[271] While brute force decryption of a blockchain itself is impossible with modern computer technologies, some argue that theoretical quantum computers will be able to decrypt the encryption commonly used in current blockchain applications, but others suggest that quantum-resistant public-key technologies and standards are being evaluated.[272]

IV. A ROADMAP TO UNIFIED BLOCKCHAIN EHR: CASE STUDIES

We have surveyed eleven use cases that demonstrate our points raised in Part III, as follows:[273]

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268. E.O. Kiktenko et al., *Detecting Brute-Force Attacks on Cryptocurrency Wallets in* BUSINESS INFORMATION SYSTEMS WORKSHOPS 232, 232 (Witold Abramowicz & Rafael Corchvelo eds., 2019). Although attacks on e-wallets have occurred, "if the attack is implemented successfully, a legitimate user is able to prove that fact of this attack with a high probability." *Id.*

269. Conti et al., *supra* note 204, at 3428. To validate a Bitcoin transaction, participant miners use a Proof of Work ("PoW") as a consensus algorithm where the miners require no authentication to join the public network, which makes the Bitcoin consensus model extremely scalable, supporting thousands of network nodes. *Id.* at 3416, 3422. The "PoW based consensus is vulnerable to *51%* attacks, in which an adversary has control over 51% of the mining power (i.e. hashrate) in the network, hence it can write its own blocks or fork the blockchain that at a later point converges with the main blockchain." *Id.* at 3422.

270. Miliard, *supra* note 10.

271. *See* Berke, *supra* note 132. Private blockchain networks are proposed for financial systems which give "their operators control over who can read the ledger of verified transactions, who can submit transactions, and who can verify them." *Id.*

272. Jerry Chow & Michael Osborne, *The Solution to Quantum Computers Cracking Cryptography Is Already Here*, QUARTZ (May 2, 2019), http://www.qz.com/1605685/the-solution-to-quantum-computers-cracking-cryptography/. Quantum computers may soon decrypt the 2048 bit RSA encryption used in blockchain currency; however, one commentator has suggested that security experts have developed post-quantum codes that even a quantum computer will not be able to crack. EMERGING TECH. FROM THE ARXIV, *supra* note 163. "[T]he National Institute of Standards and Technology (NIST) is currently running a process to evaluate and standardize one or more quantum-resistant public-key technologies." Chow & Osborne, *supra*.

273. *See* Miliard, *supra* note 10; discussion *supra* Part III.

A. *Massachusetts General Hospital and MediBloc*

In 2017, Massachusetts General Hospital, a Harvard Medical School associated hospital, partnered with MediBloc, a Korean blockchain company.[274] The pilot program was initially implemented to store and exchange EMR rather than supplant the hospital systems' existing electronic records.[275] The hospital aimed to "explore potentials of blockchain technology to provide secure solutions for health information exchange, integrate health care [Artificial Intelligence] applications into the day-to-day clinical workflow, and support [a] data sharing and labeling platform for machine learning model development."[276]

B. *Vanderbilt and FHIRChain*

As for increasing interoperability of existing EMR databases held by different health care providers, Vanderbilt University Institute for Software Integrated Systems, in a joint venture with Varian Medical Systems, developed a method of sharing medical records between health care organizations using blockchain configured as a *smart contract*.[277] The Vanderbilt team collaborated with radiation oncology treatment centers to develop a Fast Healthcare Interoperability Resources ("FHIRChain") standards framework.[278] The blockchain is configured to be a permanent distributed ledger for online transactions or exchanges between several health care providers having troves of EMR data and clinicians needing patient-masked data to analyze treatment protocols and results.[279] Unlike a traditional database that is centrally located and maintained by one party, the blockchain record is shared among a network of users.[280] With the FHIRChain blockchain program, patient data is obtained from the originating hospital or clinic and, importantly, the original EMR remains with that health care facility.[281] When a patient wants to share his or her data with an outside

274. Miliard, *supra* note 10.

275. *Id.*

276. Julie Spitzer, *Massachusetts General Hospital Might Store Patient Data on Blockchain Through New Partnership*, BECKER'S HEALTHCARE (Dec. 6, 2018), http://www.beckershospitalreview.com/ehrs/massachusetts-general-hospital-might-store-patient-data-on-blockchain-through-new-partnership.html.

277. Peng Zhang et al., *FHIRChain: Applying Blockchain to Securely and Scalably Share Clinical Data*, 16 COMPUTATIONAL & STRUCTURAL BIOTECHNOLOGY J. 267, 269, 271, 278 (2018).

278. *Id.* at 267–68.

279. *See id.* at 271–72.

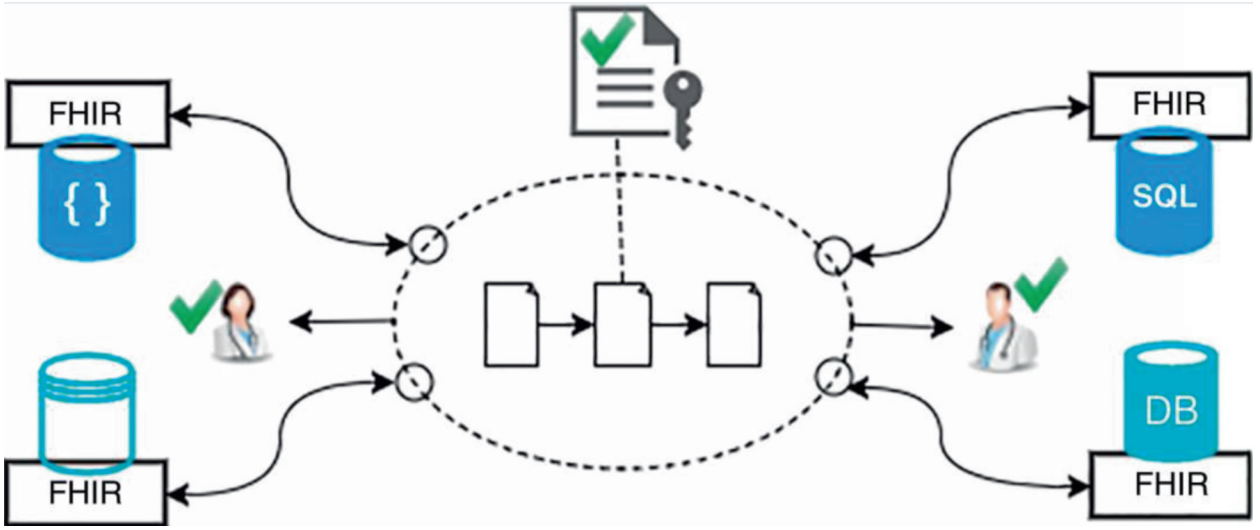
280. *See id.* at 268; Miliard, *supra* note 10.

281. *See* Zhang et al., *supra* note 277, at 277.

organization via the FHIRChain program, the hospital provides select physicians or clinics with a public key, the patient provides his or her private key, and access to the patient's health information is permitted to the selected physicians or clinics for a set period of time.[282]

The following Figure diagrammatically illustrates the FHIRChain program.[283] The blockchain (represented by papers in the ellipse) chronologically logs access, chained data input and output.[284] Original data (marked with a key in the Figure), is uploaded to the blockchain with the patient's private key.[285] The FHIRChain (the broken-line ellipse) normalizes data obtained from hospital databases (see barrel-shaped elements) which holds original EMR data.[286] The normalized data is graphically shown as siloed data on the FHIRChain (see small circles on the ellipse).[287] The FHIRChain program also controls patient privacy by masking patient identity.[288] The check-marked health care ("HC") clinicians' accesses, processes, and then uploads resultant data to the blockchain with HC private keys (confirmed as needed with the patient's key).[289]

Chart IV – FHIR Chain[290]



282. *See id.* at 271–72, 277.
283. *Id.* at 271; *see also* discussion Section IV.B.
284. *See* Zhang et al., *supra* note 277, at 271.
285. *Id.*
286. *Id.*
287. *Id.*
288. *Id.* at 271–72.
289. Zhang et al., *supra* note 277, at 271.
290. *Id.* at 271.

C. *FDA Drug Testing Compliance*

Pharmaceutical companies seeking approval from the United States Food and Drug Administration ("FDA") for new drugs must test the efficacy of the drug with large patient studies.[291] Getting accurate patient data for these studies is difficult.[292] If a patient-centric EMR is used, clinicians could (a) find the right people for a medical trial faster; (b) manage and access drug trial data for research purposes faster; and (c) provide better and more accurate clinical trial bookkeeping, that is, better tracking of efficacy.[293]

Notwithstanding the serious concerns over implementing a patient-centric blockchain EHR, blockchain systems have been specifically suggested in certain medical use cases such as: Sharing medical records between health care organizations wherein the blockchain program converts the data into a standardized format, permitting different health care providers to provide access to siloed data and maintains an access log of clinical studies to establish the efficacy of pharmaceutical drugs, maintaining patient confidentiality and complete access to a database of masked patient EHR, and employing blockchain to track the supply of designated drugs from their origin, through all distribution points, and ultimately to the end-user.[294]

D. *Boehringer Ingelheim (Canada) Ltd. ("Boehringer") and IBM Canada Clinical Trials Program ("IBM")*

Boehringer is an international pharmaceutical company that employs over 50,000 employees.[295] The company focuses on human pharmaceuticals, animal health, and biopharmaceuticals.[296] In 2019, Boehringer announced a partnership with IBM to utilize its blockchain technologies in its clinical trials.[297] Boehringer believes that a blockchain-based clinical trial EHR system will improve trial quality, reduce errors, increase completeness,

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291. *See Development & Approval Process*, U.S. FOOD & DRUG ADMIN. (Oct. 28, 2019), http://www.fda.gov/drugs/development-approval-process-drugs.

292. Arsene, *supra* note 164; *Development & Approval Process*, *supra* note 291.

293. Arsene, *supra* note 164.

294. *See id.*

295. *Boehringer Ingelheim (Canada) Ltd. and IBM Canada Announce First of Its Kind Collaboration to Integrate Blockchain Technology into Clinical Trials*, *supra* note 10; *Our Company*, BOEHRINGER INGELHEIM: ABOUT US, http://www.boehringer-ingelheim.ca/en/who-we-are/our-company (last visited May 1, 2020).

296. *Boehringer Ingelheim (Canada) Ltd. and IBM Canada Announce First of Its Kind Collaboration to Integrate Blockchain Technology into Clinical Trials*, *supra* note 10.

297. *Id.*

thereby increasing patient safety and scientific usefulness to clinical trial data sets and reducing regulatory compliance costs.[298]

E. *National Cancer Institute and Rensselaer Polytechnic Institute*

Medical imaging is seen as a "central part of diagnostics in today's health care, as a diagnostic imaging service is 'paramount in confirming, correctly assessing and documenting courses of many diseases as well as in assessing responses to treatment.'"[299] A joint venture between the National Cancer Institute and Rensselaer Polytechnic Institute is exploring a "blockchain-based [EHR] system for medical image" sharing between different entities.[300] The project seeks to create a data library of medical images for artificial intelligence/machine learning applications, with technological goals of "improv[ing] image processing, analysis, reconstruction, and enhancement" and socioeconomic goals to [1] improve security and protection of privacy; [2] "maintai[n] flexibility; and [3] enforc[e] data sovereignty."[301]

Utilizing data from the NLST, the program hopes to de-fragmentize data sets by unifying archival data to a single platform.[302] Researchers with the project noted that "[w]hile the explosion in the number and capability of tools eases the process of data collection, data retrieval and information analysis have been slow and complicated in the field of medicine, which has become a global challenge faced by both the developed and developing countries."[303] For these reasons, the project aims to develop a blockchain-based platform to: Integrate "data acquisition, storage, and transportation" between providers; strengthen privacy-preserving safeguards for patient

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298. *Id.*

299. Jianjing Lin, *Blockchain-Based Information System for Medical Image Transfer*, NAT'L CANCER INST., http://biometry.nci.nih.gov/cdas/approved-projects/2180/ (last visited May 1, 2020) (quoting *Diagnostic Imaging*, WORLD HEALTH ORG., http://www.who.int/diagnostic_imaging/en/ (last visited May 1, 2020)).

300. Donovan, *supra* note 175.

301. *Id.*

> The [National Lung Screening Trial] ("NLST") was a randomized controlled trial to determine whether screening for lung cancer with low-dose helical computed tomography (CT) reduces mortality from lung cancer in high-risk individuals relative to screening with chest radiography. Around 54,000 participants were enrolled between August 2002 and April 2004. The NLST datasets include data on participant characteristics, screening exam results, diagnostic procedures, lung cancer, and mortality. Images from over 75,000 CT screening exams are available, and more than 1,200 pathology images from a subset of NLST lung cancer patients may be viewed.

Id.

302. *See id.*

303. *Id.*

identities within the image data; develop algorithmic storage and retrieval of image data; and conduct a cost-benefit analysis as it relates to costs, patient outcomes, and provider workflow.[304]

F. *Care.Wallet*

An Estonia-based company, Solve.Care, is launching a number of partnerships with United States based health care companies to provide its blockchain-based platform, Care.Wallet, for EHR management of administrative functions, including the coordination and payment of health care benefits.[305] Solve.Care's partnership with Uber Health seeks to increase patient reliability in appointment attendance.[306] Every year, an estimated 3.6 million Americans miss their medical appointments due to a lack of reliable transportation, with the cost of missed primary care appointments estimated at US $150 billion annually.[307] Utilizing a HIPAA compliant platform, the Care.Wallet provides patients a unified platform for accessing and sharing appointment information, rescheduling options, arranging transportation, and cost-sharing with trusted, concerned individuals and entities, such as the patient's family or employer.[308] Arizona Care Network has partnered with Solve.Care and Boehringer to launch its own network, with a goal of providing concierge care management to its network of 25,000 type 2 diabetes patients.[309] Citing recent changes to diabetes treatment recommendations, Arizona Care Network believes Solve.Care provides a needed system to meet these new guidelines, which prioritize managing cardiovascular risk and general patient wellness as part of a successfully-managed treatment protocol.[310] The platform was expected to launch in the

304. Donovan, *supra* note 175.

305. Fred Donovan, *ACN Is on Healthcare Blockchain Journey to Ease Admin Burdens*, HIT INFRASTRUCTURE (Aug. 1, 2019), http://www.hitinfrastructure.com/news/acn-is-on-healthcare-blockchain-journey-to-ease-admin-burdens; *On the Road to Better Care: Solve.Care Partners with Uber Health to Deliver Medical Transport Service*, SOLVE.CARE (July 9, 2019), http://www.solve.care/on-the-road-to-better-care-solve-care-partners-with-uber-health-to-deliver-medical-transport-service/.

306. *On the Road to Better Care: Solve.Care Partners with Uber Health to Deliver Medical Transport Service*, *supra* note 305.

307. *Id.*; Laura Forman, *Doctor Visits Could Provide Relief to Uber and Lyft*, WALL STREET. J. (July 10, 2019, 7:00 AM), http://www.wsj.com/articles/doctor-visits-could-provide-relief-to-uber-and-lyft-11562756401.

308. *On the Road to Better Care: Solve.Care Partners with Uber Health to Deliver Medical Transport Service*, *supra* note 305.

309. Donovan, *supra* note 305.

310. *Id.*

United States in late Q3 2019 and be available through the Apple Store and Google Play.[311]

G. *The Payer Blockchain Initiative*

A collaboration between Aetna, Anthem, Healthcare Service Corporation, PNC Bank, IBM, Cigna, and Sentara Healthcare seeks universal interoperability and transparency in health care.[312] The members of the collaboration believe that "blockchain [technologies] can transform the industry by creating new ways to share and secure data across a business network [a] byproduct of [which] is the ability to link organizations in real-time and in ways that can ultimately improve the patient experience."[313] The main goal of the project is to accelerate new payment models and increase interoperability between health care provider's EHR systems.[314]

H. *The Pistoria Alliance*

A global network of non-profit life science stakeholders is investigating blockchain-based adoption among health care providers.[315] Focusing on education and information, the Alliance is spearheading quantitative ROI studies for blockchain-based EHR adoption, education, and research, and development support.[316]

I. *Aid.Tech*

A pilot program by Aid.Tech and PharmAccess Foundation seeks to reduce waste and fraud in aid distribution to vulnerable and under privileged pregnant women in Tanzania utilizing a blockchain-based EHR system.[317] The platform collects and stores data on pre- and post-natal services to mothers and, once born, automatically appends their child's health data into

311. *Id.*

312. Jessica Kent, *Cigna, Sentara Healthcare Join Payer Blockchain Initiative*, HEALTHPAYERINTELLIGENCE (Feb. 20, 2019), http://www.healthpayerintelligence.com/news/cigna-sentara-healthcare-join-payer-blockchain-initiative.

313. *Id.*

314. *Id.*

315. Jessica Kent, *Pistoia Alliance to Use Blockchain for Life Sciences Data Sharing*, HEALTHITANALYTICS: NEWS (Feb. 7, 2019), http://healthitanalytics.com/news/pistoia-alliance-to-use-blockchain-for-life-sciences-data-sharing.

316. *See id.*

317. Koigi, *supra* note 191.

the platform.[318] Each pregnant woman is assigned a digital identity key, which allows them access to medications, assists them with administrative functions, manages appointments, and provides a single point system to review her medical history.[319] The platform is designed to reduce fraud and waste by only allowing the assigned woman and their children access to their prescribed medications.[320] A similar platform tracks the flow of drug aid from government facilities to the patient down to the last tablet.[321] As one commentator notes:

> The success of the blockchain project in maternal care in Tanzania needs to be replicated to other African countries and to the entire health sector . . . [t]his is a game-changer that will ensure that we not only arrest fraud, but also save millions of lives and ensure [that] everyone is able to access affordable medical care without a hustle.[322]

J. *Sensyne Health*

A novel 2019 project between EY, Sensyne Health, and Guardtime will link medicine and treatment reimbursement to patient-based outcomes hosted on a blockchain-based platform.[323] Through the partnership, Sensyne Health will add clinical artificial intelligence to enable the platform to "scale faster, leading to fairer reimbursement, and access to novel treatments for patients."[324] Ultimately, the project seeks to solve a monumental challenge in health care, "accurate and fair patient reimbursement [measured] against the actual health outcome provided by care providers and drug manufacturers."[325]

K. *Estonia and National Blockchain-Based EHR*

In 2016, the Estonian E-Health Foundation launched a developmental project aimed at archiving and safeguarding all 1.3 million of

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318. *Id.*
319. *Id.*
320. *Id.*
321. *Id.*
322. Koigi, *supra* note 191.
323. Maya Vautier, *EY, Sensyne Health and Guardtime to Use AI and Blockchain to Link Health Care Reimbursement and Actual Patient Outcomes*, EY (June 25, 2019), http://www.ey.com/en_gl/news/2019/06/ey-sensyne-health-and-guardtime-to-use-ai-and-blockchain-to-link-health-care-reimbursement-and-actual-patient-outcomes.
324. *Id.*
325. *Id.*

its residents' EHR using a universal blockchain-based EHR system.[326] In lieu of digitizing all of a patient's records on a single EHR platform, the Estonian project is instead digitizing the meta-data logging the creation of, maintenance of, access to, and transportation of underlying EHR stored locally.[327] By desegregating the meta-data from the underlying EHR record, the system adds another layer of security and anonymity to patient records while meeting many of the use case goals seen in other projects.[328]

V. CONCLUSION

Recent federal laws and regulations imposed some standardization for the disparate patchwork of existing EHR systems.[329] The advent of blockchain technology presents a viable opportunity to streamline the collection and retrieval of patient data; automate audit processes through autonomous algorithms; authorize health care provider access to EHR records based on informed patient consent; reduce transaction costs in the maintenance and creation of records; and archive less critical patient data, not only for the individual's benefit, but also for the community by automatically anonymizing patient health information in the treatment and clinical context.[330]

326. Taavi Einaste, *Blockchain and Healthcare: The Estonian Experience*, NORTAL: BLOG (Feb. 21, 2018), http://www.nortal.com/us/blog/blockchain-healthcare-estonia/.

327. *See id.*

328. *See id.*

329. 42 U.S.C. § 17932 (2018); 42 C.F.R. § 495.22 (2019); 42 C.F.R. § 495.24.

330. Kuo et al., *supra* note 3, at 1214.

DIGITAL MICRO-AGGRESSIONS AND DISCRIMINATION: FEMTECH AND THE "OTHERING" OF WOMEN

BETHANY A. CORBIN*

I. INTRODUCTION

Throughout history, women's bodies have served as a playground on which politics, oppression, and control were practiced.[1] From political debates on abortion to notions that honor lies in a female's virginity, women's bodies have been used as tools both for and against their own autonomy.[2] Simultaneously serving as a marker of change and a reminder of delayed progress, the meaning of the female body has altered with time, but the undercurrents of power, control, and stigmatization remain constant.[3]

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1. *See* Katrin Zimmermann, *Female Health and Technology: Bridging the Gap*, MEDIUM (Jan. 14, 2019), http://www.medium.com/goingyellow/the-femtech-revolution-989755cb4712.

2. *See id.*; Thomas B. Edsall, *Why the Fight over Abortion Is Unrelenting*, N.Y. TIMES (May 29, 2019), http://www.nytimes.com/2019/05/29/opinion/abortion-restrictions-politics.html.

3. *See* Edsall, *supra* note 2; Zimmermann, *supra* note 1.

The woman is portrayed as an *other*, different and unequal to man, in a tale as old as time.[4]

Recently, however, a new frontier has arrived that threatens to oppress and quantify women under the guise of liberation.[5] As the world embraces the ongoing digital revolution, it welcomes new technological developments that, while well-intended, can have the devastating consequences of imposing societal perceptions of normalcy on women.[6] Known as female technology, or femtech, this market addresses women's health, with a focus on period-tracking, fertility, pregnancy, sexual wellness, and reproductive health.[7] Founders of this technology claim that it not only assists women with understanding their own bodies, but also enhances scientific knowledge and research about the female population as a whole.[8] Indeed, supporters argue that this technology "helps destigmatize women's reproductive and sexual health," at a time when women's specific health care needs have historically been underserved.[9]

The problem, however, is that this technology—funded predominantly by Caucasian males—is riddled with incorrect assumptions of female needs and desires that not only stereotype women, but also serve to define the default female body.[10] Through the use of personas, forms,

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4. *See* CAROLINE CRIADO PEREZ, INVISIBLE WOMEN: DATA BIAS IN A WORLD DESIGNED FOR MEN 176–77 (2019); Neeki Tahmassebi, *The Rise of Femtech*, PLUG & PLAY: HEALTH TECH., http://www.plugandplaytechcenter.com/resources/rise-femtech/ (last visited May 1, 2020).

5. *See* Kimberly Krueger, *Shaping the Future of FemTech*, PLUG & PLAY: HEALTH TECH., http://www.plugandplaytechcenter.com/resources/future-femtech-companies/ (last visited May 1, 2020).

6. *See* SARA WACHTER-BOETTCHER, TECHNICALLY WRONG: SEXIST APPS, BIASED ALGORITHMS, AND OTHER THREATS OF TOXIC TECH (W.W. Norton & Co., Inc. 2017) (describing how technology imposes normalcy requirements on women).

7. Bérénice Magistretti, *The Rise of Femtech: Women, Technology, and Trump*, VENTUREBEAT (Feb. 5, 2017, 10:03 AM), http://www.venturebeat.com/2017/02/05/the-rise-of-femtech-women-technology-and-trump/; *see also* Elise Mortensen, *Femtech by the Numbers: The Rise of Innovation in Women's Health Technology*, HITLAB, http://www.hitlab.org/blog/femtech-by-the-numbers (last visited May 1, 2020).

8. Suzannah Weiss, *What Is FemTech? 5 Things to Know About the New Industry*, BUSTLE (Apr. 16, 2018), http://www.bustle.com/p/what-is-femtech-5-things-to-know-about-the-new-industry-8792289.

9. Maria Simeone, *Can Femtech Deliver Radically Personalized Care to Women?*, DATACONOMY (Jan. 30, 2020), http://www.dataconomy.com/2020/01/can-femtech-deliver-radically-personalized-care-to-women.

10. *See* CRIADO PEREZ, *supra* note 4, at 176; WACHTER-BOETTCHER, *supra* note 6, at 20; Kaitlyn Tiffany, *Period-Tracking Apps Are Not for Women*, VOX (Nov. 16,

default settings, and design assumptions, femtech developers have created products that categorize women and limit their data input to a range of *normal* values, even if the woman's unique, personal biology falls outside the artificial *normal* range.[11] This results not only in arbitrary restrictions on who can use the app or digital device, but also perpetuates an environment in which women who have *abnormal* results are deemed *others* that do not conform to standard perceptions of women.[12] In other words, digital products are consistently telling women what their biology *should* be (e.g. a thirty day period cycle), what their reproductive goals *should* be (e.g. a smiley face on a period-tracking app when a woman misses her period, thus signifying that her goal should be pregnancy), and what their sexual activity and preferences *should* be (with imagery on apps highly focused on male genitalia).[13] These arbitrary standards reinforce notions of *otherness* for women who do not—and oftentimes cannot—conform.[14] In this manner, numerous subsets of women, including transgendered women, are excluded, stigmatized, and devalued during their most intimate experiences.[15]

Moreover, for women who are cautious about sharing their intimate data with apps, a strong potential exists that the inputted data will not be entirely accurate.[16] For example, a woman who uses a period-tracking app as a form of birth control, may accurately track her cycle in the app, but may alter, conceal, or misrepresent data with respect to her body temperature,

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2018, 12:35 PM), http://www.vox.com/the-goods/2018/11/13/18079458/menstrual-tracking-surveillance-glow-clue-apple-health.

11. *See* WACHTER-BOETTCHER, *supra* note 6, at 37–40; Jenny McGrath, *With Period-Tracking Apps, the Fate of Your Fertility Is Far from Clear*, DIGITAL TRENDS (Sept. 2, 2019, 1:00 AM), http://www.digitaltrends.com/mobile/the-problems-and-promises-of-period-tracking-apps/; Molly McHugh, *Does Femtech Give Users Control of Their Health or Take It Away?*, RINGER: TECH (Mar. 18, 2019, 6:30 AM), http://www.theringer.com/tech/2019/3/18/18267094/femtech-female-health-apps-menstruation-fertility-trackers-clue-glow-ava (explaining that "many health apps try to shove users and their bodies into strict categories.").

12. *See* McHugh, *supra* note 11.

13. *See* WACHTER-BOETTCHER, *supra* note 6, at 31; McHugh, *supra* note 11.

14. *See* Jonathan Todres, *Law, Otherness, and Human Trafficking*, 49 SANTA CLARA L. REV. 605, 608–09 (2009); McHugh, *supra* note 11.

15. *See* Olivia Goldhill, FemTech *Is Not and Should Not Be a Thing*, QUARTZ (Apr. 3, 2019), http://www.qz.com/1586815/why-femtech-is-a-sexist-category/. "[I]n defining women by their biology, these products only focus on the needs of cis rather than trans women." *Id.*; *see also* Todres, *supra* note 14, at 614 (articulating the role of *othering* in helping to *devalue and dehumanize* those who are deemed *other* or perceived as falling outside the bounds of societal standards for normalcy).

16. *See* McHugh, *supra* note 11 (stating that the efficacy of femtech devices "depends on how much information a user is willing to feed it").

sexual positions, or mood swings.[17] The complications from such data alteration are twofold.[18] First, the femtech app or device can no longer work as intended because the data is not an authentic representation of that individual's body.[19] Second, the data results that are then given or sold to researchers and third parties are faulty and unreliable.[20] Researchers, seeking to use this data to study women's health and better understand female biology, will inadvertently develop skewed results.[21] Further, with femtech apps excluding or ostracizing subsets of the female population, the data will continue to be biased toward the *normal* female, which creates a self-perpetuating stigmatization when researchers present their findings on what is *normal* for this population.[22] As a result, femtech products often fail to align with the needs and desires of female consumers and can result in women having diminished agency and control over their bodies and personal data.[23]

How, then, can the tech industry fix the erroneous assumptions, design flaws, and corporate practices that plague femtech to avoid stereotyping and *othering* subsets of the female population?[24] The remedy to this ailment is complex and long-term solutions will require fundamental shifts in the way society perceives and interacts with female consumers.[25] That said, there are important steps that must be taken now to begin setting the foundation for a seismic change and remedy the inadvertent discrimination that femtech users face.[26] First, consumers must use their power and autonomy to demand better, unbiased products from developers.[27] Only by recognizing and understanding the fundamental assumptions and

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17. *See id.*
18. *See id.*
19. *See id.*
20. *See* WACHTER-BOETTCHER, *supra* note 6, at 75; McHugh *supra* note 11.
21. *See* WACHTER-BOETTCHER, *supra* note 6, at 75.
22. *See id.*; Laura Hudson, *Technology Is Biased Too. How Do We Fix It?*, FIVETHIRTYEIGHT (July 20, 2017), http://www.fivethirtyeight.com/features/technology-is-biased-too-how-do-we-fix-it/. "Biased data can create feedback loops that function like a sort of algorithmic confirmation bias, where the system finds what it expects to find rather than what is objectively there." Hudson, *supra*.
23. *See* Lauren Sharkey, *Is the Rise of Femtech a Good Thing for Women? Here's What the Experts Think*, BUSTLE (July 6, 2019), http://www.bustle.com/p/is-the-rise-of-femtech-a-good-thing-for-women-heres-what-the-experts-think-17993009.
24. *See* Mick Champayne, *How Femtech Is Capitalizing on Women*, PAPAYA.ROCKS (May 17, 2019), http://www.papaya.rocks/en/trendbook/w-jaki-sposob-femtech-zarabia-na-kobietach; Hudson, *supra* note 22.
25. *See* Hudson, *supra* note 22.
26. *See id.*
27. WACHTER-BOETTCHER, *supra* note 6, at 75.

design flaws in these products can consumers incentivize manufacturers to produce more inclusive apps and technology.[28] Second, diverse representation is needed within the companies that fund and develop these devices to ensure all viewpoints are acknowledged and considered.[29] Finally, consumers must be consulted during the device design, development, and deployment stages.[30] Currently, there is a rush to market new devices without adequate testing and vetting, and an overwhelming tendency for male-dominated companies to *know* what women want.[31] This assumed knowledge—without specifically *asking* female consumers if the product meets their needs—leads to erroneous and faulty design models that do not satisfy women's needs or that alienate and *other* certain portions of the female community.[32] By incorporating diverse female feedback at the beginning, middle, and end stages of product development, femtech companies can remedy design flaws up front before the product enters the market and perpetuates perceptions of normalcy.[33]

To support this position, this Article is divided into four parts.[34] Part one presents an overview of the femtech industry, including a discussion of devices that fall under the femtech umbrella.[35] In addition, this section explains how current femtech products have relied on flawed assumptions to create unworkable and discriminatory products that alienate certain categories of women.[36] Part two then presents an analysis of *othering* in its historical context and demonstrates how existing femtech products have operated to *other* subsets of the female population.[37] Part three then presents

28. *See* Sharkey, *supra* note 23.

29. CRIADO PEREZ, *supra* note 4, at XIII, 318; WACHTER-BOETTCHER, *supra* note 6, at 18–20, 26.

30. *See* CRIADO PEREZ, *supra* note 4, at 318; WACHTER-BOETTCHER, *supra* note 6, at 39–40.

31. *See* WACHTER-BOETTCHER, *supra* note 6, at 28.

32. *See* CRIADO PEREZ, *supra* note 4, at 318; WACHTER-BOETTCHER, *supra* note 6, at 28, 39–40 (highlighting that even the use of the term *fem* has the potential to alienate transgender and non-binary individuals).

33. *See* CRIADO PEREZ, *supra* note 4, at 318.

34. *See* discussion *infra* Part I–IV.

35. Tahmassebi, *supra* note 4; *see also* discussion *infra* Part I.

36. *Does Digital Health Technology Know Women?*, MED. FUTURIST (Feb. 21, 2019), http://www.medicalfuturist.com/femtech-womens-health/; *see also* discussion *infra* Part I.

37. John A. Powell & Stephen Menendian, *The Problem of Othering: Towards Inclusiveness and Belonging*, OTHERING & BELONGING, Summer 2016, at 14, 22–23; *see also* discussion *infra* Part II.

solutions for helping to remedy the flaws associated with femtech devices.[38] Finally, Part four succinctly concludes the Article.[39]

II. A WHOLE NEW WORLD: THE FEMTECH INDUSTRY

A. *The Rise of Femtech*

Throughout medical history, the male body has been perceived as the default standard, with the female body recognized as an aberration or deviation from the male norm.[40] From the use of male rats in scientific studies to the failure to include women in clinical trials, the medical field has prioritized knowledge of the male body, with the subsequent application of medical knowledge to women on a one-size-fits-all basis.[41] This perception has dominated the medical industry despite the fact that women's symptoms of diseases, tendency to develop certain diseases more frequently, and side effect experiences can be substantially different from their male counterparts.[42] Indeed, "it wasn't until 2001 that the Institute for Medicine" determined that gender was a crucial consideration for clinical trials—and even then, there has been a failure to include women in such trials due to their *frequent hormonal changes*.[43] Presently, it is estimated that the "economic burden for women's diseases [exceeds] $500 billion."[44]

Given the tendency to de-emphasize women's health in the medical field, the development of a new industry focused on women's reproductive and hormonal wellness has garnered significant attention.[45] Known as

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38. WACHTER-BOETTCHER, *supra* note 6, at 10–11; *see also* discussion *infra* Part III.

39. *See* discussion *infra* Part IV.

40. Tahmassebi, *supra* note 4; *see also* CRIADO PEREZ, *supra* note 4, at 1.

41. *See* CRIADO PEREZ, *supra* note 4, at 1, 220–24; Reenita Das, *Femtech Fights Gender Equality: How Do Social Determinants of Health Impact Women?*, FORBES (Mar. 7, 2019, 3:38 PM), http://www.forbes.com/sites/reenitadas/2019/03/07/femtech-fights-gender-equality-how-do-social-determinants-of-health-impact-women. "Women have been highly under-represented in clinical trials for chronic conditions." Das, *supra*; *see also* Simeone, *supra* note 9. "[U]ntil 1993, the FDA excluded women with *childbearing potential* from participating in phase [one] and early phase [two] clinical studies to avoid controlling for complications like women's menstrual cycles." Simeone, *supra* note 9; Zimmermann, *supra* note 1.

42. *See* CRIADO PEREZ, *supra* note 4, at 220–24.

43. Sam Forsdick, *What is Femtech? Promoting Female Healthcare in a Male-Dominated Industry*, NS BUS. (Nov. 30, 2018), http://www.ns-businesshub.com/science/what-is-femtech/.

44. Tahmassebi, *supra* note 4.

45. *See* Mortensen, *supra* note 7.

femtech (short for female technology), this industry encompasses "any software, diagnostics, products, and services that leverage technology to improve women's health."[46] This includes digital and standard health care products that are created, designed, and directed at women, including wearables, mobile applications, and hygiene products.[47] Designed in response to a market "flooded with products tailored to the needs of men," including Viagra, penis enlargement pills, and fitness apps, femtech seeks to cater to the remaining 50% of the population by focusing on health care solutions unique to women.[48] According to the Global Wellness Summit, the overarching mission of the femtech industry is to not only identify the balance between health and wellness for women, but also to "disrupt pharma-based contraception and fertility strategies."[49] Thus, while women's health is much broader than merely the reproductive organs, a large segment of the femtech industry focuses on this aspect of women's wellness.[50]

Indeed, the term *femtech* was initially coined in 2016 by Ida Tin, an entrepreneur who founded the femtech application called Clue.[51] Focused on

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46. Kate Clark, *Femtech's Billion-Dollar Year*, TECHCRUNCH (Apr. 3, 2019, 5:46 PM), http://www.techcrunch.com/2019/04/03/femtechs-billion-dollar-year/; Magistretti, *supra* note 7; *see also* Marija Butkovic, *Top 100 Women in Fem Tech and Health Tech*, MEDIUM (Apr. 13, 2019), http://medium.com/women-of-wearables/top-100-women-in-fem-tech-and-health-tech-34eccf021053. "As an industry, [femtech] largely encompasses any digital or standard health tools aimed at women's health, including wearables, internet-connected medical devices, mobile apps, hygiene products, and others." Butkovic, *supra*; Mortensen, *supra* note 7; Celia Rosas, Note, *The Future Is Femtech: Privacy and Data Security Issues Surrounding FemTech Applications*, 15 HASTINGS BUS. L.J. 319, 320 (2019).

47. Butkovic, *supra* note 46.

48. Magistretti, *supra* note 7.

49. Annie Xu, *Femtech: Can Female Fertility Apps Replace Birth Control?*, MISCELLANY NEWS: OPINIONS (Apr. 18, 2019), http://www.miscellanynews.org/2019/04/18/opinions/femtech-can-female-fertility-apps-replace-birth-control/.

50. Magistretti, *supra* note 7. While the "best known categories of femtech are menstruation care, sexual health, fertility tracking and solutions, and pregnancy care," women's health care "is about much more than just reproductive organs." Mortensen, *supra* note 7; *see also* Simeone, *supra* note 9. "Women's health goes beyond family planning and fertility" and includes illnesses "like autoimmune diseases [that] have a [three times] higher prevalence in women than men." Simeone, *supra* note 9; *Does Digital Health Technology Know Women?*, *supra* note 36. "[W]omen's health does not only mean period tracking and pregnancy," yet "[a] lot less consideration is given to other female health problems such as menopause, cancer detection, breastfeeding troubles, troubles around bladder control, and a lot more." *Does Digital Health Technology Know Women?*, *supra* note 36. "There continues to be very little discussion on women's health, beyond pregnancy and menstruation, indicating that a large unmet need and, in effect, an untapped opportunity exists." Das, *supra* note 41.

51. Butkovic, *supra* note 46; Jessie Gabriel & Tara Ravi, *Women Investing in Women's Health: The Rise of Femtech Companies and Investors in Celebration of Women's*

period-tracking, ovulation, and fertility, Clue allows its users to monitor the length of their cycles, predict upcoming cycles, determine fertile windows, track mood swings, basal body temperature and energy levels, and read literature about these bodily functions.[52] Period-tracking apps are currently a hot commodity, ranking as the fourth most popular application for adults in health care and the second most popular among adolescent women.[53] More than one hundred million women today monitor their cycles using mobile applications.[54] Beyond Clue, popular femtech products include Glow, Flo, and Eve (period, fertility and ovulation trackers), Thinx (absorbent period underwear), Nurx and Natural Cycles (birth control), and Yarlap (pelvic floor exerciser), among others.[55] Presently, the femtech industry consists of over two hundred startups worldwide, most of which have the overarching goal of helping women understand their hormones, enhancing female agency over their bodies, and contributing to scientific research on the historically underrepresented female population.[56] These products are advertised as being designed "with a ladies first approach" to help "ditch[] the taboos around female health and sexuality" and help women who may suffer from medical conditions.[57] Accordingly, femtech products have been applauded

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History Month, BAKERHOSTETLER (Mar. 19, 2019), http://www.bakerlaw.com/alerts/women-investing-in-womens-health-the-rise-of-femtech-companies-and-investors-in-celebration-of-womens-history-month; *see also* Mortensen, *supra* note 7.

52. *See* CLUE, http://www.helloclue.com (last visited May 1, 2020).

53. *Does Digital Health Technology Know Women?*, *supra* note 36; Tiffany, *supra* note 10.

54. Champayne, *supra* note 24. "Women have long tracked personal data (including menstrual cycle, basal body temperature, and other indicators) in order to facilitate or prevent pregnancy." Karen E.C. Levy, *Intimate Surveillance*, 51 IDAHO L. REV. 679, 684 (2015).

55. *See* Marina Khidekel, *The Race to Hack Your Period Is on*, ELLE (June 25, 2018), http://www.elle.com/beauty/health-fitness/a21272099/clue-period-app/; Magistretti, *supra* note 7; Mortensen, *supra* note 7; Weiss, *supra* note 8. Other familiar femtech products on the market include Bellabeat, OvuSense, Tempdrop, and Ava, which aim to give "the modern person a chic, tech-savvy solution for monitoring their body." McHugh, *supra* note 11.

56. Anna Altman, *Mommy and Data*, NEW REPUBLIC (Jan. 14, 2019), http://www.newrepublic.com/article/152693/femtech-companies-alleviate-exploit-female-anxiety. Femtech companies advertise their products as "helping women along the path to self-determination and healthy, sustainable lifestyles" and as an opportunity to enhance female agency. *Id.* "[T]echnology can help people gain more agency over their own health — and not only as it applies to reproduction." McHugh, *supra* note 11. "The goal of FemTech is to give women more control over their health, their happiness, and their futures." Weiss, *supra* note 8.

57. *Femtech Companies Innovating Traditional Women's Healthcare*, ALLEY, http://www.alley.com/post/meet-the-femtech-companies-innovating-traditional-womens-health (last visited May 1, 2020).

for increasing the accessibility of health care services to women, and for shifting the male-dominated medical dialogue to the health care needs of women.[58]

The numbers support the observation that the femtech industry is experiencing rapid and sustainable growth under the guise of female autonomy.[59] Since 2014, femtech startups have raised over $1.1 billion in funding.[60] As of April 2019, femtech had attracted over $240 million in venture capital funding, with the sector on pace to secure nearly $1 billion in investments by the end of 2019.[61] Estimates suggest that approximately $200 billion is being spent on femtech products every year, with Frost & Sullivan predicting that the femtech market will be valued at $50 billion by 2025.[62] Thus, the femtech market represents a lucrative opportunity for investors and startups to aid women in understanding their bodies.[63]

But, there is a darker side to the femtech industry that lurks in the shadows, calling into question the altruistic nature of these devices.[64] Casting them instead as tools of consumerism and surveillance, this alternative viewpoint highlights that the investment backers of femtech devices remain largely men, with limited expertise as to the female body and female desires.[65] During the initial development of this industry, femtech was considered a niche market, with very few Silicon Valley investors willing to listen to pitches for female products, let alone invest in them.[66] Male investors perceived discussions of female biology as disgusting and

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58. *See* Reenita Das, *Women's Healthcare Comes Out of the Shadows: Femtech Shows the Way to Billion-Dollar Opportunities*, FORBES (Apr. 12, 2018, 11:01 AM), http://www.forbes.com/sites/reenitadas/2018/04/12/womens-healthcare-comes-out-of-the-shadows-femtech-shows-the-way-to-billion-dollar-opportunities/#48e6c1636159. "Femtech is part of a growing trend in medical tech that aims to make female healthcare easier to manage." Forsdick, *supra* note 43.

59. *See* Das, *supra* note 58.

60. Butkovic, *supra* note 46; Magistretti, *supra* note 7; *see also* Cotton Codinha, *What Is Femtech, and Is It the New Pink Tax?*, ALLURE: WELLNESS (Apr. 22, 2019), http://www.allure.com/story/what-is-femtech.

61. Clark, *supra* note 46; Mortensen, *supra* note 7.

62. Altman, *supra* note 56; Butkovic, *supra* note 46; Codinha, *supra* note 60; McHugh, *supra* note 11; Mortensen, *supra* note 7.

63. *See* Das, *supra* note 58.

64. *See id.*; Codinha, *supra* note 60.

65. *See* Champayne, *supra* note 24; Codinha, *supra* note 60; Magistretti, *supra* note 7.

66. Gabriel & Ravi, *supra* note 51. "[Silicon] Valley is dominated by men, and pitching a period-tracking app to a testosterone-filled room can be intimidating." Magistretti, *supra* note 7; *see also* CRIADO PEREZ, *supra* note 4, at 174–75; Mortensen, *supra* note 7.

irrelevant, refusing to fund products that did not also cater to male needs.[67] While women do participate in the investment space, they "hold only 11% of executive positions at Silicon Valley companies, and only 5%" of executive positions at startups.[68] Venture capitalist firms with female investors, however, are three times more likely to invest in companies with female CEOs, including femtech companies.[69] Further, in 2017, all-women investment teams received only "$1.9 billion of the $85 billion total invested by venture capitalists," whereas all-male teams received approximately $66.9 billion.[70] As a result, the femtech market grew incredibly slowly, with just 2% of venture capital dollars going to fund female-led startups and projects, and only 4% of health care research and development funding invested in women's health worldwide.[71]

By 2020, however, it is anticipated that the female economy will be bigger than the entire economy of China, with women influencing $20 trillion in spending (or 70% of all consumer spending).[72] Accordingly, increased focus has been paid to women as consumers, and the products that they need and desire.[73] The growth of femtech has occurred against this backdrop—male dominated investment firms seeking to serve the female population as consumers with a lucrative source of revenue, not as patients.[74] Representing about 50% of the population, women are perceived as valuable consumers in an untapped market that exudes potential, with the femtech market now "tickling the curiosity of hungry venture capitalists who are beginning to sniff an opportunity like bloodhounds."[75]

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67. *See* Zoe Kleinman, *Femtech: Right Time, Wrong Term?*, BBC NEWS: TECH. (Oct. 8, 2019), https://www.bbc.com/news/technology-49880017; Magistretti, *supra* note 7; Tahmassebi, *supra* note 4.

68. *Does Digital Health Technology Know Women?*, *supra* note 36; *see also* Champayne, *supra* note 24.

69. Butkovic, *supra* note 46.

70. *Id.* "Of the remaining 19%, 12% of funds were raised by mixed-gender teams, while 7% was raised by teams whose gender makeup" was unknown. *Id.*

71. *Id.*; Rose Acton, Femtech *Has the Potential to Improve the Lives of Millions of Women*, CAPX (Oct. 10, 2018), http://capx.co/femtech-has-the-potential-to-improve-the-lives-of-millions-of-women/; Altman, *supra* note 56; Das, *supra* note 58; Mortensen, *supra* note 7; Zimmermann, *supra* note 1.

72. Das, *supra* note 41.

73. *See id.*

74. Altman, *supra* note 56; *see also* Mortensen, *supra* note 7.

75. Butkovic, *supra* note 46; Magistretti, *supra* note 7; Simeone, *supra* note 9. Half of the global population, women "make up a market of 3.73 billion prospective customers worldwide." Mortensen, *supra* note 7. "With more or less half the population on this planet being female, there's clearly a demand for health-related products and services that meet their specific needs." Butkovic, *supra* note 46.

This is not the first time that product developers, investors, and even the Government have capitalized on women's unique biology.[76] For example, tampons and sanitary napkins—both essential products for menstruating women—have routinely been sold and taxed in the United States as a *luxury good*, not a medical necessity (which would be exempt from sales tax and purchasable through assistance programs).[77] This perspective, which is supported today by at least thirty-five states, encourages product developers to view women as a captive, vulnerable audience with limited care options.[78] In fact, the tampon/sanitary napkin industry has experienced almost no innovation in the last thirty-five years, despite women's unceasing need for these products.[79] As such, a high probability exists that the tech industry views women as consumers, not patients, and that it "[tugs] at the fears and anxieties women have about their bodies and life choices" to market these products.[80] Women's bodies are thus seen as a way to make profit, rather than a vehicle to improving long-term health care objectives for unique female health issues.[81]

B. *Misaligned Assumptions & Design Flaws*

The desire and ability to profit off women's bodies are further complicated by the misaligned assumptions and design flaws that plague femtech products today.[82] As an industry funded predominantly by males, digital health makes assumptions about women's needs and desires that do not necessarily align with reality.[83] This skewed underlying knowledge influences product creation and design, and results in femtech applications that are not only impractical, offensive, and unreliable, but that also

76. *See* Codinha, *supra* note 60.

77. *Id.*

78. *Id.*

79. Eleanor Lawrie, *People Find Anything About the Vagina Hard to Talk About*, BBC NEWS (Nov. 30, 2018), http://www.bbc.com/news/business-46345591. "The feminine hygiene market alone is worth an estimated $30 [billion], but has seen barely any innovation since the tampon was invented in the 1930s." *Id.* Similarly, "there's been little innovation in birth control since the Pill's invention in the 50s." Weiss, *supra* note 8.

80. Altman, *supra* note 56; *see also* Tiffany, *supra* note 10 (mentioning that anxiety, fear, and desire are profitable).

81. Codinha, *supra* note 60. "Women represent a huge market, and in some ways, because of a lack of care options, a vulnerable one." *Id.*

82. *See* Champayne, *supra* note 24.

83. Champayne, *supra* note 24; Jasmine Shirey, *Everything You Need to Know About* Femtech *Because You Probably Use It Everyday*, FAIRYGODBOSS, http://www.fairygodboss.com/career-topics/femtech (last visited May 1, 2020); *see* Forsdick, *supra* note 43.

contribute to the *othering* of certain female populations.[84] These design flaws arise from the male-dominated landscape of the femtech industry, and the inability of product designers to comprehend and account for unique female physiology among all members of the female population.[85]

At a product development level, femtech apps and devices have historically been funded and/or designed *for* women *by* men and marketers who do not use the products and do not have a foundational understanding of the female body.[86] Flo, an ovulation calendar, period tracker, and pregnancy app, was created by two brothers, Dmitry and Yuri Gurski from Belarus.[87] Similarly, Glow, one of the most popular period and ovulation tracking apps, was founded in 2013 by PayPal's Max Levchin and four other men.[88] As part of its design during the first two years of operation, Glow reminded women who were entering a fertile window "to wear nice underwear that day" and encouraged the woman's partner "to bring home some flowers."[89] These messages, which women may find offensive and derogatory, make clear that these applications were not created by women for women, and help to reinforce stereotypes about women and sex.[90] While Glow has since updated its products and how it communicates about women's health, its micro-aggressions against women could have been avoided altogether by asking women up front about their preferences and intended uses.[91]

Similarly, at Apple where women hold only twenty-nine percent of leadership positions and twenty-three percent of tech positions, the company debuted its *comprehensive* health-monitoring system in 2014, complete with

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84. *See* Champayne, *supra* note 24; Forsdick, *supra* note 43; Shirey, *supra* note 83.

85. *See* CRIADO PEREZ, *supra* note 4, at 167, 174, 180, 234.

86. Tiffany, *supra* note 10.

> [The] app wasn't designed for me. It wasn't designed for anyone who wants to track their period or general reproductive health. The same is true of almost every menstruation-tracking app: They're designed for marketers, for men, for hypothetical unborn children, and perhaps weirdest of all, a kind of voluntary surveillance stance.

Id.; Krueger, *supra* note 5; *see also* Acton, *supra* note 71; Das, *supra* note 58; *Does Digital Health Technology Know Women?*, *supra* note 36 (recognizing that femtech devices "were most probably designed and developed by men, and most likely not consulted by future users"). This model has been changing in recent years, as more female entrepreneurs enter the femtech space. Lawrie, *supra* note 79 (describing that female entrepreneurs are now beginning to drive these products); Xu, *supra* note 49.

87. Champayne, *supra* note 24.

88. *Id.*; Magistretti, *supra* note 7; Tiffany, *supra* note 10.

89. Tiffany, *supra* note 10; Levy, *supra* note 54, at 685.

90. *See* WACHTER-BOETTCHER, *supra* note 6, at 28; McHugh, *supra* note 11 (stating that, "[i]n many ways, [femtech devices] are not . . . made for women").

91. *See* WACHTER-BOETTCHER, *supra* note 6, at 31.

monitoring for blood pressure, blood alcohol level, steps, copper intake, and molybdenum.[92] The health monitoring system did not, however, include a basic period tracker for women.[93] This basic error "surely would have been caught by a team with enough women on it."[94] A comparable mishap occurred at Fitbit which, despite having millions of female users, did not add *female health tracking* until May 2018, even though it was one of the company's most requested features.[95] Thus, even when products are designed to be gender neutral, they are nonetheless biased towards men and male health needs.[96]

In addition, rather than use straightforward medical terminology and design characteristics that are typical of male or gender-neutral health care applications, femtech devices routinely include superfluous or insulting design elements that downplay the importance of female health.[97] Floating clouds, color palettes that emphasize pink and red, irrelevant flowers, and *faux-empowering language* are common in femtech applications today.[98] These designs emphasize fundamental (and often incorrect) assumptions about women and their desires.[99] For example, a period tracking app may have a cloud drift across the screen of a woman's smart phone, informing her in welcoming letters and a positive tone that she is seven days late for her period.[100] The woman may have to continue watching the cloud for several weeks as she prepares for an abortion—a circumstance in which the app's designers have clearly misunderstood that pregnancy is not always a welcome occurrence.[101] Further, when an abortion or miscarriage happens, some apps prevent women from logging this data, which adds insult to injury by telling women that their experience falls outside *normal* data calculations and skews the data and predictions for their next cycles.[102] Similarly, some femtech applications use incorrect terminology, referring to its users as *girls* or to sex as *hookups*, and describes sex in a way that is exclusively focused

92. CRIADO PEREZ, *supra* note 4, at 176; Tiffany, *supra* note 10.
93. CRIADO PEREZ, *supra* note 4, at 176.
94. *Id.*
95. *Does Digital Health Technology Know Women?*, *supra* note 36; McHugh, *supra* note 11.
96. CRIADO PEREZ, *supra* note 4, at 176–77.
97. WACHTER-BOETTCHER, *supra* note 6, at 28; McGrath, *supra* note 11; Tiffany, *supra* note 10.
98. *See* WACHTER-BOETTCHER, *supra* note 6, at 28; McGrath, *supra* note 11; Tiffany, *supra* note 10.
99. *See* Tiffany, *supra* note 10.
100. *See id.*
101. *See id.*
102. *See* McHugh, *supra* note 11.

on male genitalia and excludes the lesbian, gay, bisexual, transgender, and queer ("LGBTQ") population (for example, a banana with or without a condom).[103] The pattern that emerges from these designs is "an industry that is willing to invest plenty of resources in chasing *delight* and *disruption*, but [has not] stopped to think about [who is] being served by its products, and [who is] being left behind, alienated, or insulted."[104]

Indeed, a University of Washington research team found that these design characteristics formed the basis of common complaints about femtech products.[105] Yet, these design schemes are conspicuously absent in health care products that are not aimed specifically at women.[106] By including these design elements in femtech products, the overarching message conveyed to women is that their reproductive health is not a serious health concern or medically important, but instead represents an opportunity for marketers to exploit women as consumers.[107] In fact, only 5% of apps studied even cited medical literature to help women understand their bodies and health.[108] As such, it has become clear that these femtech applications are intentionally designed to emphasize underlying marketing goals and not necessarily women's health.[109] This perpetuates the longstanding stereotype that women's health concerns should be taken less seriously than men's, which can have devastating and sometimes fatal consequences.[110]

Further, femtech products have consistently failed to live up to the promises they provide women.[111] Consumers who download, purchase, or use these applications expect minimum levels of usability, reliability, and accuracy, yet these metrics are questionable for existing products.[112] First, femtech products typically operate over a range of *normal* or *average* values

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103. WACHTER-BOETTCHER, *supra* note 6, at 31; *see also* McHugh, *supra* note 11; Tiffany, *supra* note 10.

104. WACHTER-BOETTCHER, *supra* note 6, at 8; *see also* Tiffany, *supra* note 10.

> The ways in which period-tracking or fertility-tracking apps are different reveal the ways most designers think of them: As products that provide information that's not actually very serious or important medically, and that should exist mostly to convince a woman to spend as much time as possible looking at ads, while supplying the owner with as robust a data set as possible, so they can better target more ads.

Tiffany, *supra* note 10.

105. McGrath, *supra* note 11.

106. Tiffany, *supra* note 10.

107. Champayne, *supra* note 24; *see also* Tiffany, *supra* note 10.

108. McGrath, *supra* note 11.

109. *See* Tiffany, *supra* note 10.

110. Zimmermann, *supra* note 1.

111. *See* Xu, *supra* note 49.

112. *Id.*

that define the spectrum of data a woman may input into the application.[113] For instance, a *regular* period cycle may span between twenty-one and thirty-five days (the average length is twenty-eight days), with an application requiring inputted cycle data to match those timeframes.[114] An individual who experiences a cycle of forty-five or fifty days, or has bleeding for more than fourteen days may be unable to accurately log her data in the app if she is confined to those time limits.[115] For example, when Fitbit finally added period and ovulation tracking to its devices in 2018, many women were upset that they couldn't record more than ten days for a period.[116]

Second, femtech devices possess questionable reliability records with high levels of inaccuracy.[117] A 2016 study published in the Journal of the American Board of Family Medicine reported that popular period tracking apps failed to accurately predict when women will be the most fertile.[118] This data was reconfirmed in 2018 by gynecologist Alexander Freis in a study involving calendar-based and calculothermal apps.[119] Published in Frontiers in Public Health, this study found that calendar-based and calculothermal apps predict fertile cycle days and ovulation by averaging data from prior cycles.[120] This retrospective methodology, Dr. Freis explains, "is viewed as inadequately reliable as a result of the known variability of the cycle length and ovulation day from month to month, a fact that has been known to science since the 1930s."[121] The utility of this technique employed by hundreds of femtech apps is *limited*, and most fertile days will often be missed as a result of natural variation in cycle length.[122] Indeed, none of the apps examined considered the full variation of cycle characteristics, and most were inaccurate by more than a couple of days.[123] This data underscores a study from 2000, which found that only 30% of women had a fertile window even falling within the tenth to seventeenth day

113. *Id.*
114. McGrath, *supra* note 11.
115. *See id.* "Some apps won't allow you to chart periods that are longer or shorter than the average two to seven days." *Id.*
116. *Does Digital Health Technology Know Women?*, *supra* note 36.
117. *See* Xu, *supra* note 49. "A recent study . . . found that most of these apps provided sub-optimal predictive results and were off by more than a couple of days." *Id.*
118. Marguerite Duane et al., *The Performance of Fertility Awareness-Based Method Apps Marketed to Avoid Pregnancy*, 29 J. AM. BOARD. FAM. MED. 508, 509–11 (2016); Altman, *supra* note 56.
119. Alexander Freis et al., *Plausibility of Menstrual Cycle Apps Claiming to Support Conception*, FRONTIERS PUB. HEALTH, Apr. 2018, at 1, 6, 8; Xu, *supra* note 49.
120. Freis et al., *supra* note 119, at 6.
121. *Id.*
122. *Id.*
123. *Id.*; Xu, *supra* note 49.

average, thus making ovulation prediction based on tracking and algorithms unreliable.[124]

Similarly, a 2018 study from Current Research and Opinion reviewed seventy-three menstrual cycle apps and found that none could correctly predict ovulation.[125] In fact, the best app scored only a 21% accuracy rate.[126] Researchers at Columbia University Medical Center arrived at a similar conclusion after studying 108 femtech apps, in which they found that 95% of free smartphone menstrual cycle apps were inaccurate.[127] Very few of these apps had involvement or oversight from health professionals or cited medical literature.[128] However, even those femtech products that have scientific backing and approval by the Food and Drug Administration ("FDA") are not foolproof.[129] Natural Cycles, the first hormone-free, FDA-approved digital contraceptive, relies on data inputted by the user and collected from a thermometer to determine when a woman will most likely be fertile.[130] Although Natural Cycles warns users that no form of contraception is 100% effective, the use of the app led to thirty-seven Swedish women reporting unwanted pregnancies.[131]

Given these flawed assumptions, design features, and data inaccuracies, it is easy to understand how femtech can be perceived as failing women and not acknowledging the full scope of women's needs.[132] By neglecting to account not only for women's design preferences but also for their hormonal and body differences, these products cannot operate in a reliable and effective manner that furthers the underlying goals of enhancing female agency and improving women's health.[133] While femtech may be perceived as a lucrative market for investors, it is a nuanced and complex field that requires both product designers and technology that can understand important distinctions about the female body in order to add value.[134] Until

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124. McGrath, *supra* note 11.

125. Zoë LaRock, Femtech *Companies Are Likely Poised for Speedy Growth – Despite Failing to Prove That Their Tools Live Up to the Hype*, BUS. INSIDER (July 22, 2019 1:16 PM), http://www.businessinsider.com/femtech-space-booms-despite-tepid-efficacy-2019-7.

126. *Id.*

127. *Does Digital Health Technology Know Women?*, *supra* note 36.

128. *Id.*

129. *See* McGrath, *supra* note 11.

130. *See* Ryan Ayers, *Femtech: Startups Changing Women's Health Tech*, READWRITE: HEALTH (Oct. 11, 2019), http://www.readwrite.com/2019/10/11/femtech-start-ups-changing-womens-health-tech/; Das, *supra* note 58.

131. McGrath, *supra* note 11; *see also* LaRock, *supra* note 125.

132. *Does Digital Health Technology Know Women?*, *supra* note 36.

133. *See* Altman, *supra* note 56.

134. Simeone, *supra* note 9.

this occurs on a widespread scale, femtech products have the potential to perpetuate stereotypes and discrimination that harm women and diminish their agency.[135]

III. FEMTECH AND THE OTHERING OF WOMEN

The undeniable connection between femtech, society, and politics can lead to the socially undesirable consequence of *othering* subsets of women.[136] Scholars and experts have long identified a "tendency within human societies to organize and collectively define themselves along dimensions of difference and sameness" in order to "impart social meaning[] [and] help navigate [the] social world"—even on an unconscious level.[137] This tendency manifests itself in the underlying assumptions that pervade femtech products—from their conception to design to sale—which can lead to the unintended marginalization of groups of women who fail to conform to socially constructed perceptions of *normalcy*.[138] The result is devaluation and *othering* of certain classes of women based on the structure and assumptions of femtech devices, and the data they collect and normalize.[139]

A. *Defining Othering*

The term *othering* refers to "a set of dynamics, processes, and structures that engender marginality and persistent inequality across any of the full range of human differences based on group identities."[140] In this manner, *othering* results in the construction of an identity in reference to others, and is a manner of "propagating group-based inequality and marginality".[141] Through this process, a virtuous *self* and a lesser *other* are created.[142] *Othering* thus operates to define and secure one's identity by

135. *See Does Digital Health Technology Know Women?*, *supra* note 36.

136. Powell & Menendian, *supra* note 37, at 17; *see also* Champayne, *supra* note 24; McHugh, *supra* note 11.

137. Powell & Menendian, *supra* note 37, at 23–24.

138. *See* WACHTER-BOETTCHER, *supra* note 6, at 51; McHugh, *supra* note 11.

139. Powell & Menendian, *supra* note 37, at 25–26; Todres, *supra* note 14, at 609; *see also* McHugh, *supra* note 11.

140. Powell & Menendian, *supra* note 37, at 17.

141. *Id.*; Natalie J. Grove & Anthony B. Zwi, *Our Health and Theirs: Forced Migration, Othering, and Public Health*, 62 SOC. SCI. & MED. 1931, 1933–34 (2006); Joy L. Johnson et al., *Othering and Being Othered in the Context of Health Care Services*, 16 HEALTH COMM. 253, 254 (2004); Susan J. Stabile, *Othering and the Law*, 12 U. ST. THOMAS L.J. 381, 382–83 (2016).

142. Stabile, *supra* note 141, at 382; Todres, *supra* note 14, at 607.

stigmatizing and distancing those who are different.[143] This results in the exclusion, devaluation, and dehumanization of others from the self's locus of concern.[144]

A key feature of *othering* is that group-based identities can become so fundamental that they are seen as natural and inform everyday behavior and decisions.[145] Even at an unconscious level, this continual process of *othering*—or *us versus them*—can lead to individual acts of discrimination based on stereotypes that are perpetuated and approved by general society.[146] "When replicated across society and over time, individual acts of discrimination have a cumulative and magnifying effect that may help explain many group-based inequalities."[147] Accordingly, even if unintentional, *othering* practices can "reinforce and reproduce positions of dominance and subordination."[148]

By enforcing projections of difference on those who fall outside the self and societally-proclaimed norms, *othering* contributes to alienation, marginalization, and internalized oppression.[149] The *other* becomes trapped in her uniqueness and is reduced to an object that can be analyzed, categorized, and discriminated against.[150] Although this discrimination may, at times, be overt, it can also take the form of microaggressions.[151] A microaggression occurs if there is indirect, subtle, or unintentional discrimination against members of a marginalized or *other* group.[152] This behavior can extend to commonplace verbal and environmental indignities that reinforce stereotypes without intending to do so.[153] When such microaggressions occur, they create distance between the *self* and the *other*,

143. Grove & Zwi, *supra* note 141, at 1933.

144. Stabile, *supra* note 141, at 386; Todres, *supra* note 14, at 613–14.

145. Powell & Menendian, *supra* note 37, at 17.

146. *See id.*

147. *Id.* at 25.

148. Johnson et al., *supra* note 141, at 254.

149. Mary K. Canales, *Othering: Difference Understood??: A 10-Year Analysis and Critique of Nursing Literature*, 33 ADVANCES NURSING SCI. 15, 16, 19 (2010).

150. *See* Michal Krumer-Nevo & Mirit Sidi, *Writing Against Othering*, 18 QUALITATIVE INQUIRY 299, 299 (2012).

151. Sophia Seawell, *The Differential Use of Digital Platforms to Make Space for Microaggressions*, HASTAC (Apr. 29, 2014), http://www.hastac.org/blogs/sseawell/2014/04/29/differential-use-digital-platforms-make-space-microaggressions.

152. *See Microaggression*, MERRIAM-WEBSTER: DICTIONARY, http://www.merriam-webster.com/dictionary/microaggression (last visited May 1, 2020); Seawell, *supra* note 151.

153. *See* Seawell, *supra* note 151.

with the *other* often "internaliz[ing] the devalued sense of self portrayed in the dominant discourse."[154]

While there are multiple dimensions across which *othering* may occur, sex and gender are two common forms of *othering* that are deeply engrained in human existence.[155] As early as 1949, French philosopher Simone de Beauvoir provided a framework for understanding the construction of gender, asserting that *man* is considered default while *woman* is characterized as the *Other*.[156] As part of this framework, humanity is perceived as being male, with man defining *woman not [as] herself* but as relative to him.[157] Stated differently, men are represented as the norm in Western society, while "women [are] viewed as deficient."[158] This perception of male as dominant and normal persists today, even in technological apps like Apple's comprehensive health tracker that are gender-neutral but fail to include basic tracking applications for women.[159] As technology propels society into an age of endless screens and code, it also serves to fragment and divide society.[160] Thus, seventy years after Simone de Beauvoir's publication of *The Second Sex*, some of the most privileged men in Silicon Valley—able-bodied, cisgender, heterosexual, and Caucasian—are restricting meaningful innovation in the health care technology space for their non-male counterparts due to ingrained gender bias.[161]

B. *Femtech: Using Digital Technology to* Other *Women*

Beyond the traditional male-female bias, a new dimension of *othering* has arisen with respect to femtech products: The construction of female identities along artificial lines of what society and males perceive as

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154. Todres, *supra* note 14, at 618.

155. *See* Canales, *supra* note 149, at 19; Todres, *supra* note 14, at 619; Powell & Menendian, *supra* note 37, at 18.

156. CRIADO PEREZ, *supra* note 4, at XII; SIMONE DE BEAUVOIR, THE SECOND SEX 19, 26 (Constance Borde & Sheila Malovany-Chevallier trans., Vintage Books 2011) (1949) (ebook); Goldhill, *supra* note 15.

157. DE BEAUVOIR, *supra* note 156, at 26.

158. Kenneth B. Nunn, *The Child as Other: Race and Differential Treatment in the Juvenile Justice System*, 51 DEPAUL L. REV. 679, 693 (2002).

159. *See Does Digital Health Technology Know Women?*, *supra* note 36 (noting that Apple Health appeared on the market without a period tracker and did not add one for an entire year afterwards); McHugh, *supra* note 11.

160. *See* Goldhill, *supra* note 15.

161. *See id.* (acknowledging that while "[t]he terminology and industries have changed . . . the othering of women remains stubbornly resistant to progress."); McHugh, *supra* note 11.

normal.[162] The design features and assumptions built into femtech products reveal the dissonance between what many women are and want, and what society expects them to be and desire.[163] In particular, the act of measurement itself is never neutral, yet, femtech decidedly measures the most intimate and subjective experiences by simplifying them to analytical and comparable data points.[164] Once the data is collected and averaged, it operates to create socially acceptable versions of *normal*, against which women compare their own health and experiences.[165] By charting, graphing, and comparing one woman's experience or performance with another's, app developers can simplify highly personal interactions and "normatively construct[] the *quality* of intimate behaviors along a very limited set of axes."[166] Such simplification and normative constructions can introduce *algorithmic subjectivity* into society's understanding of intimate and reproductive behavior.[167]

While marketing for femtech devices promotes themes of agency and self-determination, the messaging can sound like a veneer of feminism for a product that is more concerned with manipulating women's fears and insecurities about their bodies for the sake of profit.[168] Because self-tracking tools are designed for consumers who are assumed to be young and fit, they present a restricted image of wellbeing, often assuming a certain type of user who is unburdened by poverty or mental or physical illness.[169] This is evidenced on the homepages of many femtech websites, where a presumably able-bodied, cis-presenting woman holds or wears a product related to sex or reproduction.[170] These images reinforce the message that these devices and products help the user achieve normative femininity.[171] This not only leaves behind women who do not menstruate or cannot get pregnant, but it also neglects women whose sexual experiences are not heterosexual in nature.[172]

Specifically, every time a woman's data or experience fails to conform to the artificial standard, she faces repeated microaggressions and

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162. *See* McHugh, *supra* note 11; Tiffany, *supra* note 10.
163. *See* McHugh, *supra* note 11.
164. Levy, *supra* note 54, at 687–88; Tiffany, *supra* note 10.
165. *See* Levy, *supra* note 54, at 688; McHugh, *supra* note 11.
166. Levy, *supra* note 54, at 688.
167. *Id.*
168. *See* Altman, *supra* note 56.
169. DEBORAH LUPTON, THE QUANTIFIED SELF 140 (2016).
170. *See Thinx*, http://www.shethinx.com (last visited May 1, 2020).
171. *See* McHugh, *supra* note 11.
172. *See* Levy, *supra* note 54, at 687–88; McHugh, *supra* note 11.

othering that highlight her failure to adhere to societal expectations.[173] In this manner, femtech "legitimates certain forms of knowledge and experience, while rendering others invisible."[174] For instance, apps that limit data entry for the length of a woman's cycle implicitly tell women with longer-than-average cycles that they are *abnormal* and that their data is not even worth recording.[175] Similarly, the app that congratulates women on missing their period marginalizes the experiences of individuals who may have been raped, sexually abused, or are uninterested in parenting a child.[176] These women are implicitly told that their experiences are unnatural and atypical for *normal* women, thus working to *other* and distance this sub-population.[177] In that same vein, the app that monitors sexual activity using male genitalia conveys to all LGBTQ individuals that they deviate from the arbitrary norm of the heterosexual female—a societally created and imposed standard.[178] Stated differently, femtech products "tell[] queer, unpartnered, infertile, and/or women uninterested in procreating that they aren't even women."[179] As such, each assumption that is built into a femtech device—without careful vetting and understanding of the entire consumer population—can serve to ostracize and *other* subsets of women.[180] These women are made to feel unequal, as if they have inherently less value than their *normal* counterparts, despite the fact that each individual body is unique.[181] This has the artificial effect of placing women into hierarchical categories based on their ability to conform to arbitrary criteria.[182] In this manner, femtech not only creates and defines what is normal for female

173. Levy, *supra* note 54, at 687–88; *see also* McHugh, *supra* note 11; *Microaggression*, *supra* note 152.

174. Levy, *supra* note 54, at 687; Tiffany, *supra* note 10.

175. *See* Tiffany, *supra* note 10.

176. *See* Krueger, *supra* note 5; Tiffany, *supra* note 10 (mentioning that the "strong assumptions built into [femtech] design[s] . . . can marginalize a lot of women's sexual health experiences"). "The assumption from the outset is that pregnancy drives period tracking — an assumption that may immediately exclude a broad swath of the female population." Krueger, *supra* note 5.

177. *See* Kruger, *supra* note 5.

178. Miranda Hall, *The Strange Sexism of Period Apps*, VICE (July 25, 2017, 9:00 AM), http://www.vice.com/en_us/article/qup5yd/the-strange-sexism-of-period-apps.

179. Tiffany, *supra* note 10 (quoting Maggie Delano, *I Tried Tracking My Period and It Was Even Worse than I Could Have Imagined*, MEDIUM (Feb. 23, 2015), http://www.medium.com/@maggied/i-tried-tracking-my-period-and-it-was-even-worse-than-i-could-have-imagined-bb46f869f45).

180. *See* WACHTER-BOETTCHER, *supra* note 6, at 72, 110–13, 141–45; Tiffany, *supra* note 10.

181. *See* Tiffany, *supra* note 10.

182. *See* CRIADO PEREZ, *supra* note 4, at 176–77.

reproductive health and sexual wellness, but it does so with little thought to the consequences that befall the *othered* population groups.[183] This leads to exclusion and disempowerment for subsets of the female population that may already be marginalized.[184]

In particular, the Lambda Legal survey on discrimination aptly notes that queer Americans regularly encounter "disrespectful attitudes, discriminatory treatment, inflexible or prejudicial policies, and even refusals of essential care."[185] But, "in defining women primarily by their biology, many femtech companies focus singularly on the needs of cis [and not] trans women."[186] This not only *others* trans women, but it also categorically excludes trans men who often have similar physiologies to cis women.[187] This double exclusion peels back any illusion that most femtech companies are first and foremost concerned with assisting the most vulnerable and underserved populations.[188] Rather, although an opportunity exists for scientific innovation to address the unique health needs of intersex and non-binary (including trans) individuals, this population is further ignored and marginalized through the product assumptions that are built into femtech devices.[189]

Moreover, this *othering* by femtech devices results in a self-perpetuating cycle that first imposes constructs of normalcy on the female population and then uses the collected data to further define societal standards of normalcy.[190] By limiting the data that users can input into these devices, the femtech industry has defined the *normal* data range from the start.[191] Given that some femtech devices then use or sell the inputted data to third parties and researchers, this data is subsequently analyzed to average and normalize the female experience across populations.[192] Defining

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183. *See* Canales, *supra* note 149, at 16; Champayne, *supra* note 24.

184. *See* WACHTER-BOETTCHER, *supra* note 6, at 51; Tiffany, *supra* note 10.

185. LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY ON DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE LIVING WITH HIV 5 (2010).

186. Goldhill, *supra* note 15; *see also* Hall, *supra* note 178.

187. *See* Goldhill, *supra* note 15.

188. *Id.*; *see also* LAMBDA LEGAL, *supra* note 185, at 5.

189. *See* Champayne, *supra* note 24. "There are strong assumptions built into [the] design [of femtech products] that can marginalize a lot of women's sexual health experiences." *Id.*

190. Hudson, *supra* note 22; McHugh, *supra* note 11.

191. *See* CRIADO PEREZ, *supra* note 4, at 234–35.

192. McHugh, *supra* note 11. "Many of the same systems in health apps that help people chart their cycles and related markers are collecting that data and offering it to third parties for marketing and advertising purposes." *Id.*; *see also* Khidekel, *supra* note 55; Levy, *supra* note 54, at 689.

normalcy and then using data that is inputted in accordance with those standards to construct normalcy excludes the experiences of large portions of the female population.[193]

Further, given the sensitive nature of data collection for femtech devices (i.e., menstrual and sexual data input), women are often uncomfortable providing data on every intimate aspect of their lives.[194] Some femtech apps, for example, request data such as sexual position, cycle length and flow, weight, mood, medications, intensity of cramps, acne, time of sexual activity, color and thickness of cervical fluid, and basal body temperature.[195] Women who are uncomfortable providing the full data requested will either avoid data input in certain categories or, when data avoidance is not possible to continue using the app, they will enter incorrect or false data to avoid full surveillance into their private lives.[196] These actions not only decrease the effectiveness of the femtech devices, but they also skew the underlying data that is then used to normalize female experience.[197] This skewed data not only biases the algorithms that function within these femtech devices to normalize data and predict fertility windows, cycle lengths, etc., but it also negatively impacts scientific research studies that are being performed on this data to understand and improve women's health conditions.[198]

Thus, design technologies in the femtech space frequently fail to acknowledge the scope of women's medical needs and instead rely on gendered assumptions that can marginalize women's health experiences.[199] It is increasingly evident that the distance in social locations between investors and designers in Silicon Valley and patient-consumers exacerbates existing inequalities in terms of access to medical care and full

193. *See Does Digital Health Technology Know Women?*, *supra* note 36.

194. *See* McHugh, *supra* note 11.

195. Adam Jacobson, *The Risks of Pregnancy-Tracking Apps*, July–Aug. 2019, at 24, 24–26; *see also* McHugh, *supra* note 11 (noting that women are routinely asked to "input data [into femtech tracking devices] like when their periods start and end, how heavy their cycles are, and related factors like mood, sexual activity, physical pain, body temperature, and pulse . . . [with] fertility-oriented apps even ask[ing] [women] to log their sexual positions.") McHugh, *supra* note 11.

196. McHugh, *supra* note 11.

197. *See id.*

198. *See id.* "Using femtech apps without inputting detailed information not only decreases their efficacy, but those flawed outcomes can lead to incorrect predictions that become data points informing the larger health market." *Id.*

199. Champayne, *supra* note 24.

personhood.[200] In this manner, femtech devices can reproduce social inequalities that maintain systems of gendered dominance.[201]

IV. FIXING FEMTECH TO AVOID DIGITAL MICRO-AGGRESSIONS AND DISCRIMINATION

Given the current status of femtech and the perpetuation of gendered stereotypes and dominance, it is crucial that future products be designed to create an inclusive environment for all users without the imposition of biased standards of normalcy.[202] "[T]he more technology becomes embedded in all aspects of life, the more it matters whether that technology is biased, alienating, or harmful."[203] The assumptions that designers and technologists weave into their products should be reflective of the collective user experience, rather than seeking to impose normalcy on a diverse population.[204] As technology becomes more pervasive, users must begin demanding inclusive platforms and interfaces that promote health and wellbeing, rather than reinforcing biases.[205]

To do this requires first and foremost that consumers acknowledge their power and autonomy in the digital marketplace, and their control over spending on biased products.[206] Because heterosexual Caucasian female normalcy has long been recognized and paraded as the golden standard, it is easy to ignore—even unintentionally—the subtle discriminatory messaging that some femtech products convey.[207] Further, these digital micro-aggressions are merely another snub in a long chain of discriminatory events towards diverse consumers, making them a daily part of life that can go unnoticed at a conscious level.[208] While tech is not overtly or purposely discriminatory in most circumstances, the assumptions that underlie these products must be challenged and reformed.[209]

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200. *See id.*; Ayers, *supra* note 130.

201. *See* Hudson, *supra* note 22.

202. *See* Ayers, *supra* note 130.

203. WACHTER-BOETTCHER, *supra* note 6, at 10–11; Acton, *supra* note 71 (recognizing that "[d]eveloping technology for women's health . . . is a big responsibility that entrepreneurs and companies must take seriously" to avoid *a crisis of confidence*.).

204. *See* Simeone, *supra* note 9; McHugh, *supra* note 11.

205. *See* WACHTER-BOETTCHER, *supra* note 6, at 196–97.

206. *See* Sharkey, *supra* note 23; Tiffany, *supra* note 10.

207. McHugh, *supra* note 11; Tiffany, *supra* note 10.

208. WACHTER-BOETTCHER, *supra* note 6, at 72. "These little slights add up — day after day, week after week, site after site — making assumptions about who you are and sticking you into boxes that just don't fit." *Id.*

209. *See id.* at 196.

The problem, however, is not the lack of a solution but rather the lack of an incentive.[210] Femtech designers have experienced success with their current marketing strategies and products; yet, success does not equal inclusion.[211] Femtech consumers also enthusiastically embrace the notion that women's health is finally stepping into the forefront of issues that developers and society recognize, and they see the future potential of these products.[212] When each consumer focuses on how the femtech app helps her in her own daily life and how these products might contribute to the improvement of women's health worldwide, it becomes easy to forget the biased assumptions that form the basis of these products.[213]

Thus, until consumers begin demanding more inclusive products that avoid gender dominance and normalcy, tech companies have little incentive to change.[214] With a primary focus on the bottom line, femtech developers are more interested in attracting a large user base and monetizing data collection than they are with correcting social injustices or ensuring full representation.[215] It is up to consumers to request product changes and inclusion through expression of dissatisfaction and conscious spending on products that promote diversity and inclusion.[216] Until consumer priorities shift, tech companies lack the incentive to increase spending on their devices to ensure inclusion.[217] However, as more daily interactions take place in the digital world, these technologies hold increasing power over the development of cultural norms.[218] As such, technology does not exist merely to be marveled at by consumers; instead, it exists as part of the collective

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210. *Id.* at 21; Sharkey, *supra* note 23.

211. Clark, *supra* note 46; Champayne, *supra* note 24.

212. *See* Champayne, *supra* note 24; Codinha, *supra* note 60; *Femtech Companies Innovating Traditional Women's Healthcare*, *supra* note 57; McHugh, *supra* note 11 (describing the current status of women's health as *a global crisis* and noting the historic "lack of concern from the medical industry" regarding this issue). "Caring for the female body is still being regarded as a luxury and sold at that price." Codinha, *supra* note 60.

213. *See* Codinha, *supra* note 60; *Femtech Companies Innovating Traditional Women's Healthcare*, *supra* note 57; McHugh, *supra* note 11.

214. *See* WACHTER-BOETTCHER, *supra* note 6, at 40, 75 (calling on consumers to demand that designers create more inclusive products); Hudson, *supra* note 22. "The first step is to start demanding that the institutions using these tools make deliberate choices about the moral decisions embedded in their systems." Hudson, *supra* note 22.

215. *See* Champayne, *supra* note 24; Codinha, *supra* note 60.

216. *See* WACHTER-BOETTCHER, *supra* note 6, at 40, 75; Hudson, *supra* note 22.

217. *See* WACHTER-BOETTCHER, *supra* note 6, at 40, 75; Hudson, *supra* note 22.

218. WACHTER-BOETTCHER, *supra* note 6, at 197.

consumer experience.[219] Product developers must be held accountable for the biased and exclusionary assumptions that pervade their products.[220] Only by demanding better can consumers alter the landscape of female technology to ensure comprehensive representation and inclusion.[221]

In addition, broader societal shifts are needed in the perception of female normalcy.[222] The existing femtech devices reflect commonly accepted societal perceptions of the female body, which implies widespread societal discrimination.[223] While activism has greatly contributed to increased inclusion of the LGBTQ population, more must be done to ensure that micro-aggressions and discrimination are the exception, not the norm.[224] This general societal shift will inevitably take time, but the seeds of change must be planted now.[225] First, consumers must move beyond the instant gratification that accompanies technology and try to understand the assumptions and inputs that are woven into the devices they use, and the impact of each assumption on other population groups.[226] By examining technology with an eye towards understanding rather than blind acceptance, flaws can be more readily identified and remedied.[227]

Second, representation in technology companies and Silicon Valley must become increasingly diverse to ensure all viewpoints are heard, acknowledged, and considered.[228] Although gender diversity has increased in femtech companies, the Silicon Valley investment firms that approve and back these products have seen little change from the historically male-

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219. *See* Champayne, *supra* note 24; Sharkey, *supra* note 23.

220. Hudson, *supra* note 22.

221. *Id.*

222. *See* Codinha, *supra* note 60.

223. Hall, *supra* note 178.

224. *See* WATCHER-BOETTCHER, *supra* note 6, at 11; Faroat Andasheva, *Aren't I a Woman? Deconstructing Sex Discrimination and Freeing Transgender Women from Solitary Confinement*, 12 FIU L. REV. 117, 140 (2016).

> To avoid othering transgender and non-gender conforming individuals, while simultaneously challenging the binary sex system, a solution should consist of trans inclusivity to the level where trans individuals fit perfectly within the understanding of sex and gender; not occupy a small, capricious class where their existence is divided between two sides.

Andasheva, *supra*, at 140.

225. *See* Andasheva, *supra* note 224, at 150.

226. *See* Hudson, *supra* note 22.

227. *Id.*

228. *See* CRIADO PEREZ, *supra* note 4, at XIII; WACHTER-BOETTCHER, *supra* note 6, at 26. "[W]hen we are designing a world that is meant to work for everyone we need women in the room." CRIADO PEREZ, *supra* note 4, at XIII.

dominated environment.[229] The product creation teams and funding groups that design and financially support these devices must be reflective of the broader population groups they serve.[230] Unfortunately, the lack of diversity in this area is a key contributor to the development of products that does not match consumer expectations and that inadvertently discriminate against sub-populations.[231]

Finally, femtech products should be heavily vetted by diverse consumer groups before launch.[232] While a number of femtech companies currently do this, some companies nonetheless feel pressure to *rush to market*, and do not ensure adequate testing among representative consumers.[233] The perspective among these organizations is that the rush to market will enable the company to capture available market share while fixing bugs or product complaints at a later date.[234] Extensive testing, however, can help to identify implicit biases in products before they hit the market, and can ensure that companies better understand what the consumer population is seeking in the product.[235] Thus, consumers, product developers, and investors all play a fundamental role in altering the femtech landscape to promote inclusion and diversity.[236]

V. CONCLUSION

The femtech industry is rapidly developing, growing, and changing with women perceived as a lucrative consumer base upon which fears, desires, and anxieties can be exploited.[237] While these products are, theoretically, designed with good intentions to bring greater insight and attention to women's health concerns, their development and design can inadvertently marginalize subsets of the population.[238] At the current stage

229. *Does Digital Health Technology Know Women?*, *supra* note 36. "In spite of the slogan of diversity pinned on the flag of many tech companies, the field is highly dominated by men." *Id.*

230. CRIADO PEREZ, *supra* note 4, at XIII; *see also* Tahmassebi, *supra* note 4.

231. CRIADO PEREZ, *supra* note 4, at XIII. "[F]ailing to include the perspective of women is a huge driver of an unintended male bias that attempts (often in good faith) to pass itself off as *gender neutral*." *Id.*

232. *See Does Digital Health Technology Know Women?*, *supra* note 36.

233. *Id.* (stating that future users were *most likely not consulted* by femtech designers before the products were released into the market).

234. *See id.*; Tiffany, *supra* note 10.

235. WACHTER-BOETTCHER, *supra* note 6, at 28, 71.

236. *See* Tahmassebi, *supra* note 4; *Does Digital Health Technology Know Women?*, *supra* note 36.

237. *See* Tiffany, *supra* note 10.

238. *See* WACHTER-BOETTCHER, *supra* note 6, at 37–38, 51.

of development, numerous femtech products contain incorrect assumptions about consumers' needs and desires, and instead seek to impose arbitrary standards of *normalcy* upon all members of the female population.[239] Individuals whose data, desires, or lifestyles do not conform with these assumptions experience micro-aggressions and discrimination that serve to distance or *other* them from the *normal* standard.[240] Fundamental societal shifts are necessary to ensure full representation and inclusion of all consumers for femtech products, and consumers must be empowered to demand better products from the companies that develop this technology.[241] Digital tools must be viewed "not as a wonder, or even as a villain, but rather as a series of choices that designers and technologists have made."[242] Presently, there is a collective abdication of responsibility that must be remedied to ensure women's health concerns are addressed not only among all subsets of the population, but also among all dimensions—including, but not limited to, reproductive and sexual wellness.[243]

239. *Does Digital Health Technology Know Women?*, *supra* note 36; McHugh, *supra* note 11.

240. *Does Digital Health Technology Know Women?*, *supra* note 36; McHugh, *supra* note 11; Tiffany, *supra* note 10.

241. CRIADO PEREZ, *supra* note 4, at XIII–XV; Hudson, *supra* note 22.

242. WACHTER-BOETTCHER, *supra* note 6, at 200.

243. *See* McHugh, *supra* note 11; Tiffany, *supra* note 10.

BAYH-DOLE ACT, SUPREME COURT OF THE UNITED STATES DECISION IN *STANFORD V. ROCHE*, AND PUBLIC HEALTH

KISHOR DERE*

I. INTRODUCTION

Ideally, health care, science-technology, and law should go hand in hand to protect weak and vulnerable patients.[1] Bearing in mind the concerns over public health amidst the frenzy of proprietary patent claiming, escalating prices of medicines, and the letter and spirit of the Bayh-Dole Act, this Article critically analyzes the impact of the judgment of the Supreme Court of the United States case in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* ("*Stanford v. Roche*")[2] on the interests of ordinary patients.[3] The passage of the Bayh-Dole Act is termed as a landmark legislative development to enhance university

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1. *See* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOVATION FOUND. (Mar. 4, 2019), http://www.itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system.

2. 563 U.S. 776 (2011).

3. *See id.* at 783; Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018); Ezell, *supra* note 1; discussion *infra* section III.B.

competitiveness by increasing incentives for universities to exploit intellectual property.[4] Before the Bayh-Dole Act was passed, universities did not have effective systems for technology transfer, making ownership rights unclear.[5] As a result, companies were less likely to collaborate with universities because they did not want to invest in technologies the university may not actually own or that the inventor may assign to another entity.[6] The United States Congress passed the Bayh-Dole Act to clarify ownership rights to promote collaboration between industry and nonprofits, including universities.[7] The primary purpose was to encourage future research and discovery.[8]

The judgment of the Supreme Court of the United States in *Stanford v. Roche* offers a new interpretation of the Bayh-Dole Act that differs from the pre-*FilmTec Corp. v. Allied-Signal Inc.*[9] era.[10] It does not seem to accord with the spirit in which Congress had adopted this law.[11] There was widespread criticism of this judicial verdict fearing that uncertainty over patent ownership might dampen enthusiasm of entrepreneurs keen to invest in new inventions.[12] The United States District Court of the Northern District of California had ruled in favor of Stanford as a lawful title bearer following the federal government.[13] Popular understanding was that the opinion of the United States District Court of the Northern District of California in favor of Stanford was correct, which had held that the inventor was not at all interested in assigning it to Cetus Corporation ("Cetus").[14]

The adjudication done by the United States District Court of the Northern District of California was considered to be appropriate owing to the provisions of the Bayh-Dole Act itself.[15] By assigning the rights in future inventions to Cetus, the inventor had created a discontinuity in the title

4. Ezell, *supra* note 1; *see also* 35 U.S.C. §§ 200–212.
5. Ezell, *supra* note 1; *see also* 35 U.S.C. §§ 200–212.
6. *See* Ezell, *supra* note 1.
7. 35 U.S.C. § 200.
8. *Id.*
9. 939 F.2d 1568 (Fed. Cir. 1991).
10. Ashlie Depinet, *The Public Is Paying Twice: How* Stanford v. Roche *Undermines the Congressional Intent of the Bayh-Dole Act*, 41 CAP. U. L. REV. 729, 738 (2013); *see also* 35 U.S.C. §§ 200–212; Stanford v. Roche, 563 U.S. 776, 776; *FilmTec Corp.*, 939 F.2d at 1573–74.
11. Depinet, *supra* note 10, at 738; *see also* 35 U.S.C. § 200; *Stanford*, 563 U.S. at 776; *FilmTec Corp.*, 939 F.2d at 1573–74.
12. Depinet, *supra* note 10, at 750.
13. *Id.* at 738; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 783.
14. Depinet, *supra* note 10, at 738; *see also* 35 U.S.C. §§ 200–212.
15. Stanford v. Roche, 487 F. Supp. 2d 1099, 1119 (N.D. Cal. 2007); Depinet, *supra* note 10, at 738, 749; *see also* 35 U.S.C. §§ 200–212.

contrary to the stipulations of the Bayh-Dole Act.[16] The United States District Court of the Northern District of California's judgment echoed the Congressional logic behind passing the Bayh-Dole Act, vested patent ownership in the university operating under the said law, incentivized the university to undertake research along with its commercialization, and encouraged the industry to contribute to the commercialization of the invention made by the university.[17] Unfortunately, the Federal Circuit adopted a different approach, and it was also endorsed by the Supreme Court of the United States.[18]

The inventor, while joining the university, had signed an agreement to assign his rights and title to prospective inventions to his employer, i.e. Stanford.[19] While serving Stanford, the inventor got an opportunity to deal with Cetus.[20] It was in 1991 that Roche acquired polymerase chain reaction (PCR)-related assets of Cetus.[21] As soon as he began to pay visits to Cetus, he signed a Visitor's Confidentiality Agreement expressly stating that he transferred his rights to future invention to Cetus.[22] The Federal Circuit construed that the Visitor's Agreement with Cetus alluded to assignment of present rights while the employment contract with Stanford talked about assignment of future rights.[23] As a result of this peculiar interpretation, Cetus got the rights to the invention at hand.[24] Thus, by the time the invention was made and Stanford submitted its invention disclosure statements, Cetus had already procured and/or secured rights from the inventor through the confidentiality agreement it had him sign at the outset.[25]

16. *Stanford*, 563 U.S. at 780; Depinet, *supra* note 10, at 749; *see also* 35 U.S.C. §§ 200–212.

17. *Stanford*, 487 F. Supp. 2d at 1124; Depinet, *supra* note 10, at 738–39; *see also* 35 U.S.C. §§ 200–212.

18. *Stanford*, 563 U.S. at 793; Stanford v. Roche, 583 F.3d 832, 844 (Fed. Cir. 2009); Depinet, *supra* note 10, at 739; *see also* 35 U.S.C. §§ 200–212.

19. Depinet, *supra* note 10, at 739; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 783; *Stanford*, 583 F.3d at 845.

20. Depinet, *supra* note 10, at 739; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 781; *Stanford*, 583 F.3d at 837.

21. Depinet, *supra* note 10, at 739; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 781; *Stanford*, 583 F.3d at 837.

22. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 781; *Stanford*, 583 F.3d at 837.

23. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 841.

24. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 842.

25. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 842.

This was the majority judgment.[26] The dissenting judge did not agree with this kind of hairsplitting done by the majority because, in his view, it defeated the purpose of the Bayh-Dole Act, i.e. to oversee relationships of small businesses and voluntary sector grantees with the government.[27] The majority judgment had rather focused on regulating the relationship between the recipients of grants and their employee-inventors.[28] Net result of such an approach would be the government funded universities, nonprofit research organizations, and small businesses would not have inventions nor would they have patent rights, held the minority judgment.[29]

In this judgment, the Supreme Court of the United States asserted that the Bayh-Dole Act did not supplant the patent law standards and did not *proprio motu* vest rights and title to federally funded inventions in federal contractors.[30] The Court held that its opinion was grounded in the benchmarks of patent law, which were substituted by the Bayh-Dole Act.[31] The Supreme Court of the United States relied on common law to rule in favor of Roche, while the Bayh-Dole Act was precisely passed to do away with the patent ownership uncertainty caused by the common law.[32]

The judicial unpredictability, as demonstrated in *Stanford v. Roche*, would embitter relationships between the universities making inventions, and private organizations seeking to commercialize such inventions under the Bayh-Dole Act.[33] It will compel universities to downgrade their research priorities, in spite of receiving federal funds for this purpose.[34] Private companies will also hesitate to license such university patents thanks to their ambiguous ownership status.[35] Researchers may be frightened of penal

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26. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 842.

27. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 797–98 (Breyer, J., dissenting); *Stanford*, 583 F.3d at 845.

28. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 842.

29. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 784; *Stanford*, 583 F.3d at 842.

30. *Stanford*, 563 U.S. at 780; *see also* 35 U.S.C. §§ 200–212.

31. Depinet, *supra* note 10, at 749; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 780.

32. Depinet, *supra* note 10, at 749; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 780.

33. Depinet, *supra* note 10, at 740; *see also* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 776.

34. Depinet, *supra* note 10, at 739–40; *see also* 35 U.S.C. §§ 200–212.

35. Depinet, *supra* note 10, at 747; *see also Stanford*, 563 U.S. at 781; Liza Vertinsky, *Universities as Guardians of Their Inventions*, 2012 UTAH L. REV. 1949, 1966–67 (2012).

consequences of commercializing their inventions.[36] It has far-reaching consequences.[37]

In the wake of the unexpected judicial verdict in *Stanford v. Roche*, university and other public employees could be apprehensive about the legal status of their inventions.[38] A careful look at the federal conflict of interest rules shows that these rules treat royalties emanating from a source other than the employer of the inventor as a financial conflict of interest.[39] This would inevitably force the researchers from playing any role that gives rise to a conflict of interest and attracts a criminal penalty.[40] It would end up in an anti-climax of the Bayh-Dole Act because inventors from government-run institutions and their prospective industry supporters would be afraid of working together.[41]

The most devastating impact of such judicial confusion and uncertainty is on the hundreds of millions of patients suffering from a wide variety of existing and emerging diseases.[42] Small businesses, universities, inventors, and public employers would hesitate from undertaking new research and experiments in the health care sector meant to provide relief to patients.[43]

II. HISTORY OF THE BAYH-DOLE ACT OF 1980

Since this Article deals with one of the United States patent laws and its interpretation by the Supreme Court of the United States in a 2011 case, as well as the impact of that particular judicial pronouncement on public health, it becomes pertinent to familiarize oneself with the historical background of the relevant issues.[44]

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36. Depinet, *supra* note 10, at 747; *see also Stanford*, 563 U.S. at 781; Vertinsky, *supra* note 35, at 1966–67.

37. *See Stanford*, 563 U.S. at 798 (Breyer, J., dissenting).

38. *See id.* at 786; Vertinsky, *supra* note 35, at 2003.

39. Depinet, *supra* note 10, at 756; *see also* 35 U.S.C. § 200; *Stanford*, 563 U.S. at 798; Robert M. Patino, *Moving Research to Patient Applications Through Commercialization: Understanding and Evaluating the Role of Intellectual Property*, 49 J. AM. ASSOC. FOR LABORATORY ANIMAL SCI. 147, 148 (2010).

40. Depinet, *supra* note 10, at 756; *see also* 35 U.S.C. § 200; *Stanford*, 563 U.S. at 798; Patino, *supra* note 39, at 148.

41. Depinet, *supra* note 10, at 756; *see also* 35 U.S.C. § 200; *Stanford*, 563 U.S. at 798; Patino, *supra* note 39, at 148.

42. *See* Patino, *supra* note 39, at 147.

43. *See id.*

44. *See* 35 U.S.C. §§ 200–212; *Stanford*, 563 U.S. at 793; Patino, *supra* note 39, at 147, 150.

A. *Government Funds Research but Companies Own Patents*

The early 1900s were an eyewitness to the launch of a host of modern medicines.[45] The new era of medicines began with the discovery of insulin and the introduction of sulfa drugs, barbiturates, amphetamine, and heparin.[46] At the far end of the 1940s, there were applications for penicillin drugs, morphine, phenobarbital, epinephrine, niacin, codeine, testosterone, progesterone, conjugated estrogens, digitalis, benzocaine, and theophylline, which are considered to be indispensable even in the second decade of the twenty-first century.[47] The major development took place when scholars teamed up with the forerunners of contemporary research-based companies.[48] The pharmaceutical companies inaugurated on average forty-three new chemical entities annually in the decade of the 1950s.[49] The Federal Drug Administration ("FDA") received applications for acetaminophen and new antibiotics, for example, as well as drugs to treat hypertension, anticoagulants, early cancer drugs, and the first oral contraceptive.[50] The era of the 1950s is also known as the period of the wonder drugs.[51]

It is interesting to recall the paradox that while the nineteenth-century pioneering inventors of these medicines sought patent protection, the medical and scientific establishments objected to the patenting of pharmaceutical products.[52] The grounds of resistance to pharmaceutical patenting were preventing crass commercialism and avoiding secrecy created by patenting which was a domain of quack medicines.[53] Moreover, the American Medical Association ("AMA") had made it illegal to hold patents

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45. *See* Suzanne White Junod, *FDA and Clinical Drug Trials: A Short History*, *in* A QUICK GUIDE TO CLINICAL TRIALS 25, 28 (Madhu Davies & Faiz Kermani eds., 2008).

46. *See id.*

47. *See* WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 1–7 (2017).

48. *See* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 118–22 (2010) (ebook); Joseph M. Gabriel, *Pharmaceutical Patenting and the Transformation of American Medical Ethics*, 49 BRIT. J. HIST. SCI. 577, 587 (2016); Nicolas Rasmussen, *The Drug Industry and Clinical Research in Interwar America: Three Types of Physician Collaborator*, 79 BULL. HIST. MED. 50, 55 (2005).

49. SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS 13 (1974).

50. *See* WORLD HEALTH ORG., *supra* note 47, at 1–7.

51. HARRY M. MARKS, THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900–1990 149 (1997).

52. *See* Gabriel, *supra* note 48, at 578–582, 585, 587; White Junod, *supra* note 45, at 27; Patino, *supra* note 39, at 147, 150.

53. Gabriel, *supra* note 48, at 578–79, 585, 587.

and had forbidden prescribing patented goods.[54] The contemporary generation obsessed with intellectual property rights ("IPRs") may be shocked to learn that the leading United States corporations, like Parke-Davis (today's Pfizer) and E.R. Squibb (now Bristol-Myers Squibb), in their early phases had deliberately avoided seeking patents and trade secrets.[55] There was, however, a gradual yet perceptible attitudinal change towards the issue of pharmaceutical patents in the first quarter of the twentieth century.[56]

Members of the academic community began to patent their inventions either by assigning patents to their host institutions or institutions of their affiliation.[57] For instance, the patent on insulin was held by the University of Toronto in 1923.[58] Research-oriented pharmaceutical companies in the United States also started patenting their inventions.[59] For example, Parke-Davis (predecessor of Pfizer) possessed eight patents granted in the 1920s on chemicals for medicinal use or various methods used in medical treatment.[60] The scientific and public health establishments continued to remain uncertain about the need to patent medicines for many more decades.[61] The path-breaking collaboration between the university-based medical researchers and research-driven pharmaceutical industry in the 1950s and 1960s generated, according to Gabriel, *impressive therapeutic dividends*.[62] In the wake of this paradigm shift, the patenting of pharmaceutical products began to be seen as an "ethically legitimate and even necessary" incentive mechanism encouraging researchers to develop effective drugs.[63]

The federal administrative machinery that curtails the life span or term of a patent also became visible around the same time.[64] While a premarket review of biological medicines was introduced in 1902 and of new

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54. *Id.* at 580.

55. *Id.* at 581; *Bristol-Myers Squibb Company*, ENCYCLOPEDIA BRITANNICA, http://www.britannica.com/topic/bristol-myers-squibb-company (last visited May 1, 2020); *2000: Pfizer Joins Forces with Warner-Lambert*, PFIZER, http://www.pfizer.com/about/history/pfizer_warner_lambert (last visited May 1, 2020).

56. Gabriel, *supra* note 48, at 584–85.

57. *Id.* at 588.

58. *Id.*; U.S. Patent No. 1,469,994 (filed Oct. 9, 1923); Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 67 n.70 (2018).

59. Gabriel, *supra* note 48, at 588.

60. *See* U.S. Patent No. 1,717,198 (filed June 11, 1929); Lietzan, *supra* note 58, at 66–67.

61. Gabriel, *supra* note 48, at 589.

62. *Id.* at 592.

63. *Id.* at 592–93.

64. *See* Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 49 (2018).

medicines in 1938, its previous applications were founded on safety data.[65] Those were quite modest in size as well as in scope.[66] In the 1940s, the patent office regulators and university researchers evolved "the randomized, controlled, blinded clinical trial [to prove] therapeutic claims."[67] In the 1950s, it was commonplace for the FDA to demand the data on outcomes.[68] It was in the year 1962 that the United States Congress legislated a premarket approval requirement and prescribed that companies should provide substantial evidence of the effectiveness of drugs.[69] As expected, there was new rigor in expectations of the FDA about the content and scope of applications in the subsequent decades.[70] The period between 1950 and 1965 witnessed a dramatic rise in the standard time required from the maiden clinical trial to an approval by the FDA, approximately seven years.[71] This was also the period that saw preclinical testing trials become more rigorous and lengthy.[72] As a result of these developments, in the second half of the 1960s, average patent life for new drugs was 13.9 years, and in the early 1970s, it was 12.4 years.[73] It was further reduced to 9.5 years by 1979.[74] A research study recorded that twenty-five percent of the reduction in the original patent term was caused by "an increase in the time between patent filings and the start of clinical trials."[75] Fifty percent of the loss in the legally stipulated term of the patent was caused by "an increase in the time between the start of clinical trials and [obtaining] regulatory approval."[76]

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65. *Id.*; Biologics Control Act of 1902, Pub. L. No. 57–244, § 1, 32 Stat. 728, 728–29 (1902); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75–717, § 505, 52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 301).

66. Lietzan, *supra* note 64, at 49.

67. Lietzan, *supra* note 58, at 67; *see also* Geoffrey Marshall et al., *Streptomycin Treatment of Pulmonary Tuberculosis: A Medical Research Council Investigation*, 2 BRIT. MED. J. 4582, 4582 (1948) (reporting of first such trial).

68. Lietzan, *supra* note 58, at 67; *see also* Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 21 Fed. Reg. 5576, 5578 (July 25, 1956) (to be codified at 21 C.F.R. § 130.4).

69. Lietzan, *supra* note 64, at 51–52.

70. Drug Amendments of 1962, Pub. L. No. 87–781, § 104, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 301); *see also* Lietzan, *supra* note 64, at 52–54.

71. Lietzan, *supra* note 58, at 67.

72. *Id.* at 68.

73. Peter Barton Hutt, *The Importance of Patent Term Restoration to Pharmaceutical Innovation*, HEALTH AFF., Spring 1982, at 6, 16–17.

74. *Id.*; *see also* Leonard G. Schifrin, *Lessons from the Drug Lag: A Retrospective Analysis of the 1962 Drug Regulations*, 5 HARV. J.L. & PUB. POL'Y 91, 91 (1982).

75. Lietzan, *supra* note 58, at 68.

76. *Id.* The remaining twenty-five percent of the patent term could be saved only because the patent office mercifully issued patents relatively faster. *Id.*

The advent of the rigorous patent administration in the United States meant that the cradle to grave welfare state was doing its best to award patents only to the deserving inventions and thereby protecting larger public interest as well.[77] The welfare state was also, and still is, a generous sponsor of the research on patentable inventions in university laboratories and non-profit sector institutions.[78] It is a fact of life that in liberal, progressive, democratic, and welfare states like the United States, the federal government is a major sponsor of academic research.[79] This claim can be bolstered by empirical evidence produced through academic research done by the National Science Foundation ("NSF").[80] The NSF website states that a team of researchers reckoned relationships between grants made by the government and innumerable United States patents along with scientific research papers between 1926 and 2017.[81] The said research shows that at least one-third of patents in the United States solely rely on the federally-financed research.[82] It is noteworthy that this number has risen constantly during the last nine decades.[83] This report makes a stunning revelation that industrial corporations increasingly rely on research supported by the federal government.[84] Moreover, this effect is across the board, not confined to any particular discipline.[85] For example, the report mentions that about two-thirds of the United States patents in chemistry and metallurgy emanate from federally subsidized research.[86] Hillary Greene from the University of

77. *See* RONDA BRITT, NAT'L SCI. FOUND., UNIVERSITIES REPORT $55 BILLION IN SCIENCE AND ENGINEERING R&D SPENDING FOR FY 2009; REDESIGNED SURVEY TO LAUNCH IN 2010 2 (2010); L. Fleming et al., *Government-Funded Research Increasingly Fuels Innovation*, 364 SCI. 1139, 1139–40 (2019).

78. *See* BRITT, *supra* note 77, at 1; Fleming et al., *supra* note 77, at 1139–40.

79. Fleming et al., *supra* note 77, at 1139–40. For example, in 2009, United States' universities and colleges spent $54.9 billion on science and engineering research and development ("R&D"). *See* BRITT, *supra* note 77, at 3. Of that amount, about sixty percent, or $32.6 billion, came from the federal government. *See id.*

80. Fleming et al., *supra* note 77, at 1139; *Government-Funded Research Increasingly Fuels Innovation*, NAT'L SCI. FOUND. (June 26, 2019), http://www.nsf.gov/discoveries/disc_summ.jsp?cntn_id=298793&org=NSF&from=news.

81. Fleming et al., *supra* note 77, at 1140; *Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

82. Fleming et al., *supra* note 77, at 1140; *see also Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

83. Fleming et al., *supra* note 77, at 1140; *see also Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

84. *See* Fleming et al., *supra* note 77, at 1140; *Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

85. *See* Fleming et al., *supra* note 77, at 1141; *Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

86. Fleming et al., *supra* note 77, at 1139; *see also Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80. "A new study finds that almost one-

Connecticut School of Law and a co-author of the report writes, "[t]echnological progress is seen as a process through which inventions build on one another."[87] She adds, "[i]n this study we examine the importance of government-supported research as contributing to subsequent inventions."[88] These findings were published in the journal *Science*.[89] The report critically notes that the ratio of overall foreign patenting in the United States system that relies on federal research still lags behind that of the United States inventors.[90] For instance, in 2017, 28.2% of the United States patents by American inventors, and 12.4% of the United States patents by foreign inventors relied on federally funded research.[91] As per the report, foreign inventors include those from Japan, Germany, Korea, England, France, China, Taiwan, and India.[92] It is popularly argued that, by default, ownership of federally funded inventions should go to the tax payers or general public, whose hard-earned money replenishes the federal treasury.[93] It may be noted that, in addition to public ownership, the ownership of patentable inventions emanating from the federal funding could also go to a few other parties such as: (a) the government; (b) the contractor-universities; (c) the inventors; and (d) the private entrepreneurs keen on exploiting such inventions.[94] Our experience of day-to-day life shows that contractor-universities are owners of several inventions stemming out of federal research grants and salaries.[95] Thus, there is empirical evidence to prove that

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third of [United States] patents rely on federal research." *Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80.

87. *Id.*; UCONN Communications, *Government-Funded Research Increasingly Fuels Innovation*, UCONN: RES. (June 21, 2019), http://www.today.uconn.edu/2019/06/government-funded-research-increasingly-fuels-innovation/; *see also* Fleming et al., *supra* note 77, at 1139.

88. *Government-Funded Research Increasingly Fuels Innovation*, *supra* note 80; UCONN Communications, *supra* note 87; *see also* Fleming et al., *supra* note 77, at 1139.

89. Fleming et al., *supra* note 77, at 1139.

90. *Id.* at 1140.

91. *Id.*

92. *Id.*

93. *See* Rebecca S. Eisenberg, *Public Research & Private Development: Patents & Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1690–91 (1996).

94. *Id.* at 1725–26.

95. *UC Patent Acknowledgment*, UCNET: COMPENSATION & BENEFITS, http://ucnet.universityofcalifornia.edu/compensation-and-benefits/patent-acknowledgment/ (last visited May 1, 2020) (illustrating the University of California's mandatory employee invention assignment agreement); STANFORD UNIV., RESEARCH POLICY HANDBOOK 38 (2019). Stanford University's Employee Research Policy Handbook, requiring that "inventions shall be assigned to the University, regardless of the source of funding." STANFORD UNIV., *supra*, at 38.

the United States Government has a lion's share in supporting health related research and development.[96]

Besides overseeing and financing research, the government's support to academic institutions and training of young scientists have enabled and nurtured the world's leading biomedical infrastructure.[97] Government funded fundamental research has facilitated the rise of biotechnology companies.[98] The government's money does not remain confined to primary research alone.[99] Had that not been the case, there would not have been a great deal of patentable inventions, because no patent is granted for conducting basic research, but exclusively for those implementations of fundamental research that have tangible and proven usefulness.[100] Nonetheless, the industry naturally and regularly lays claim to success in its eventual profit-orientation.[101] In spite of such self-serving assertions by the industry, the allocation of resources by the government for health-related research and development by the government is too high.[102] Government spending on health-related research and development is not the only aspect of public funding.[103] In addition to this, there are also staggering tax credits and whopping deductions that amount to public investment in these private enterprises.[104] The recent stress on managed care has mounted pressures to enhance government funding and thereby counterbalances even more toward public investment without clear cut regulatory provisions.[105] Since ordinary

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96. BRITT, *supra* note 77, at 1, 3; *see also UC Patent Acknowledgment*, *supra* note 95; STANFORD UNIV., *supra* note 95, at 38.

97. Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 636 (2001); *see also* Lynne G. Zucker et al., *Intellectual Capital and the Birth of U.S. Biotechnology Enterprises* 7–10 (Nat'l Bureau of Econ. Research, Working Paper No. 4653, 1994).

98. Arno & Davis, *supra* note 97, at 636.

99. *See* Jeff Gerth & Sheryl Gay Stolberg, *Drug Companies Profit from Research Supported by Taxpayers*, N.Y. TIMES: SCI. (Apr. 23, 2000), http://www.nytimes.com/library/national/science/health/042300hth-drugs.html [http://archive.nytimes.com/www.nytimes.com/library/national/science/health/042300hth-drugs.html].

100. *See* 35 U.S.C. § 101 (2018). An invention can be patented only if it first satisfies, among other elements, the demonstrable utility requirement of the Patent Act. *Id.*

101. Gerth & Stolberg, *supra* note 99; Peter G. Gosselin & Paul Jacobs, *DNA Device's Heredity Scrutinized by U.S.*, L.A. TIMES, May 14, 2000, at Al.

102. *See* Gosselin & Jacobs, *supra* note 101.

103. Arno & Davis, *supra* note 97, at 639.

104. *Id.* at 637.

105. *See* Alan M. Garber & Paul M. Romer, *Evaluating the Federal Role in Financing Health-Related Research*, 93 PROC. NAT'L. ACAD. SCI. U.S. 12,717, 12,724 (1996). A move toward managed care in the delivery of health care services is desirable only to the

people also contribute to public exchequer by paying taxes, the members of the general public also have moral as well as legal rights to inventions resulting from government-funding.[106] Public funding done via the National Institutes of Health ("NIH") is the most obvious source of taxpayer support for health-related research and development.[107] One must not forget that tax credits and tax deductions availed by the pharmaceutical industry are another main indirect source of taxpayer support for health-related research and development.[108]

B. *Bayh-Dole Act Heralds New Era of Patents*

The Bayh-Dole Act tackles the thorny issue of patenting and commercialization of scientific and technological research sponsored by the federal government.[109] This innovative law has multidimensional effects.[110] First and foremost, this unique law harmonizes research funding policies of federal agencies.[111] Unlike in the past, it does not leave it to those agencies to individually decide whether inventions originating from federally funded research may be patented and if so, who would be the owner of such patent rights.[112] Secondly, the new law permits the federal government to continue to have a non-exclusive, paid-up license to practice the patented invention and to *march-in* and take necessary steps if the recipient of the grant failed in making reasonable efforts to use the patented invention for the larger good of the public.[113] There are hardly any instances of federal agencies ever asserting and exercising their *march-in* rights under the Act in question.[114] Thirdly, the Bayh-Dole Act does not let non-U.S. institutions exploit the U.S.

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extent that it reduces the utilization of some medical technologies. *Id.* It will have a side effect of diminishing private sector incentives to conduct research leading to innovations in health care. *See id.* This change requires higher public support for biomedical research. *Id.* The suitable policy, therefore, should dovetail greater government support for research in some areas with stronger property rights and a move toward increasing dependence on the private sector in other areas. *Id.*

106. Arno & Davis, *supra* note 97, at 637.

107. *Id.* The NIH happens to be a major public agency funding health-related research and development; it finances over 80% of all federal government expenditure in this field. *Id.* at 638, no.26.

108. *Id.* at 638.

109. *Id.* at 646; *see also* Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018).

110. Arno & Davis, *supra* note 97, at 646–48; *see also* Emily Michiko Morris, *The Many Faces of Bayh-Dole*, 54 DUQ. L. REV. 81, 86 (2016).

111. Morris, *supra* note 110, at 86.

112. Eisenberg, *supra* note 93 at 1671; Morris, *supra* note 110, at 86 (citing Brett Frischmann, *Innovation & Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 398 (2000)).

113. 35 U.S.C. §§ 202(c)(2)–203; Eisenberg, *supra* note 93, at 1679.

114. Arno & Davis, *supra* note 97, at 642; Frischmann, *supra* note 112, at 403.

funded research by requiring that manufacturing under subject patents occurs "substantially in the United States."[115] Yet another feature is that the Bayh-Dole Act also supports small businesses by expressly according a preference for patent licensing to small businesses wherever possible.[116]

Thus, the Bayh-Dole Act deals with the issue of ownership of intellectual property rights emanating from research financed by the government.[117] It allows United States' non-profit organizations, universities, and small businesses to possess title of their respective inventions.[118] The government retains a right to use the technology.[119] The Bayh-Dole Act's principal aim is to foster the transfer of technology originating from federal government supported *upstream research* for development into *downstream* applications.[120] The prevalent feeling before the advent of this law on the legislative horizon was that most of this pioneering research could have been of critical value and use to the general public.[121] There was a great deal of hesitation in the private industry to put money into developing and commercializing such unutilized or underutilized government funded research.[122] Prior to the Bayh-Dole Act, the government used to enjoy the IPRs to the inventions funded by it.[123] There was a viewpoint that the frontier research was not being exploited, either because it was not patented or the government was the owner of patent rights and that the patent rights were coveted by recipients of grants or the following licensees.[124] In order to address these concerns, the United States Government allowed fund-receiving contractors to cling to the patent rights on their research with a hope that this step would offer incentives for

115. Rebecca S. Eisenberg, *A Technology Policy Perspective on the NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 650 (1994); *see also* 35 U.S.C. § 202(a).

116. Arno & Davis, *supra* note 97, at 643; *see also* 35 U.S.C. § 202(a).

117. 35 U.S.C. § 202(a); Eisenberg, *supra* note 93, at 1665, 1667, 1693, 1705.

118. 35 U.S.C. § 202(a); Eisenberg, *supra* note 93, at 1665, 1667, 1691–93, 1705.

119. 35 U.S.C. § 202(a); Eisenberg, *supra* note 93, at 1689, 1718.

120. 35 U.S.C. § 202(a); Eisenberg, *supra* note 93, at 1664; Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503, 1508 (2012); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 97–98 (1999).

121. Eisenberg, *supra* note 93, at 1678.

122. *See id.* at 1680, 1701.

123. *See* 35 U.S.C. § 202(a); *Federal Technology Transfer Act and Related Legislation*, EPA (Oct. 7, 2019), http://www.epa.gov/ftta/federal-technology-transfer-act-and-related-legislation.

124. *See* Eisenberg, *supra* note 93, at 1702; F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 707 (2001).

harnessing the inventions.[125] With the passage of the Bayh-Dole Act, there was a mind-boggling rise in patents secured by the universities, as well as the resources invested by the universities in the lengthy and cumbersome process of patenting.[126] Ever since its enforcement in 1980, the Bayh-Dole Act has triggered a wave of inventions and innovations in the United States.[127] It did so by promising proprietorship of technologies funded by the federal government to universities and small businesses that develop such technologies.[128] Parker Tresemer opines that the judgment of the Supreme Court of the United States in *Stanford v. Roche*, unfortunately, weakens the framework of the Bayh-Dole Act, and worries that the Court's judgment may bring to a standstill the ongoing advantageous implementation of the said law.[129]

After the end of the Second World War and the consequent surge in the American industrial output, the United States' leaders expected domestic industry and universities to lead the world in production and innovation.[130]

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125. *See* Eisenberg, *supra* note 93, at 1680–81; Lee, *supra* note 120, at 1512–13; Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 ME. L. REV. 259, 260 (2007). It is remarkable that the Stevenson-Wydler Technology Innovation Act of 1980 instructs federal agencies to transfer federally owned technology to both state and local governments and to the private sector. Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311, 2311 (1980) (codified as amended at 15 U.S.C. § 3701); Arno & Davis, *supra* note 97, at 644. Arno and Davis point out that the revised version of the said law allows government-financed and run laboratories to sign research and development collaboration agreements with private contractors and to license, or to assign title to, any patents being granted. Arno & Davis, *supra* note 97, at 644; *see also* Stevenson-Wydler Technology Innovation Act of 1980 § 2318; Wei-Lin Wang, *A Critical Study on the Cooperative Research and Development Agreements of U.S. Federal Laboratories: Technology Commercialization and the Public Interest*, 9 NANOTECHNOLOGY L. & BUS., 50, 53–55 (2012).

126. David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 989 (2005); Mireles, *supra* note 125, at 264; Kristen Osenga, *Rembrandts in the Research Lab: Why Universities Should Take a Lesson from Big Business to Increase Innovation*, 59 ME L. REV. 407, 419 (2007) (revealing that between 1991 and 2004, universities spent six times more on patenting); *see also* Bayh-Dole Act, Pub. L. No. 96-517, § 301, 94 Stat. 3015, 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212).

127. Eisenberg, *supra* note 93, at 1708–09; Mireles, *supra* note 125, at 264; *see also* Bayh-Dole Act § 301.

128. Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018); *see also* Eisenberg, *supra* note 93, at 1708–09.

129. Parker Tresemer, *Renewing the Bayh-Dole Act as a Default Rule in the Wake of* Stanford v. Roche, 6 J. LEGAL TECH. RISK MGMT. 173, 173 (2012); *see also* 35 U.S.C. §§ 200–212; Stanford v. Roche, 563 U.S. 776 (2011).

130. Steve L. Bertha, *Intellectual Property Activities in U.S. Research Universities*, 36 IDEA: J.L. & TECH. 513, 514 (1996); Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 93 (2004); Tresemer, *supra* note 129, at 173.

The harsh reality, however, was that in the 1970s, the United States had emerged as an international laggard, primarily due to the federal policy of holding on to the patents created by technologies funded by federal authorities.[131] In the pre-1980 period, it was unthinkable for the government to relinquish patent rights to the private industry, especially when inventions were funded by the federal institutions.[132] The paradox was that the government did not have adequate resources to satisfactorily exploit those inventions.[133] Private companies were reluctant to invest in the commercialization of nascent technologies in the absence of sole patent rights to technologies funded by the government.[134] Unlike many other members of the United States Congress, Senators Bob Dole (R., KS) and Birch Bayh (D., IN) were of the view that by hanging on to exclusive rights to inventions funded by federal sources, the government was consciously or unconsciously tearing down any incentive for the private industry and researchers to harness such beneficial technologies.[135]

> The Bayh-Dole Act has stimulated American innovation by guaranteeing ownership of federally funded technologies to the small businesses and universities best suited to develop them. The Supreme Court of the United States' holding in *Stanford v. Roche*, however, undermines the Bayh-Dole Act's framework and threatens to stall its continued beneficial application. In the wake of World War II and the resulting spike in American production, United States policymakers looked to universities and domestic industries to be international leaders in innovation and production.[136]

The legislative backdrop of the Bayh-Dole Act reveals that the United States Congress envisaged a law that involved allocation of inventions developed under government contracts; the resulting patent rights would go to the small business or nonprofit contractors firstly, and a conditional mechanism for assignment to the employee-inventor if the contractor decided not to maintain title, secondly.[137]

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131. Stevens, *supra* note 130, at 94.
132. *See* Eisenberg, *supra* note 93, at 1663, 1672, 1708–09.
133. Tresemer, *supra* note 129, at 173–74.
134. *Id.* at 174.
135. *Id.* at 174–75; *see also* Stevens, *supra* note 130, at 94, 96.
136. Tresemer, *supra* note 129, at 173; *see also* 35 U.S.C. §§ 200-212; Stanford v. Roche, 563 U.S. 776, 780 (2011).
137. James G. McEwen et al., *The Impact of* Stanford v. Roche *on Technology Licensing Under Bayh-Dole*, PROCUREMENT LAW., Winter 2012, at 5, 12; *see also* Bayh-Dole Act, Pub. L. No. 96-517, § 202, 94 Stat. 3015, 3020 (1980) (codified as amended at 35 U.S.C. §§ 200-212).

> [T]he legislative history for both the Senate and House indicates the legislat[ors] contemplated a statutory scheme that involved assignment of inventions developed under government contracts and resulting patent rights to the small business or nonprofit contractors in the first instance, and a contingent mechanism for assignment to the employee-inventor in the event the contractor did not elect to retain title.[138]

Universities have invariably been in the forefront of the research and development of many new scientific and technological inventions.[139] Throughout the United States, billions of dollars are earmarked annually to promote research in a number of disciplines and the development of innumerable inventions to transform the market.[140] Regrettably, not even a tiny portion of that sum is spent on commercialization of all such path-breaking inventions.[141] This approach forbids the introduction of novel technology into society.[142] University technology transfer programs attempt to reduce the effects of that barrier by collaborating with the industry to take a new technology through the commercialization process with the ultimate goal of market entry.[143] These programs educate students as well as customers as they work jointly to analyze and prepare all aspects of the invention for penetration into market.[144]

Irrespective of its scintillating success, the Bayh-Dole Act has been criticized from time to time.[145] The fulcrum of the criticism has been that the common people should not be forced to pay twice for goods manufactured out of inventions for which taxpayers have already paid.[146] It has been

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138. McEwen et al., *supra* note 137, at 12.

139. Bertha, *supra* note 130, at 514; Stevens, *supra* note 130, at 95.

140. Stevens, *supra* note 130, at 95.

141. *Id.*

142. *See id.* at 96.

143. *See* Margaret G. Mastrodonato, Comment, Stanford v. Roche*: Another Hurdle for Technology Transfer Programs?*, 20 DIG.: NAT'L ITALIAN AM. B. ASS'N L.J., 79, 79 (2012).

144. *Id.*

145. John H. Raubitschek & Norman J. Latker, *Reasonable Pricing — a New Twist for March-in Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 150 (2005); *see also* Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018). *The Economist* reported that "since 1980, American universities witnessed . . . a ten-fold increase in their patents and created [over] 2,200 companies to exploit their technology, which in turn has produced 260,000 new jobs; they now contribute $40 billion annually to the American economy." Raubitschek & Latker, *supra*, at 150; *see also* 35 U.S.C. §§ 200-212.

146. *See The Univ. & Small Bus. Patent Procedures Act: Hearings Before the Comm. on the Judiciary U.S. S.*, 96th Cong. 153, 157 (1979) (statement of Adm. Hyman G. Rickover, Dir. of the Div. of Naval Reactors, Dep't of Energy). Admiral Hyman Rickover

repeatedly argued by critics that the Bayh-Dole Act was not meant to provide innovators an absolute right to determine market prices for their inventions, which has escalated the prices of medicines, mainly for patented drugs.[147]

The most basic question haunting the minds of experts and lay people alike has been: "Do American taxpayers, who finance a majority of research and development ("R&D") projects related to public health, ever receive a fair return on their investment?"[148] In a market-driven economy like the United States, it is interesting that—to talk about public taxpayer returns on health-related R&D—one ought to confine the discussion to returns in kind or non-monetary returns because the taxpayers hardly ever see a monetary benefit.[149]

The professed claim of promoting public-private partnerships has been to serve the public interest by researching and commercially utilizing inventions that emerge out of federal funding through the transfer of new technology, material resources, staff, and know-how among industry, academic community, and federal government agencies.[150] There is also a view that the public interest can be better served by competitively encouraging private companies to market products developed by university researchers or scientists working in government institutions.[151] They alluded to the gains of novel treatments, the employment generation, and the growth of individual businesses.[152] The antagonists of this opinion hold that the corporate world has an accountability deficit despite its heavy utilization of public resources and return on investment of the taxpayer is far from sufficient.[153] In favor of this contention, these detractors refer to expensive

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frankly stated "[i]n my opinion, Government contractors — including small businesses and universities — should not be given title to inventions developed at Government expense . . . These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit." *Id.*

147. Raubitschek & Latker, *supra* note 145, at 151; *see also* 35 U.S.C. §§ 200–212.

148. *See* Arno & Davis, *supra* note 97, at 634.

149. *See id.* at 634 n.10 (mentioning that the Federal Government receives less than a one percent return in royalties on government inventions).

150. *Id.* at 634.

151. *Id.* Stating the alleged rationale behind the Bayh-Dole Act: "At least insofar as it adopted a *title*, as opposed to a *licensing*, approach to government-developed patents—and the legislative history is replete with claims that granting title, as opposed to a mere license, to federal contractors would expedite technological progress." *Id.* at 634 n.11 (citing *Gov't Patent Policy: Hearings Before the Subcomm. on Sci., Research & Tech. of the Comm. on Sci. & Tech. U.S. H. of Rep.*, 96th Cong. 4–5 (1979)).

152. Arno & Davis, *supra* note 97, at 634–35.

153. *Id.* at 635. It may be pertinent to recall Sanders' Amendment to the House appropriations bill, which prescribed that federally funded inventions must be subject to reasonable pricing requirements. 146 CONG. REC. H4224, H4291 (2000) (statement of Rep.

products even though they are an outcome of research done by the government funds in the form of grants, licenses, tax credits for businesses, and fund allocations.[154] Such critics also contend that official subsidies for research and development twist incentives for investment and consumption besides bringing in interest group pressures that can conceal market cues.[155]

III. JUDICIAL INTERPRETATION OF THE 1980 ACT

A. Stanford v. Roche *and Judicial Uncertainty*

1. District Court Favors Stanford

In *Stanford v. Roche*, the question before the court was the ownership of patents to test efficacy of anti-HIV treatments.[156] The procedure involved in this activity calculated the quantity of HIV in the blood of a patient.[157] It was developed by Dr. Mark Holodniy, a researcher from Stanford University.[158] Interestingly, he also used to serve at Cetus, a research company located in California.[159] Initially, an employment agreement was signed by Dr. Holodniy with Stanford which required him to allot to Stanford patent rights to any invention originating from his employment at Stanford.[160] Subsequently, in order to acquire entrance to Cetus, Dr. Holodniy signed another contract with Cetus which prescribed that Dr. Holodniy "would allocate and does hereby allocate to Cetus" all rights to inventions made as a result of his ingress into the Cetus laboratories.[161] Following his return to Stanford, Dr. Holodniy and his fellow researchers in Stanford converted that technique into practice or

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Sanders). In other words, it stressed that march-in rights provided for by the Bayh-Dole Act ought to be enforced to ensure affordable pricing of such crucial drugs. *See id.*

154. Arno & Davis, *supra* note 97, at 635; *see also* James Love, *The Other Drug War*, AM. PROSPECT (Nov. 20, 2001), http://www.prospect.org/health/drug-war/; *Health Care Reform: Hearings Before the Subcomm. on Health of the Comm. on Ways & Means H.R.*, 103d Cong. 444–48 (1993) (testimony of Abbey S. Meyers, Exec. Dir. Nat'l Org. for Rare Disorders).

155. U.S. CONG., OFFICE OF TECH. ASSESSMENT, MULTINATIONALS AND THE U.S. TECHNOLOGY BASE 12 (1994).

156. Stanford v. Roche, 563 U.S. 776, 780–81 (2011).

157. *Id.* at 781.

158. *Id.*

159. *See id.*

160. *Id.* at 799. Dr. Holodniy *agree(d) to assign* to Stanford patent rights to any invention resulting from his employment at Stanford. *Stanford*, 563 U.S. at 799.

161. *Id.* at 781. Dr. Holodniy "will assign and do[es] hereby assign" to Cetus all rights to inventions made "as a consequence of [his] access to Cetus." *Id.*

introduced commercial utility to the said invention.[162] On the basis of written allocation of rights secured from its researchers including Dr. Holodniy, Stanford applied for and obtained patents to the HIV measurement process.[163] In the intervening period, Roche Molecular Systems, Inc. ("Roche"), a pharmaceutical entity known for its expertise in screening of diagnostic blood, took over assets of Cetus meant for and related to the testing technology.[164] Undoubtedly, this transaction also included all rights acquired by Cetus under the aegis of its agreement signed with Dr. Holodniy.[165] In the wake of completion of clinical trials, Roche went ahead and commercialized the procedure as well as profitably packaged and sold the HIV test kits.[166] In the aftermath of this development, Stanford sued Roche for violation of its patent rights.[167] Roche claimed that it was a co-owner of the HIV computation procedure.[168] This claim of Roche was based on the agreement it had signed with Dr. Holodniy under which he had undertaken to transfer his rights in that invention to Cetus.[169] Stanford contended that such an agreement went against the letter and spirit of the Bayh-Dole Act, which explicitly stated that research institutions in receipt of federal grants may choose to retain title to any subject invention that was a result of such government sponsored research.[170] One, to quote exact words of the Bayh-Dole Act, "may . . . elect to retain title to any subject invention."[171] Stanford asserted that since its HIV quantification research was based on federal grants, the Bayh-Dole Act conferred the exclusive rights in the patented technology upon Stanford by virtue of being the beneficiary of the federal grant.[172] This fact and law naturally ejected Dr. Holodniy's transfer of his IPRs to the Cetus.[173] The court of first instance, or District Court, admitted Stanford's contentions.[174]

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162. *Id.*
163. *Id.*
164. *Stanford*, 563 U.S. at 781.
165. *Id.*
166. *Id.* at 781–82.
167. *Id.* at 783.
168. *Id.*
169. *Stanford*, 563 U.S. at 783.
170. *Id.* at 782–83; *see also* Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018).
171. 35 U.S.C. § 202(a); *Stanford*, 563 U.S. at 782.
172. Stanford v. Roche, 487 F. Supp. 2d 1099, 1115 (N.D. Cal. 2007); *see also* 35 U.S.C. §§ 200–212.
173. *See Stanford*, 487 F. Supp. 2d at 1105.
174. *Id.* at 1124.

2. Appellate Courts Help Employee and Third Party

a. *CAFC Negates District Court Ruling*

The United States Court of Appeals for the Federal Circuit ("CAFC") turned it upside down.[175] Since the dispute revolved around the question as to which of the two separate assignments signed at different times by Dr. Holodniy with two institutions would prevail over another, the CAFC relied upon its precedent in *FilmTec* and adjudicated that Dr. Holodniy's first agreement signed with Stanford was nothing more, nor better than, a promise to assign IPRs at an unspecified time in the future, while Dr. Holodniy's later pact signed with Cetus as a matter of fact then and there, allocated his rights to Cetus in his future inventions.[176] Thus, the CAFC attached significance to different wording of the two different agreements, not chronologically to determine which one would repudiate another.[177] The CAFC dismissed Stanford's recourse to the Bayh-Dole Act, arguing that the said Act did not automatically rescind a right of an inventor in an invention born out of the government financed research.[178] In other words, Dr. Holodniy's subsequent agreement with Cetus, and thereby his decision to allot his IPRs to Cetus, remained flawless.[179] To be precise, the CAFC adjudged that Bayh-Dole Act could not frustrate the arrangement between Cetus and Dr. Holodniy.[180]

b. *Supreme Court Disregards Act*

On June 6, 2011, the Supreme Court of the United States delivered a crucial judgment to clarify the ownership rights in inventions financed by grants from the federal government.[181] The judgment in *Stanford v. Roche* was the maiden encounter of the Supreme Court of the United States with the Bayh-Dole Act.[182] The highest Court was dealing with a three-decade old federal law that governs the allocation of these rights among individual inventors, research institutions receiving government grants, and the federal government.[183] The Supreme Court of the United States ruled that the Bayh-

175. Stanford v. Roche, 583 F.3d 832, 849 (Fed. Cir. 2009).
176. *Id.* at 842; FilmTec Corp. v. Allied-Signal Inc., 939 F.2d 1568, 1572 (Fed. Cir. 1991).
177. *Stanford*, 583 F.3d at 842.
178. *See id.* at 844; Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018).
179. *See Stanford*, 583 F.3d at 844.
180. *See id.* at 845; 35 U.S.C. §§ 200–212.
181. *See* Stanford v. Roche, 563 U.S. 776, 793 (2011).
182. *See id.*; 35 U.S.C. §§ 200–212.
183. *See Stanford*, 563 U.S. at 793; 35 U.S.C. §§ 200–212.

Dole Act does not change the long-standing philosophy of the United States patent legislation that a third party may acquire a right to an invention only through an assignment by the inventor.[184] By reiterating this principle, the Supreme Court of the United States chose the course of action that hardly impacts the prevalent law.[185] In spite of this, the research institutions in general and universities in particular, which are recipients of federal grants, are required to critically analyze the employment agreements signed with their researchers to guarantee that these agreements succeed in *tout de suite* assignment of all upcoming patent ownership rights to the institution.[186] The majority opinion, authored by Chief Justice Roberts, ordered that even though an inventor could assign his or her rights emanating from an invention to a third party, including an employer who facilitated this research, an employer does not *suo moto* get rights in an invention made by its employee.[187]

The Supreme Court of the United States in its majority judgment upheld the opinion of the CAFC.[188] The Chief Justice, John Grover Roberts Junior, wrote the judgment.[189] Justices Scalia, Kennedy, Thomas, Alito, Sotomayor, and Kagan, joined Justice Roberts; Justice Sotomayor authored a concurring opinion.[190] The Chief Justice observed that the most basic premise of the United States Patent Act is that an inventor enjoys the rights in an invention.[191] "[R]ights in an invention belong to the inventor."[192] Despite the fact that an inventor can assign his or her rights to the third party, including an employer whose facility ushered in the invention and patent, even such a proprietor does not *proprio motu* earn such rights in an invention made by its employee.[193] According to the majority opinion, the employee researcher ought to categorically assign his rights to the employer so that the latter gets those rights.[194] The employee "must expressly grant his [or her] rights in an invention to his [or her] employer if the employer is to obtain those rights."[195] One wonders how on earth the highest Court overlooked the District Court's appropriate interpretation of the Bayh-Dole Act, *vis a vis* Dr.

184. *See Stanford*, 563 U.S. at 792; 35 U.S.C. §§ 200–212.
185. *See Stanford*, 563 U.S. at 792–93.
186. *See id.*; 35 U.S.C. §§ 200–212.
187. *Stanford*, 563 U.S. at 789.
188. *Id.* at 793.
189. *Id.* at 779.
190. *Id.*
191. *Id.* at 780.
192. *Stanford*, 563 U.S. at 780.
193. *Id.* at 789.
194. *Id.* at 786.
195. *See id.* (quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933)).

Holodniy's initial assignment agreement with Stanford that predated his subsequent assignment agreement with Cetus, and affirmed the CFAC's unbelievable construction of the said Act privileging the latter contract.[196] The Supreme Court of the United States seems to have supposed that Cetus acquired patent rights in the HIV reckoning technique, developed by Dr. Holodniy through such allocation of rights.[197]

The majority opinion did not construe the Bayh-Dole Act as changing this time-honored practice that could rearrange the usual hierarchy of rights in an invention right, when the invention is thought of, or first abridged, to practice with the contribution of federal grants.[198] The apex Court could not discover the intention of the lawmakers in the United States Congress, who had voted in favor of this bill to replace one of the elementary norms of the patent legislation, and deny inventors rights in their own inventions.[199] Merely because the wording of assignment of Dr. Holodniy's rights to Cetus was correct, the Supreme Court of the United States ordered that the contract could not be adversely affected by the Bayh-Dole Act.[200] According to the Supreme Court, its interpretation of the Bayh-Dole Act merely echoed the widely prevalent practice among a large number of signatories to pacts invoking the said Act.[201] The Supreme Court of the United States stressed that universities generally sign agreements with their research staff stipulating the allocation of rights in inventions to the universities.[202] This is a legal necessity under the Bayh-Dole Act for the research institutions that receive federal money.[203]

The honorable Supreme Court in its majority opinion took it for granted that most of the research bodies getting the federal grants under the provisions of the Bayh-Dole Act thus far needed lawful assignment of rights from their employees.[204] It teaches a bitter lesson to all government contractors receiving the Bayh-Dole funds that they ought to draft and sign only those accords with researchers that perfectly guarantee enforceable assignments of rights to the institutions.[205] Another lesson to be drawn from the refusal of the Supreme Court of the United States to interfere with the ruling of the CAFC on the basis of the precedent in *FilmTec*, is that the

196. *See id.* at 784; Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018).
197. *Stanford*, 563 U.S. at 784.
198. *Id.* at 786; 35 U.S.C. §§ 200–212.
199. *See Stanford*, 563 U.S. at 782.
200. *Id.* at 781, 787; 35 U.S.C. §§ 200–212.
201. *See Stanford*, 563 U.S. at 792–93; 35 U.S.C. §§ 200–212.
202. *Stanford*, 563 U.S. at 793.
203. *Id.*; 35 U.S.C. §§ 200–212.
204. Igor Timofeyev, Stanford v. Roche *Decision Requires Greater Diligence*, INTELL. PROP. MAG., Sept. 2011, at 63, 63.
205. *Id.* at 64.

agreement signing bodies should not undermine the existing assignment arrangements even for future inventions and patents.[206] Yet another painful lesson to be drawn from the majority opinion is that research institutions receiving federal funds should incorporate non-disclosure clauses in their employment contracts or necessitate the prior consent of the employer for signing agreements with outside institutions.[207] Last, but not the least, the official contractors must keep track of the appeals before the CAFC on this specific query.[208] If at all, the Supreme Court of the United States is persuaded to look at the CAFC's determination in *FilmTec* as it could bring in desirable changes in the patent law and ownership of inventions-cum-patents.[209] The Supreme Court of the United States' 2011 judgment in *Stanford v. Roche* endowed IPRs in the inventor or researcher.[210] The judicial verdict prevented an independently contracting party or a university from monitoring developments made by students or faculty without radically different agreements.[211] In the wake of this change, technology programs meant for commercialization of technologies at universities will undoubtedly become much more difficult to steer for various stakeholders due to the augmented thrust in licensing agreements necessary to secure IPRs under the newly devised use of the Bayh-Dole Act.[212] In the wake of the Supreme Court of the United States' decision, public organizations may lose the rights to intellectual property that is generated under various contracts signed before the rendering of the Court's judgment.[213] The holding could deter the useful research partnerships between private industries and universities that Congress sought to support while adopting the University and Small Business Patent Procedures Act of 1980.[214] The Court's judgment will also prevent inventors "from developing useful intellectual property, due to potential problems arising from state ethics laws and federal conflict of

206. *Id.*; FilmTec Corp. v. Allied-Signal Inc., 939 F.2d 1568, 1568 (Fed. Cir. 1991).

207. Timofeyev, *supra* note 204, at 64.

208. *Id.*

209. *FilmTec Corp.*, 939 F.2d at 1568; Timofeyev, *supra* note 204, at 64.

210. 563 U.S. 776 (2011); *see also* Timofeyev, *supra* note 204.

211. Mastrodonato, *supra* note 143, at 86; Gene Quinn, *Supreme Court Affirms CAFC in* Stanford v. Roche *on Bayh-Dole*, IPWATCHDOG (June 6, 2011), http://www.ipwatchdog.com/2011/06/06/supreme-court-affirms-cafc-instanford-v-roche-on-bayh-dole/.

212. Mastrodonato, *supra* note 143, at 86; *see also* Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018).

213. Depinet, *supra* note 10, at 729; Mastrodonato, *supra* note 143, at 87.

214. *Stanford*, 563 U.S. at 793; *The Univ. & Small Bus. Patent Procedures Act: Hearings Before the Comm. on the Judiciary U.S. S.*, 96th Cong. 1 (1979) (statement of Adm. Hyman G. Rickover, Dir. of the Div. of Naval Reactors, Dep't of Energy).

interest regulations."[215] "Private investment in these activities will be actively discouraged because of uncertainties about ownership of the inventions."[216] The decision raises a big question mark on the ownership of inventions and may dismay the society that always keenly awaits news from universities for frontier research and inventions that promote welfare of ordinary people.[217] "The decision ultimately puts a cloud on the ownership of inventions and will have a negative impact on a society that looks to universities for research and inventions."[218]

James G. McEwen, Sean M. O'Connor, John E. McCarthy, Jr., and Susan Warshaw Ebner opine that, as a result of this case, it will be essential for universities or other research institutions to introspect and proceed by being extra cautious to decide whether the employment agreements have foolproof assignments to their prior assigned inventions, to inventions licensed from outside parties, and to inventions that would be assigned to them under impending federal sponsorships.[219]

As a result of this case, it will be critical for Stanford—and universities or other entities similarly situated—to look backward and move forward by exercising due diligence to determine whether it has clear and valid assignments to its prior assigned inventions, to inventions it has licensed from third parties, and to those inventions that will be assigned to it under future federal funding agreements.[220]

c. *Minority View Echoes District Court*

The dissenting opinion of the Supreme Court of the United States, written by Justice Breyer and joined by Justice Ginsburg, decreed that the Court's majority ruling ignored the contextual or surrounding norm that declines individual researchers or inventor IPRs for which people have already paid through taxes to the government.[221] Justice Breyer disagreed with the rule adopted by the CAFC in *FilmTec*, which states that an inventor's current awarding of rights in a forthcoming invention, like Dr. Holodniy's issuing of rights to Cetus, would spontaneously cede a legal title to such inventions.[222] Justice Breyer opined that such an assignment, like the initial one secured by Stanford from Dr. Holodniy, conveyed only an

215. Depinet, *supra* note 10, at 730.
216. *Id.*
217. *See id.*
218. *Id.*
219. McEwen et al., *supra* note 137, at 11.
220. *Id.*
221. Stanford v. Roche, 563 U.S. 776, 794 (2011) (Breyer, J., dissenting).
222. *Id.* at 799–802.

equitable title to the invention.[223] He added that Stanford's assignment being first in time took precedence.[224]

B. *Supreme Court's Order and Public Health*

It may be timely to analyze the verdict of the Supreme Court of the United States in *Stanford v. Roche* with reference to the ongoing public health debate in the United States.[225] The Heritage Foundation Report points out that the United States Heritage policymakers are discussing "whether Congress should [implement] a single-payer [health care] system or set up a system based on personal choice and market competition."[226] The basic issue, however, is whether government officials or individuals and their families will decide on critical health care issues.[227] If a single-payer system is to be adopted, it necessitates a major bargain.[228] It may include long waiting lists, care delays and denials, a loss of personal and economic freedom, the loss of existing health coverage, the levying of new federal taxes, and significant reductions in payment for doctors and medical professionals.[229] Authors of the report argue that there is no clear cut public opinion on this contentious issue.[230] The report suggests that conservatives in Congress have to come out with reasonable and effective policy choices or be ready to lose the game and pave the way for victory of proponents of a single-payer program.[231]

The Brookings Institution Report notes that the central theme of policy discussions of the 2020 presidential election will be health care.[232] Democratic challengers and Republican incumbent President Donald Trump have their pre-decided, but diametrically opposite views on a host of issues associated with the access of individuals to the health care system.[233]

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223. *Id.*
224. *Id.* at 799–801.
225. *Id.*
226. ROBERT MOFFIT ET AL., THE NATIONAL DEBATE OVER GOVERNMENT-CONTROLLED HEALTH CARE 1 (2019).
227. *Id.*
228. *Id.*
229. *Id.*
230. *Id.*
231. MOFFIT ET AL., *supra* note 226, at 1.
232. Tamari Dzotsenidze, *Behind the Scenes of Policy 2020, a New Brookings Resource to Inform Americans About Issues in the Presidential Election*, BROOKINGS (Dec. 19, 2019), http://www.brookings.edu/blog/brookings-now/2019/12/19/behind-the-scenes-of-policy-2020-a-new-brookings-resource-to-inform-americans-about-issues-in-the-presidential-election/.
233. John Hudak, *Health Care Is an Opportunity and Liability for Both Parties in 2020*, BROOKINGS (July 12, 2019),

Regardless of political parties having the golden opportunity to use the issue to their electoral advantage, both parties are evading popular stance on issues that Americans think are vital to the future.[234] Gallup in its November 2018 poll had asked participants: "How important will [health care] be to your vote in Congress this year?"[235]

Interestingly, eighty percent of the respondents replied that it would be an extremely important issue for them.[236] This finding would not at all astonish an astute observer of United States health care politics because irrespective of what one hears from the vote-seeking politicians or news-hungry cable news shows, it is the ordinary Americans who deal with the health care system and its problems on a day-to-day basis.[237] They do so through sojourns in hospitals, visits to doctors, caring for old parents, noticing the insurance premium deducted from their paycheck, or paying a co-pay for an x-ray.[238] Since health care constitutes "one-sixth of the [United States] economy," it has become a ubiquitous issue across the United States.[239] Therefore, their views are of primary importance.[240] In a scenario where a particular policy issue is dear to voters and those voters think that it determines their electoral choices, the political party or candidate in the election fray having similar ideas that resonate with those of the voters, can emerge successful.[241]

Both the rival parties Democrats and Republicans, however, have serious problems of answerability on this divisive issue.[242] One may briefly look at the challenges (besides opportunities) of Democrats on a perennially polarizing topic of health care.[243] There are certain dimensions of health care that help Democrats because their views find favor with majorities of the public opinion.[244] For example, as per a 2018 Gallup poll, 57% of Americans want the government to ensure that "all Americans have health"

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http://www.brookings.edu/blog/fixgov/2019/07/12/health-care-is-an-opportunity-and-liability-for-both-parties-in-2020/.

234. *Id.*

235. *Id.*; Frank Newport, *Top Issues for Voters: Healthcare, Economy, Immigration,* GALLUP: POL. (Nov. 2, 2018), http://news.gallup.com/poll/244367/top-issues-voters-healthcare-economy-immigration.aspx.

236. Hudak, *supra* note 233; *see also* Newport, *supra* note 235.

237. *See* Hudak, *supra* note 233.

238. *Id.*

239. *Id.*

240. *See id.*

241. *Id.*

242. Hudak, *supra* note 233.

243. *Id.*

244. *Id.*

care coverage.[245] Likewise, a 2019 poll conducted by CNN showed that 56% of Americans opine that the "government should provide a national health insurance program for all Americans," even though it could lead to higher taxes.[246] Besides this, the Kaiser Family Foundation's ("KFF") 2018 polling results showed that over 75% of Americans supported shutting the down of the Medicare prescription, expansion of Medicaid, eliminating out-of-pocket expenses for availing preventive care, subsidies for poor Americans to procure health care, and retaining children on parents' insurance until they attain the age of 26.[247] These are part and parcel of the Democratic-supported Affordable Care Act ("ACA").[248] It is a hard fact that despite enjoying some of these advantages on health care, quite a few Democratic presidential candidates have supported policies contradicting popular opinion.[249] For instance, the same CNN opinion poll revealed that only 38% of Americans favored health insurance coverage for undocumented individuals, while the majority 59% resisted it.[250] Moreover, 56% of the participants were in favor of a national health insurance program, but 57% of those supporters stated that any such plan should not jeopardize private health insurance.[251]

The aforesaid opinion poll findings by CNN merely confirm a KFF study held in June 2019 which indicated that although 63% of the Americans hailed *Medicare for All*, most of them did not know how that policy would be executed.[252] It is noteworthy that how the questions were framed also mattered.[253] It was reported that while 63% percent supported *Medicare for all*, only 49% percent endorsed "a single payer health care system."[254] In reality, the KFF study discovered that 55% percent of Americans were of the view that under a *Medicare for all* plan, they could retain their private health

245. *Id.*; *see also* Frank Newport, *Government Favored to Ensure Healthcare, but Not Deliver It*, GALLUP: WELLBEING (Dec. 3, 2018), http://news.gallup.com/poll/245105/government-favored-ensure-healthcare-not-deliver.aspx.

246. Hudak, *supra* note 233; *see also* SSRS, POLL 8 (2019).

247. Hudak, *supra* note 233; Ashley Kirzinger et al., *Kaiser Health Tracking Poll – March 2018: Views on Prescription Drug Pricing and Medicare-for-all Proposals*, KAISER FAM. FOUND. (Mar. 23, 2018), http://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals/.

248. Hudak, *supra* note 233; *KAISER* FAM. FOUND., *Summary of the Affordable Care Act*, (Apr. 25, 2013), http://www.kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/.

249. Kirzinger et al., *supra* note 247.

250. *Id.*

251. Hudak, *supra* note 233.

252. *Id.*

253. *See id.*

254. *Id.*

insurance.[255] A 2019 poll by Hill-HarrisX indicated that only a handful (13%) of Americans welcomed a system calling for dismantling the extant private health insurance.[256]

This fluidity in public opinion, and paradoxical views of voters about the Democratic health care plans precipitate a situation in which voters look for nitty-gritty details rather than catchy words and phrases.[257] Even if many presidential candidates support the popular *Medicare for All*, there are several candidates who support much less popular positions including the closure of private health insurance and coverage for individuals who are not documented.[258] In most of the cases, the candidates are adopting a principled position when they contend that health care is an inalienable human right and therefore, everybody must be covered regardless of one's social, economic, or any other status in society.[259] It seems that health care being a household concern for all Americans, the Democratic Party candidates would be required to persuade people who doubt parts of their health care plans.[260] It is also time to look at the handicaps of Republicans on health care.[261] In 2010 and 2014, the Republican Party succeeded in midterm congressional polls by attacking the ACA or Obamacare.[262] It promised to abrogate the widely condemned piece of legislation.[263] In the 2016 presidential campaign, the Republican candidate who promised to revoke the law and substitute it with a better one won, but a Democrat who assured to retain and reform the law lost the election.[264] In spite of emerging victorious in the race to occupy the White House, down the road, Republicans encountered a serious political problem that emerged in the early phases of President Trump's administration.[265] The American people made a volte-face on health care.[266] During the former President Obama administration, appeal of ACA had declined to thirty-three percent, recorded the KFF poll.[267] However, as the law began to face an existential threat from the Republican White House and Republican Congress, Republicans willy-nilly popularized Obamacare.[268]

255. *Id.*
256. Hudak, *supra* note 233.
257. *Id.*
258. *Id.*
259. *Id.*
260. *Id.*
261. *See* Hudak, *supra* note 233.
262. *Id.*
263. *Id.*
264. *Id.*
265. *Id.*
266. Hudak, *supra* note 233.
267. *Id.*
268. *See id.*

By early 2018, the ACA commanded majority support and continues to do so.[269] The American people realized that, while the brand name *ACA* or *Obamacare* was unpopular, there was a lot in the law they wanted.[270] Thanks to the about turn in the public opinion, the Republicans, even after controlling the executive and legislative branches of the government, could not scrap the law.[271] Therefore, President Trump has attempted to get the law repealed through judicial decisions.[272] In a case recently decided by a federal appeals court—*Texas v. United States*[273]—which the Supreme Court of the United States has granted certiorari, the validity of the ACA or Obamacare law is in question.[274] While President Trump's administration, among its varied stances on the law, has promised to throw this law, lock, stock and barrel, the annulment of the ACA could be strategically used by Democrats against President Trump in the next presidential election.[275]

It should be realized that even if the nullification of the ACA may appeal to the President's fans, it would in fact discard some of the essential ingredients of the law that are popular among several Americans, including Republican voters.[276] A yardstick of the growing unpopularity of the President's ACA repeal position can be estimated from the November 2018 levels of support for following nine cardinal provisions of the ACA.[277]

> [1] Coverage for pre-existing [c]onditions (65%); [2] Medicaid expansion (77%); [3] Closing the Medicare drug doughnut hole (81%); [4] Subsidies for [poor] Americans' coverage (81%); [5] Payroll tax increases for the rich (65%); [6] Children staying on parents insurance until 26 (82%); [7]

269. *Id.*
270. *Id.*
271. Hudak, *supra* note 233.
272. *Id.*
273. 945 F.3d 355 (5th Cir. 2019).
274. *Id.* at 368–69, 402; *see also* California v. Texas, No. 19-840, 2020 WL 981804, at *1 (S. Ct. Mar. 3, 2020); Hudak, *supra* note 233; MaryBeth Musumeci, *Explaining Texas v. U.S.: A Guide to the Case Challenging the ACA*, KAISER FAM. FOUND. (Mar. 10, 2020), http://www.kff.org/health-reform/issue-brief/explaining-texas-v-u-s-a-guide-to-the-case-challenging-the-aca/. "In striking down the entire Affordable Care Act, the district court [in *Texas v. United States*] disregarded the clearly expressed intent of the democratically elected representatives of the people." *Texas v. United States*, CONST. ACCOUNTABILITY CTR: HEALTH CARE, http://www.theusconstitution.org/litigation/texas-v-united-states/ (last visited May 1, 2020); *see also Texas*, 945 F.3d at 368–69, 402. That ruling is *insupportable*. *Texas v. United States*, *supra*; *see also Texas*, 945 F.3d at 368–69, 402. "Congress's intent here could not be clearer: [T]he rest of the law should stand in the absence of an enforceable mandate." *Texas v. United States*, *supra*; *see also Texas*, 945 F.3d at 368–69, 402.
275. Hudak, *supra* note 233.
276. *Id.*
277. *Id.*

> Eliminating out-of-pocket costs for preventive care (79%); [8] ACA exchanges (82%), [and] [9] The employer mandate (69%).[278]

This opinion survey should serve as a warning to those who seek rescission of the ACA.[279] The President's crazily unpopular position has become less popular with the passage of time.[280] The President's claims on socialism, socialized medicine, and a philosophical argument about the proper role of government would go unheard if the administration abolishes ACA provisions that voters rely upon.[281] As the health care debate in the United States moves ahead, both the major parties can objectively assess their own as well as their rival's positions on health care.[282] Even if an ideological commitment of candidates may prevail upon them, the only thing that matters at the ballot box is public opinion, particularly on a sensitive issue like health care.[283] However, President Trump faces a unique challenge.[284] The federal courts could dramatically transform the United States health care system.[285] Democrats obviously cannot one-sidedly enforce *Medicare for All*, or ban private health insurance without having sufficient votes in the House of Representatives and Senate.[286] Eventually, if the ACA is revoked or drastically changed against the popular will, Republicans cannot go scot-free from the electoral radar screen.[287]

It is common knowledge that health care systems of various nations have evolved along different routes.[288] In some countries there is a prevalence of private insurance, while in others there is universal health care, and in few others there is a hybrid form of the two.[289] It is observed that in most of the industrialized nations, health care is regarded as a human right and is therefore "provided universally, [usually] free at the point-of-care."[290] The United States has developed a deeply divided profit-oriented system that is much "more expensive than those of its counterparts [in Europe] and delivers poorer outcomes than the health care systems in other high-income countries, while leaving a substantial proportion of Americans without health

278. *Id.* (listing public support for elements of the ACA).
279. *See id.*
280. Hudak, *supra* note 233.
281. *Id.*
282. *See id.*
283. *Id.*
284. *Id.*
285. Hudak, *supra* note 233.
286. *Id.*
287. *Id.*
288. Greg Jones & Hagop Kantarjian, *The Many Roads to Universal Health Care in the USA*, 20 LANCET ONCOLOGY e601, e601 (2019).
289. *Id.*
290. *Id.*

coverage."[291] It is pertinent to analyze the health care system in the United States and suggest measures for accomplishing universal health care across the United States.[292] Three principal ingredients of such a blueprint are: "[1] support and improve the Affordable Care Act; [2] maintain the existing private insurance system; [and] [3] offer in parallel a government-sponsored health care insurance, [or slowly and steadily] expand Medicare to more people [so that eventually] all Americans not covered under existing health care insurances" are also fully insured.[293]

It is essential to study health care policy and practice in the United States.[294] A critical analysis shows that there have been "impassioned debates about the best solutions to health care in America" among political leaders, public policy analysts, members of the medical profession, and the people at large.[295] The divide over the Health Care Reform Act of 2010 highlighted a "multitude of fears, challenges, obstacles, and passions" that often complicated rather than clarified the debate.[296] The discourse has forever been heated.[297] The complexity of issues animating the health care debate has compelled the United States public to grapple with the exigencies of the present system in respect of economic, fiscal, and monetary policy, especially as they relate to philosophical, often ideologically driven approaches to the problem.[298] Americans have also examined their ideas about the relationship of the individual to and interaction with the state and the varied social and cultural beliefs about what a United States solution to the problem of health care appears to be.[299] Prominent and perennially important debates provide readers with views on multiple sides of the complex issue.[300] The United States public health discourse is overshadowed

291. *Id.*
292. *Id.*
293. Jones & Kantarjian, *supra* note 288, at e601.
294. Jennie Jacobs Kronenfeld et al., *Description* to DEBATES ON U.S. HEALTHCARE (2012).
295. *Id.*
296. *Id.*
297. *Id.*
298. *Id.*
299. Kronenfeld et al., *supra* note 294.
300. *See id.*; Joshua Cohen, *2020 Election's Healthcare Debate: Truths, Half-Truths, and Falsehoods*, FORBES (July 8, 2019, 9:06 AM), http://www.forbes.com/sites/joshuacohen/2019/07/08/2020-elections-healthcare-debate-truths-half-truths-and-falsehoods/; Matthew Fiedler & Christen Linke Young, *Current Debates in Health Care Policy: A Brief Overview*, BROOKINGS: POL'Y 2020 (Oct. 15, 2019), http://www.brookings.edu/policy2020/votervital/current-debates-in-health-care-policy-a-brief-overview/.

by four major questions.[301] First, what should be done to lower health care costs for consumers?[302] Second, what is to be done to curb hospital prices?[303] Third, how to control drug prices?[304] Fourth, what is to be done about long-term care?[305] These questions are in addition to the ongoing debate on Medicare.[306]

In order to gauge the scale, magnitude, and gravity of the ever-deepening public health care crisis in the United States, it may be worthwhile to look at some of the stunning research findings.[307] Data from the Commonwealth Fund suggests that the number of underinsured Americans has doubled in the first two decades of the twenty-first century.[308] It simply means although these people have an insurance card, their coverage fails to provide adequate financial protection if there is a health crisis.[309] The grievance against Obamacare is that even most of the lawfully sold plans require subscribers to pay thousands of dollars from their own pockets.[310] Moreover, the ratio of those who have an employer-sponsored insurance and are still being rendered underinsured has tripled since the turn of the present century.[311] As a consequence of this, as found by Gallup in a survey, a quarter of Americans said they had avoided seeking health care in the previous year because of concerns over cost.[312] Adam Gaffney of the Harvard Medical School, who favors single payer asks, "[h]ow would you reduce or eliminate the deductibles faced by people who are covered by their employer?"[313] In response to the uproar over surprise medical bills—often incurred at hospitals—and the instances of hospitals suing patients to recover unpaid bills, it has become imperative for the United States public health policy makers to look at this crucial part of the health care machinery.[314] For instance:

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301. *See* Dylan Scott, *4 Health Care Questions, Besides Medicare-For-All, Every 2020 Democratic Candidate Should Answer*, VOX (Sept. 12, 2019, 9:55 AM), http://www.vox.com/policy-and-politics/2019/9/12/20859515/september-democratic-debate-2020-presidential-candidates-health-care.

302. *Id.*

303. *Id.*

304. *Id.*

305. *Id.*

306. Scott, *supra* note 301.

307. *See id.*

308. *Id.*

309. *Id.*

310. *Id.*

311. Scott, *supra* note 301.

312. *Id.*

313. *Id.*

314. *Id.*

> For inpatient care, hospital prices grew 42% from 2007 to 2014 while physician prices rose 18% according to researchers who studied the Health Care Cost Institute's claims data for people with employer-sponsored insurance from Aetna, Humana, and UnitedHealthcare Group. Similarly, for hospital-based outpatient care, hospital prices increased 25% while physician prices grew 6%, the new Health Affairs study found.[315]

This is how hospitals consume a lot of patients' resources when it comes to health care expenditure.[316] Despite this, the hard fact is that popular discourse on health care mainly blames pharmaceutical companies and health insurers.[317] Larry Levitt, Senior Vice President at the Kaiser Family Foundation, said, "[t]here is a lot of discussion about drug prices. How about hospital prices? . . . What would you do to bring them down?"[318] It is indeed a tough question.[319]

The reason behind the frequent uproar over drug prices is because, in addition to visiting the doctor, patients have to buy prescription drugs at the pharmacy at high costs.[320] Almost fifty percent of Americans purchase a prescription drug every month.[321] Twenty five percent of Americans say their medication is not affordable.[322] Reflecting upon these common concerns, Rachel Sachs, who teaches at Washington University in St. Louis and is an expert in drug prices, posed questions to the leading 2020 Democratic presidential candidates on the critical topic of rising prices of drugs.[323] Her penetrating questions on the monster of ever-rising drug prices could be summarized as follows:

> 1] For Joe Biden: Why didn't his work on the cancer Moonshot Initiative focus more on reducing the price of costly new cancer drugs?
>
> 2] For Kamala Harris: Are there medications she would consider good candidates for march-in rights or compulsory licensing (when the government effectively revokes a drug

315. *Id.* (quoting Alex Kacik, *Hospital Price Growth Driving Healthcare Spending*, MOD. HEALTHCARE (Feb. 4, 2019, 12:00 AM), http://www.modernhealthcare.com/article/20190204/NEWS/190209984/hospital-price-growth-driving-healthcare-spending).

316. Scott, *supra* note 301.

317. *Id.*

318. *Id.*

319. *See id.*

320. *Id.*

321. Scott, *supra* note 301.

322. *Id.*

323. *Id.*

> maker's patent on a treatment and ends their monopoly on producing it) and why?
>
> 3] For Bernie Sanders: Why should the United States try to match the prices paid for drugs in other developed countries, rather than focus on fixing the [United States] market on its own terms?
>
> 4] For Elizabeth Warren: Does she think the government actually has the capacity to manufacture (or contract with private companies to manufacture) generic drugs, as she has proposed in Senate legislation?
>
> 5] For Pete Buttigieg: What is your plan to lower drug prices?[324]

Similarly, long-term care for senior citizens or the chronically ill is too costly.[325] The official data of the average costs is as follows: "$225 a day or $6,844 per month for a semi-private room in a nursing home. Two hundred and fifty-three dollars ($253) a day or $7,698 per month for a private room in a nursing home. One hundred and nineteen dollars ($119) a day or $3,628 per month for care in an assisted living facility (for a one-bedroom unit)."[326]

A recent study indicates that the "average lifetime cost for long-term care is $172,000."[327] The analysis shows that these problems will be aggravated as the baby boomers become senior citizens who desperately need long-term services as well as support.[328] This very report estimates that the overall expenditure on long-term care—including informal care and lost productivity for people who have to look after their near and dear ones—is expected to "double from $2.8 trillion to $5.6 trillion by 2047."[329] Those who are prosperous can afford to pay for it on their own.[330] Those who are not wealthy spend so much money that they become eligible for Medicaid, which, however, is meant for poor Americans.[331] Long-term care has been a neglected issue in the United States health care discourse.[332] It may not be an exaggeration to say that with or without single-payer, the long-term care crisis is going to deepen unless the decision-makers have an innovative plan to rectify the situation.[333]

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324. *Id.*
325. *Id.*
326. Scott, *supra* note 301.
327. *Id.*
328. *Id.*
329. *Id.*
330. *Id.*
331. Scott, *supra* note 301.
332. *Id.*
333. *Id.*

There are few more worrisome statistics to reveal the much deeper malaise of the public health care system in the United States.[334] "The United States spent $10,209 per person on health care in 2017," and sadly this figure is more than "2.5 times the average spent by [other] member countries of the OECD ($3,992 per person)."[335] It shows the escalating prices of health care in the United States.[336] Likewise, the United States five-year survival rate for all types of cancers is 67%, over 10% higher than the five-year cancer survival rate in the United Kingdom at 54%, and 7% higher than Canada.[337] It is also shocking that "medical debt is the [top] reason for people to file bankruptcy in the United States."[338] It is alarming that 28.5 million people in the United States (8.8% of the United States population) lack health insurance.[339] Among those who do have health insurance, "67.2% have private insurance while 37.7% have government-provided coverage."[340] The latter comes through programs such as Medicaid or Medicare.[341]

The most common type of coverage is employer-based health insurance that includes 56% of the United States population.[342] The research shows that the United States is the only nation among the thirty-six Organization for Economic Co-operation and Development ("OECD") member states that does not have universal health care in practice as well as by constitutional right.[343] Supporters of the right to health care, on one hand, argue that nobody in the United States should be excluded from the coverage of health care.[344] They believe that a right to health care would prevent bankruptcies in medical domain, significantly improve public health, slash general health care spending, assist small businesses, and that health care should be offered by the government as an essential service.[345] Critics, on the other hand, contend that a right to health care leads to communism and that it should be the responsibility of every individual to secure health care

334. *Id.*

335. *Should All Americans Have the Right (Be Entitled) to Health Care?*, PROCON.ORG (Feb. 14, 2019), http://healthcare.procon.org.

336. *Id.*

337. *Id.*

338. *Id.*

339. *Id.*; *History of the Right to Health Care*, PROCON.ORG (Oct. 22, 2018), http://healthcare.procon.org/history-of-the-right-to-health-care/.

340. *History of the Right to Health Care*, *supra* note 339; *Should All Americans Have the Right (Be Entitled) to Health Care?*, *supra* note 335.

341. *History of the Right to Health Care*, *supra* note 339; *Should All Americans Have the Right (Be Entitled) to Health Care?*, *supra* note 335.

342. *History of the Right to Health Care*, *supra* note 339.

343. *Id.*

344. *Id.*

345. *Id.*

for him or herself.[346] They apprehend that provision of health care by the government would adversely affect, not only the quality, but also the availability of health care, and would cause whopping government debt and deficits.[347]

Amidst efforts by President Trump's administration to impose Medicaid work requirements and reduce abortion and LGBTQ protections, aggrieved people hope that a Democratic president could move in the opposite direction having a new executive agenda on health care.[348] Walid Gellad, an expert in drug prices and other health issues at the University of Pittsburgh, wonders: "If [Medicare for All] is a no-go in Congress, then what changes would they make to the current system?"[349] Dylan Scott writes that if a radical reform of the United States health care system is not in the agenda in January 2021, then skyrocketing drug prices, the ballooning opioid crisis, the ever growing hospital spending, and long-term care are all critical problems that a new Democratic president would have to deal with.[350] It must be noted that the executive branch of the United States has an extraordinary power to handle health care.[351] It is in charge of Medicare and Medicaid, the two largest insurance programs in the United States, and it directs a vast public health apparatus and the regulations that keep it in check.[352] One can say that, ideally, even a Republican president would have to tackle these problems because health care is an issue that concerns all.[353]

After having looked at the Bayh-Dole Act, the Supreme Court opinion on *Stanford v. Roche*, and the public health situation in the United States, one is compelled to say that the top Court's verdict has unfortunately done injustice to the law itself and the sacrosanct cause of public health.[354] Supporters of the Bayh-Dole Act assert that said legislation permits universities and other recipients of federal research funds to retain the patent rights of their research to stimulate further development and commercialization of the scientific and technological inventions and

346. *Id.*
347. *History of the Right to Health Care*, *supra* note 339.
348. Scott, *supra* note 301.
349. *Id.*
350. *Id.*
351. *Id.*
352. *Id.*
353. *See* Scott, *supra* note 301.
354. *See* Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2018); Stanford v. Roche, 563 U.S. 776, 780 (2011); Alex Philippidis, *Supreme Court Decision in* Stanford v. Roche *Does Not Change Bayh-Dole*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS: INSIGHTS (June 9, 2011), http://www.genengnews.com/insights/supreme-court-decision-in-stanford-v-roche-does-not-change-bayh-dole/.

innovations that would otherwise remain underutilized or not even known.[355] Emily Michiko Morris, however, points out that critics have vehemently questioned this proposition by arguing that the Bayh-Dole Act is, at best, redundant, and at worst a nuisance to the process of innovation.[356] In other words, the Bayh-Dole Act has become a bit contentious, especially with respect to patents granted to federally financed research pursued in the universities.[357] An answer to the controversial question on university patenting under the Bayh-Dole Act—whether it is right or wrong—is that it is highly subjective and relative.[358] In some instances, university patenting is useful; while in other instances, it is harmful, and often, it is simply immaterial.[359]

IV. CONCLUSION

This Article suggests that those United States research institutions availing of federal grants ought to come up with rigorously drafted foolproof employment agreements.[360] The contracts must include clauses on non-disclosure, prior permission to be sought by employees, while signing agreements with third parties, and third parties not subverting already existing agreements between employees and their employers.[361] The government bodies ought to get their patent rights, including the pharmaceutical ones, by entering into infallible contracts with employees.[362] The general population should not be made to pay more than once for the inventions that they have already paid for through taxes.[363] While protecting the legitimate interests of inventors and private companies, public interest, especially public health, should not be compromised.[364] Moreover, the United States policymakers and regulators need to regulate skyrocketing drug prices.[365] The honorable justices are humbly requested to accord top

355. Eisenberg, *supra* note 93, at 1663–64; Frischmann, *supra* note 112, at 399–400; Rai, *supra* note 120, at 97–98; *see also* 35 U.S.C. §§ 200–212.

356. Morris, *supra* note 110, at 82; *see also* 35 U.S.C. §§ 200–212; Dovid A. Kanarfogel, *Rectifying the Missing Costs of University Patent Practices: Addressing Bayh-Dole Criticisms Through Faculty Involvement*, 27 CARDOZO ARTS & ENT. L.J. 533, 533 (2009).

357. Morris, *supra* note 110, at 82; *see also* 35 U.S.C. §§ 200–212.

358. Morris, *supra* note 110, at 82; *see also* 35 U.S.C. §§ 200–212.

359. Morris, *supra* note 110, at 82; *see also* 35 U.S.C. §§ 200–212.

360. *See* Timofeyev, *supra* note 204, at 64.

361. *Id.*

362. *Id.*

363. *See* Eisenberg, *supra* note 93, at 1167–68.

364. *See* Arno & Davis, *supra* note 97, at 635.

365. *See* Scott, *supra* note 301.

priority to public health.[366] This may happen more frequently if the legislative intent behind the passage of the law in question is looked into by all the courts of law in the judicial hierarchy.[367]

366. *See* Rachel A. Nugent & Gerald T. Keusch, *Global Health: Lessons from Bayh-Dole*, *in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION 153, 156 (Anatole Krattiger et al. eds., 2007).

367. *Id.*

THE CRIMINALLY DAMAGED BRAIN AND THE NEED TO EXPAND MENTAL HEALTH COURTS: A LOOK AT THE TRAUMATIZED MIND, UNFORTUNATE CRIMINAL CONSEQUENCES, AND THE DIVERGENT PATHS OF PRISON OR TREATMENT

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H. G. Wells may have given us *The Invisible Man*,[1] but head trauma has given many of us fractured minds.*

I. INTRODUCTION

Many medical professionals now consider crime to be a disease brought on by mental deficiencies.[2] This does not mean that the deficiency need be present since birth, but can be brought about through head trauma such as concussions, sub-concussive impacts, or explosions, which may lead to a traumatic brain injury ("TBI"), chronic traumatic encephalopathy ("CTE"), frontal lobe issue(s), etc.[3] These injuries can cause an individual to lose the ability "to regulate emotion and behavior."[4] The individual becomes prone to act violently and even criminally—sometimes going from being cool, calm, and collected to exploding in an uncontrollable fit of rage with no apparent trigger.[5]

It is a common assumption that everyone makes their own choices and these choices are the determining factor in what they do.[6] "However, neuroscience indicates that our choices sometimes are based upon electrical impulses and neuron activity that are not a part of conscious behavior. This includes not only criminal activity, but also decisions made by police, prosecutors, and jurors to arrest, prosecute, or convict."[7] When looking at

1. H. G. WELLS, THE INVISIBLE MAN (Macdonald Daly ed., Everyman 1995).
2. Richard E. Redding, *The Brain-Disordered Defendant: Neuroscience and Legal Insanity in the Twenty-First Century*, 56 AM. U. L. REV. 51, 56 (2006).
3. *What Is CTE?*, CONCUSSION LEGACY FOUND.: CTE RESOURCES, http://www.concussionfoundation.org/CTE-resources/what-is-CTE (last visited May 1, 2020); *see also* Gillian Mohney, *Could a CTE Diagnosis Have Changed the Aaron Hernandez Verdict?*, HEALTHLINE: HEALTH NEWS (Oct. 12, 2017), http://www.healthline.com/health-news/aaron-hernandez-cte-diagnosis.
4. John McDermott, *The Connection Between Concussions, CTE and Acts of Violence*, MEL (July 12, 2017), http://www.melmagazine.com/the-connection-between-concussions-cte-and-acts-of-violence-65330058f80.
5. *See id.*
6. KEVIN DAVIS, THE BRAIN DEFENSE: MURDER IN MANHATTAN AND THE DAWN OF NEUROSCIENCE IN AMERICA'S COURTROOMS 28 (2017).
7. *Id.*

crime, it is necessary to understand what the prosecution must prove.[8] For a verdict of guilty, the prosecution must prove the elements of a crime beyond a reasonable doubt.[9] Typically, this includes the element of intent to commit the crime.[10] The question then is whether the element of intent can be proven in individuals with severe neurological disorders caused by neurological trauma.[11] Serious rationality impairments may undermine or even diminish criminal responsibility.[12] One study has shown that TBIs are roughly seven times higher in prisoners than the general population.[13] There is evidence that over one million inmates suffer from some form of mental illness.[14] If mental impairment due to brain trauma was taken into account at trial, how many people would be in institutions receiving help, instead of rotting away in prison as the environment furthers their criminal nature?[15]

The groups most known for cranial impacts in the United States are the players of the National Football League ("NFL").[16] These men may experience thousands of bodily impacts throughout their careers.[17] Most of these will be of the sub-concussive variety which do not normally lead to immediate cognitive or other neurological issues.[18] Instead, problems tend to arise years later, often during retirement.[19] However, football players have been shown to be charged with violent crimes at a far higher rate than the general population.[20] This is likely a result of the repeated head trauma over

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8. *See* Patterson v. New York, 432 U.S. 197, 210 (1977).

9. *Id.*

10. *Id.* at 198, 209.

11. *See id.* at 199–201; Mohney, *supra* note 3.

12. Paul Litton, *Traumatic Brain Injury and a Divergence Between Moral and Criminal Responsibility*, DUQ. L. REV., Winter 2018, at 35, 38.

13. Chandra Bozelko, *Traumatic Brain Injury Should Be a Factor When Judging Individuals Accused of Crimes*, STAT: OPINION (Dec. 7, 2017), http://www.statnews.com/2017/12/07/traumatic-brain-injury-crime/.

14. Jillian Peterson & Kevin Heinz, *Understanding Offenders with Serious Mental Illness in the Criminal Justice System*, 42 MITCHELL HAMLINE L. REV. 537, 538 (2016).

15. *See* Etienne Benson, *Rehabilitate or Punish?*, MONITOR ON PSYCHOL., July/Aug. 2003, at 46, 46.

16. J. Amy Dillard & Lisa A. Tucker, *Is C.T.E. a Defense for Murder?*, N.Y. TIMES, Sept. 23, 2017, at A21(L); *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, BAEZ LAW FIRM (Oct. 20, 2017), http://www.baezlawfirm.com/chronic-traumatic-encephalopathy-cte-as-a-criminal-defense/.

17. *See* Dillard & Tucker, *supra* note 16; *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, *supra* note 16.

18. *See* Mohney, *supra* note 3.

19. *See id.*

20. *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, *supra* note 16.

time.[21] This trauma can potentially lead to CTE.[22] As explained in Part IV below, this disease slowly destroys the brain, thus causing permanent, debilitative, and potentially serious behavioral changes to many people once looked up to as heroes.[23]

Unlike TBIs where diagnosis can be found through the use of Computed Tomography Scans ("CTs") and Magnetic Resonance Imaging ("MRI"), there is no definitive test for CTE that can be used on a living person.[24] However, a recent study at Boston University showed that out of 111 brains of deceased NFL players, 110 suffered from CTE.[25] Like our football heroes, our American heroes, those who serve our country and maintain the freedom we are all accustomed to, seem to be suffering much of the same fate.[26] As a result of the various combat injuries experienced by veterans, out of the 125 brains examined of deceased soldiers, 74 were positive for CTE.[27] In situations of violence, such as the 2015 murder of Odin Lloyd by former New England Patriots star Aaron Hernandez, how might the outcome of Hernandez's trial been different if it was then known that he suffered from not only CTE, but what turned out to be an extreme case?[28]

Luckily, there is a relatively new set of courts that seek to help those with mental health issues.[29] Instead of *helping* society by shuttering mentally ill defendants behind bars, the mental health courts seek to help the individuals themselves so that they can return to being productive members of the society that would so willingly turn a blind eye to the help these individuals need.[30]

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21. *See* Julia Jacobo, *Former NFL Player Confirmed as 1st Diagnosis of CTE in Living Patient*, ABC NEWS (Nov. 15, 2017, 10:23 PM), http://www.abcnews.go.com/US/nfl-player-confirmed-1st-diagnosis-cte-living-patient/story?id=51181721; Mohney, *supra* note 3.

22. *What Is CTE?*, *supra* note 3.

23. *See id.*; discussion *infra* Part IV.

24. *See* Mohney, *supra* note 3; *Traumatic Brain Injury (TBI) and Concussion*, AM. SOC'Y NEURORADIOLOGY, http://www.asnr.org/patientinfo/conditions/tbi.shtml (last visited May 1, 2020).

25. Dillard & Tucker, *supra* note 16.

26. *See* Sharyn Alfonsi, *Combat Veterans Coming Home with CTE*, CBS NEWS: 60 MINUTES (Sept. 16, 2018), http://www.cbsnews.com/news/60-minutes-combat-veterans-coming-home-with-cte-brain-injury/.

27. *Id.*

28. *See id.*; Mohney, *supra* note 3.

29. *See* Ursula Castellano, *The Politics of Benchcraft: The Role of Judges in Mental Health Courts*, 42 L. & SOC. INQUIRY 398, 398 (2017); Laura Snodgrass & Brad Justice, Death Is Different*: Limits on the Imposition of the Death Penalty to Traumatic Brain Injuries*, 26 DEV. MENTAL HEALTH L. 81, 83–85 (2007).

30. *See* Castellano, *supra* note 29, at 398–99.

This Article seeks to highlight the sad plight of individuals who commit criminal acts due to having suffered neurological trauma.[31] Part II of this Article presents a series of case studies that show the disheartening changes that befell a model employee; a happy father; an American hero; and a football legend.[32] Parts III and IV explain different forms of brain injuries and what they each entail.[33] Part V provides an overview of the four most prominent tests for insanity in American jurisprudence.[34] Part VI looks at brain damage, criminal sentencing, and the remarkable volume of persons with TBIs in the American prison population.[35] Parts VII and VIII examine a series of three Supreme Court of the United States opinions and analogizes individuals with brain damage to persons with intellectual disabilities or persons who were juveniles at the time they committed a capital crime.[36] Part IX considers whether an individual with brain damage—who was competent at the time of committing a crime—can later be deemed incompetent to stand trial as a result of their brain deteriorating between the time of the crime and their day in court.[37] Part X is a brief overview of the American mental health court system and the Author's proposal for an expansion of this system to broaden the scope of the type of individuals permitted before the bench.[38]

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31. *See* Bozelko, *supra* note 13; Mohney, *supra* note 3; discussion *supra* Part I.

32. *See Aaron Hernandez Biography*, BIOGRAPHY (Jan. 16, 2020), http://www.biography.com/people/aaron-hernandez; discussion *infra* Part II.

33. *See 4 Types of Brain Injuries and 3 Levels of Severity*, DOLMAN L. GROUP: BLOG (Oct. 7, 2019), http://www.dolmanlaw.com/4-types-brain-injuries-3-levels-severity/; discussion *infra* Part III–IV.

34. *See* Insanity Defense Reform Act of 1984, Pub. L. No. 98-473, § 402, 98 Stat. 1837, 2057 (1984) (codified as amended at 18 U.S.C. § 17); State v. Felter, 25 Iowa 67, 82–83 (1868); M'Naghten's Case (1843) 8 Eng. Rep. 718, 718; Model Penal Code § 4.01 (AM. LAW INST. 1962); *M'Naghten Rule*, FREE DICTIONARY: LEGAL DICTIONARY, http://legal-dictionary.thefreedictionary.com/M%27Naghten+Rule (last visited May 1, 2020); discussion *infra* Part V.

35. *See* Lydia D. Johnson, *Guilty or Innocent? . . . Just Take a Look at My Brain — Analyzing the Nexus Between Traumatic Brain Injury and Criminal Responsibility*, 37 S.U. L. REV. 25, 25–26 (2009); Stacey Wood & Bhushan S. Agharkar, *Traumatic Brain Injury in Criminal Litigation*, 84 UMKC L. REV. 411, 412–13 (2015); discussion *infra* Part VI.

36. *See* Hall v. Florida, 134 S. Ct. 1986, 1989 (2014); Roper v. Simmons, 543 U.S. 551, 556 (2005); Atkins v. Virginia, 536 U.S. 304, 305 (2002); Snodgrass & Justice, *supra* note 29, at 82; discussion *infra* Part VII–VIII.

37. *See* Wood & Agharkar, *supra* note 35, at 416; discussion *infra* Part IX.

38. *See* Michael L. Perlin, *"Who Will Judge the Many When the Game Is Through?": Considering the Profound Differences Between Mental Health Courts and* Traditional *Involuntary Civil Commitment Courts*, 41 SEATTLE U. L. REV. 937, 957–58 (2018); discussion *infra* Part X.

II. CASE STUDIES: BROKEN MINDS AND WHAT CHANGES MAY COME

There is an unfortunate reality in life in that bad things happen to good people.[39] Granted, bad things also happen to bad people.[40] Anyone may be subjected to a brain injury.[41] Generally speaking, brain injuries are equal opportunity aggressors that leave the recipient in a worse condition than where they began.[42] Sadly, many injuries have a tendency to go unnoticed due to the lingering harm hiding in the shadow of apparent recovery.[43] The following stories are about real people who suffered neurological trauma and were never fully themselves again.[44]

A. *Phineas Gage*

The case of Phineas Gage is one of the most famous cases of all time of an individual with a neurological disorder.[45] On September 13, 1848, twenty-five-year-old Phineas Gage was working as the foreman of a blasting crew for the Rutland & Burlington Railroad of Vermont.[46] On this particular day, an explosion occurred that caused an iron rod to shoot through his cheek, behind his eye, and up through the top of his skull.[47] Miraculously, not only was he alive, but he was awake and able to speak.[48] After several months of being tended by a physician, he returned to work.[49]

Prior to the accident, he was kept in high regard; having a good mind and good temper.[50] After the accident, "he became 'fitful, irreverent, and grossly profane.'"[51] He became very antisocial and could not maintain a job.[52] He passed away in 1861.[53] In 1868, Gage's treating physician

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39. Robert Puff, *Bad Things Happen to Everyone*, PSYCHOL. TODAY (June 4, 2017), http://www.psychologytoday.com/us/blog/meditation-modern-life/201706/bad-things-happen-everyone.

40. *See id.*

41. *See* Lauren Reed-Guy, *Head Injury*, HEALTHLINE (Apr. 9, 2018), http://www.healthline.com/health/head-injury.

42. *See id.*

43. *See id.*

44. *See* DAVIS, *supra* note 6, at 3–4.

45. *Id.* at 17.

46. *Id.*

47. *Id.* at 17–18.

48. *Id.* at 18.

49. DAVIS, *supra* note 6, at 18.

50. *Id.* at 19.

51. *Id.* (quoting JOHN M. HARLOW, PASSAGE OF AN IRON BAR THROUGH THE HEAD 13 (photo. reprt. 1869) (1868).

52. *Id.*

53. *Id.*

published a paper where he quoted Gage's friends who stated that after the accident, "Gage *was no longer Gage*."[54]

B. *David Alfonso*

David Alfonso was a family man who lived at home with his wife, Debra, and twenty-four-year-old daughter, Malori.[55] Early on the morning of June 8, 2012, he tripped while walking up the stairs of his home, fell backwards, and struck his skull on the wooden floor at the bottom of the staircase.[56] He spent six hours in a coma at the local hospital.[57] Although a bit disoriented upon waking, a neurologist authorized his release.[58] Once home, he began manifesting odd behavior.[59] He became paranoid that someone was coming to kill his family, refused to go outside, and spent most of his time hiding on the couch.[60]

The world changed for the Alfonso family when Dante Alighieri's Seventh Circle of Hell opened up in their bedrooms on June 13, 2012.[61] Malori was awakened just after dawn and saw a darkened figure in her doorway.[62] The man walked over to her bed and smashed the back of her skull with what turned out to be a five-pound metal dumbbell.[63] He proceeded to strike her at least twenty additional times before turning around and leaving the room.[64] Somehow conscious, she left her bedroom and saw her mother exiting the master bedroom.[65] It was clear that her head had been struck as well.[66] When she finally saw her father, he was smashing the dumbbell into his head and he was still hitting himself when the police arrived.[67] The neighbors described the scene as a vision out of *Carrie*.[68]

David spent the next five months in a rehabilitative hospital recovering from his self-inflicted injuries.[69] He claimed he could not

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54. DAVIS, *supra* note 6, at 19 (quoting HARLOW, *supra* note 51, at 14).
55. *Id.* at 67–68.
56. *See id.*
57. *Id.* at 67.
58. *Id.*
59. DAVIS, *supra* note 6, at 68.
60. *Id.*
61. *See id.*; DANTE ALIGHIERI, THE INFERNO 110 (John Ciardi trans., New American Library 2001) (1320).
62. DAVIS, *supra* note 6, at 68.
63. *Id.*
64. *Id.*
65. *Id.*
66. *Id.*
67. DAVIS, *supra* note 6, at 69.
68. *Id.*; CARRIE (MGM Productions 1976).
69. DAVIS, *supra* note 6, at 72.

remember anything that happened and did not find out until Malori told him just before his arrest.[70] He was charged with attempted murder.[71] Debra and Malori fought for David.[72] In the end, he was found not guilty by reason of insanity.[73] Malori stated that on the morning of the attack she "knew right then and there, he was not in the right state of mind, his eyes had changed . . . [i]t was not him."[74]

C. *Chris Ayres*

In April 2004, Marine First Lieutenant Chris Ayres nearly died when his amphibious assault vehicle was attacked by a rocket grenade in Iraq.[75] As a result of the blast, he suffered from severe chronic leg, tooth, and mouth pain, lost vision in one eye, and "cognitive decline, agitation, and depression."[76] Prior to the attack, he was described as "happy all the time [and] best friends with [his eldest] daughter" who suffers from Down Syndrome.[77] After the attack, he was diagnosed with a TBI and Post Traumatic Stress Disorder ("PTSD").[78]

As a result of his injuries, he was both distant and violent.[79] He became forgetful, and his cognitive abilities declined to the point that according to his wife, he "wr[ote] like a third grader [and could not] manage money."[80] At one point, he grabbed his wife by the neck and choked her.[81] According to Chris, he "zoned out . . . [h]er face was crystal clear but everything else was a blur. I was going to eliminate the threat. I had that much rage and anger. My brain was trying to process that she [was not] a

70. *Id.* at 72–73.
71. *Id.* at 73.
72. *Id.* at 74–75.
73. *Id.* at 75.
74. DAVIS, *supra* note 6, at 75.
75. Sharon Kay, *Veteran's War Wounds Cut Deep into Family*, EVERYDAY HEALTH, (Oct. 11, 2012), http://www.everydayhealth.com/emotional-health/veterans-war-wounds-cut-deep-into-family.aspx.
76. *Id.*
77. *Id.*
78. *Id.* "PTSD is a mental health problem that some people develop after experiencing or witnessing a life-threatening event, like combat, a natural disaster, a car accident, or sexual assault." *PTSD: National Center for PTSD*, U.S. DEP'T VETERANS AFF., http://www.ptsd.va.gov/ (last visited May 1, 2020).
79. Kay, *supra* note 75.
80. *Id.*
81. *Id.*

threat; she's my wife."[82] He was arrested, but his wife successfully pled with the prosecutor to get him the help he needed.[83]

D. *Aaron Hernandez*

Aaron Hernandez was a star Gator on the University of Florida's football team; was an honorable mention All-American for the 2008 National Championship team, and named All-American the following year.[84] He joined the New England Patriots as the 113th pick of the 2010 NFL Draft.[85] He was a star on the team, setting the "rookie record for tight ends with [forty-five] catches" during his first season.[86] The following year, he was part of an *unstoppable New England offense*, where he participated in "[twenty-four] touchdowns and 2237 regular-season receiving yards."[87] He was definitely an American football hero.[88] That is, until he was charged with the June 17, 2013 murder of his friend Odin Lloyd.[89]

The case went to trial in January, 2015, and lasted for over two months.[90] In the end, the jury deliberated for six days, found him guilty, and he was sentenced to life in prison without the possibility of parole.[91] During this time, he was also charged and acquitted for a 2012 drive-by shooting outside of a Boston nightclub where two men were killed.[92] On April 19, 2017, at age twenty-seven, he committed suicide by hanging himself in his prison cell with a bedsheet.[93] After his death, his brain was analyzed, and he was diagnosed with the worst case of CTE found in anyone below the age of forty-six.[94]

When looking at each of the above cases, it should be clear that horrors can befall anyone exposed to a brain injury.[95] What may not be clear is just how prevalent brain injuries are in everyday life.[96]

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82. *Id.*
83. *Id.*
84. *Aaron Hernandez Biography*, *supra* note 32.
85. *Id.*
86. *Id.*
87. *Id.*
88. *See id.*
89. *See Aaron Hernandez Biography*, *supra* note 32.
90. *Id.*
91. *Id.*
92. *Id.*
93. *Id.*
94. Associated Press, *Aaron Hernandez's Brain Severely Affected by CTE, Researcher Says*, L.A. TIMES: SPORTS (Nov. 9, 2017, 12:30 PM), http://www.latimes.com/sports/nfl/la-sp-aaron-hernandez-cte-study-20171109-story.html.
95. *See* DAVIS, *supra* note 6, at 17–18, 68; *Aaron Hernandez Biography*, *supra* note 32; Kay *supra* note 75; Reed-Guy, *supra* note 41; discussion *infra* Part II.

III. NEUROLOGICAL CONSEQUENCES OF BRAIN DAMAGE

Trailing behind heart disease, cancer, diabetes, and stroke, TBIs rank in the top public health crises that we face today.[97] The American Association of Neurological Surgeons defines TBIs "as a blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain."[98] The concept of the TBI is an overarching umbrella of brain disorders that may result from anything from banging one's head, to being exposed to an Improvised Explosive Device, to the skull being physically cracked open.[99] The result being around 2.5 million visits to the emergency room each year.[100] In the United States alone, it is estimated that around 138 people die daily as a result of a TBI.[101] However, most people survive but suffer from temporary or permanent impairments to their emotional and cognitive functioning.[102] People who suffer from a history of TBIs tend to have greater degrees of impairments in terms of "attention, processing speed, working memory, episodic memory, and tasks of executive functioning."[103] Unfortunately, they also tend to demonstrate high levels of "disinhibition, apathy, poor judgment, and limited insight into their [own] disorder[s]."[104] Depending on the degree and severity of either a single TBI or a series of TBIs, an individual can go from being a well-functioning and productive member of society, to an impulsive, anti-social, and potentially dangerous person.[105]

TBIs come in four distinct varieties: Mild, moderate, severe, and penetrating.[106] A key element of TBIs is that the individual is subjected to an injury that in turn results in some form of concussion.[107] Concussions occur where there is an impact to the head strong enough to cause the brain to crash

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96. *See* Reed-Guy, *supra* note 41.

97. Johnson, *supra* note 35, at 27.

98. *Sports-Related Head Injury*, AM. ASS'N NEUROLOGICAL SURGEONS, http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Sports-related-Head-Injury (last visited May 1, 2020).

99. Robert H. Ambrose, *Assessing Soldiers' Mental Health: Meeting the Needs of Veterans with PTSD, TBI, and CTE — Pre-Deployment, at Home, and in Court*, 41 WM. MITCHELL L. REV. 886, 893–96 (2015); Wood & Agharkar, *supra* note 35, at 411; *What Is CTE?*, *supra* note 3.

100. Wood & Agharkar, *supra* note 35, at 411.

101. *Id.*

102. *Id.*

103. *Id.* at 415.

104. *Id.*

105. *See* Litton, *supra* note 12, at 37–38.

106. Ambrose, *supra* note 99, at 894–96.

107. *Id.* at 895; *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33; Reed-Guy, *supra* note 41.

into the skull due to the acceleration and deceleration forces of the impact.[108] They usually result in a "short-lived impairment of neurological function that resolves spontaneously."[109] In addition, CTE is essentially a subset of TBIs.[110] Where TBIs typically involve concussions, CTE is brought on by repetitive sub-concussive impacts over time.[111] It is not uncommon that many people may believe that most people suffer TBIs due to accidents; however, some of the more prevailing causes are sports injuries, domestic violence, and military deployment.[112] According to the United States Consumer Product Safety Commission, sports-related head injuries alone accounted for 446,799 visits to emergency rooms in 2009.[113]

Before delving into the different forms of TBIs, it is first important to understand what an injury to the frontal lobe of the brain can mean for an individual, as this is both the area most accessible to injury due to its cranial location and it controls and maintains many of the cognitive functions that are regularly taken for granted.[114]

A. *Frontal Lobe Damage*

As we know, the different parts of the brain perform different functions.[115] For the purposes of this Article, a very general explanation of a few select parts of the brain will be provided for the limited purpose of providing a basis of comparison that will be addressed below.[116]

As the brain has both a right hemisphere and left hemisphere, the brain also contains four lobes.[117] The Parietal lobe processes spatial and visual perceptions, along with the senses of touch, pain, and temperature.[118] The Occipital lobe processes vision and the Temporal lobe processes language, memory, and hearing.[119] Should anything happen to any of these

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108. Reed-Guy, *supra* note 41.

109. *Sports-Related Head Injury*, *supra* note 98.

110. Ambrose, *supra* note 99, at 896.

111. Caleb Korngold et al., *The National Football League and Chronic Traumatic Encephalopathy: Legal Implications*, 41 J. AM. ACAD. PSYCHIATRY & L. 430, 431 (2013).

112. Ambrose, *supra* note 99, at 894–96; Helen M. Farrell, *Football Fallout: The Legalities of CTE*, CRIM. JUST., Fall 2018, at 4, 4–5; Reed-Guy, *supra* note 41.

113. *Sports-Related Head Injury*, *supra* note 98.

114. *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33; *see also* Snodgrass & Justice, *supra* note 29, at 88; discussion *infra* Section III.A.

115. *See* MAYFIELD BRAIN & SPINE, ANATOMY OF THE BRAIN 1 (2018).

116. *See id.* at 3–4; discussion *infra* Section III.A.

117. MAYFIELD BRAIN & SPINE, *supra* note 115, at 3–4.

118. *Id.* at 3.

119. *Id.* at 3–4.

lobes, it seems clear what some of the outcomes may be.[120] However, and most importantly for the purposes of this Article, there is the fourth lobe: The Frontal lobe.[121] Unlike the other three lobes that mostly deal with the processing and interpretation of physical stimuli, the primary functions of the frontal lobe deal with executive functioning, personality, emotions and behavior, intelligence, concentration, and self-awareness.[122] Now consider what might be the consequences of damage to this area of the brain.[123]

Damage to the frontal lobe has been acknowledged as a possible causal factor for violent criminal acts.[124] Persons with severe frontal lobe damage "tend to be overresponsive to stimuli from the world around them, lack the capacity to ignore their environment even when the response seems bizarre or inappropriate to others, react immaturely and without foresight or contemplation of the consequences, and make risky decisions to achieve short-term rewards."[125]

Studies show that the frontal lobes are what regulate appropriate behavior via the executive functioning capabilities.[126] Further, the frontal lobes act as the *braking mechanism* for bad or inappropriate behavior.[127] Therefore, an individual exhibiting *bad behavior* or *bad character* may, in fact, be suffering from an unknown injury to the frontal lobes.[128] An individual possessing damaged frontal lobes could arguably be less culpable for exhibiting traits of negative or poor behavior due to the individual's impulse controls being shuttered as a result of the structural abnormalities of the damaged area of the brain.[129] Due to the frontal lobes being located directly behind the forehead, that area of the brain is more susceptible to trauma.[130] Individuals who suffer from frontal lobe damage tend to "display marked apathy, tactlessness, impulsivity, irritability, and the inability to 'empathize with the feelings of others.'"[131] More disturbingly, frontal lobe

120. *See id.*
121. *Id.* at 3.
122. MAYFIELD BRAIN & SPINE, *supra* note 115, at 3.
123. *See id.* at 3–4.
124. Snodgrass & Justice, *supra* note 29, at 88.
125. *Id.*
126. Michael L. Perlin & Alison J. Lynch, *"In the Wasteland of Your Mind": Criminology, Scientific Discoveries and the Criminal Process*, 4 VA. J. CRIM. L. 304, 332 (2016); Jessie A. Seiden, *The Criminal Brain: Frontal Lobe Dysfunction Evidence in Capital Proceedings*, 16 CAP. DEF. J. 395, 396 (2004).
127. Snodgrass & Justice, *supra* note 29, at 88.
128. Wood & Agharkar, *supra* note 35, at 418.
129. *See* Perlin & Lynch, *supra* note 126, at 333.
130. Seiden, *supra* note 126, at 398.
131. *Id.* at 400; Tiffany W. Chow & Jeffrey L. Cummings, *Frontal-Subcortical Circuits*, *in* THE HUMAN FRONTAL LOBES: FUNCTIONS AND DISORDERS 3, 6–7 (Bruce L. Miller & Jeffrey L. Cummings eds., 3d ed. 1999).

damage has been shown to cause disinhibition or pseudo-psychopathic behaviors.[132] As a result, an argument can be made that a person with a defective or damaged frontal lobe may commit violent or impulsive acts that are out of their character.[133]

Now that we have an understanding of what it means for an individual to suffer an injury to the frontal lobe, the time has come to gain a better understanding of the different forms of TBIs and their potential consequences.[134] Each type of TBI will be addressed individually.[135]

B. *Mild TBI*

Mild TBI is the most prevalent form of TBI.[136] Based on data compiled by the Department of Defense ("DOD"), United States troops suffered from roughly 250,000 mild TBIs between 2000 and 2014.[137] Luckily, the mild TBI is the least severe TBI form with the most common injuries leading to concussions with a loss of consciousness of just a few seconds, but less than thirty minutes.[138] Although a loss of consciousness is common, it is not a requirement of the mild TBI.[139] Some victims merely become dazed or disoriented.[140] Other symptoms may include but are not limited to nausea or vomiting, excess sleeping, difficulty sleeping, speech problems, mood changes or mood swings, or feelings of depression or anxiety.[141] It is important to note that any TBI, regardless of level or symptom, can have long-lasting effects, and many times, an injury may occur but not appear on tests.[142]

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132. Seiden, *supra* note 126, at 400.
133. *Id.* at 396; Snodgrass & Justice, *supra* note 29, at 88.
134. *See* Seiden, *supra* note 126, at 396.
135. Ambrose, *supra* note 99, at 894–96; *see also* discussion *infra* Sections III.B–E.
136. Ambrose, *supra* note 99, at 894–95.
137. *Id.* at 894.
138. *Id.* at 895; *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
139. *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
140. *Id.*; *Traumatic Brain Injury*, MAYO CLINIC: PATIENT CARE & HEALTH INFO, http://www.mayoclinic.org/diseases-conditions/traumatic-brain-injury/symptoms-causes/syc-20378557 (last visited May 1, 2020).
141. *Traumatic Brain Injury*, *supra* note 140.
142. Ambrose, *supra* note 99, at 895; *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.

C. *Moderate TBI*

As the name indicates, the moderate TBI is more serious than the mild TBI.[143] Unlike the mild TBI where a loss of consciousness is not required, the moderate TBI includes a loss of consciousness that can last for several hours, but less than a full day.[144] Temporary memory loss is a common side effect but should last for less than one week.[145] Additional physical symptoms include, but are not limited to, "convulsions or seizures, [d]ilation of one or both pupils," and an inability to wake up.[146] Cognitive symptoms may include "profound confusion; [a]gitation, combativeness, or other unusual behavior; [and] [s]lurred speech."[147] Further, some physical, cognitive, or behavioral complications may endure for months, or in some cases, become permanent.[148]

D. *Severe TBI*

Severe TBIs happen rarely and, according to the DOD, were present in around one percent of the TBIs suffered by United States forces between 2000 and 2014.[149] Typical characteristics of the severe TBI are a loss of consciousness for more than twenty-four hours and memory loss that lasts for more than one week.[150] Many of the symptoms of both mild and moderate TBIs are present as well.[151] Some cases may result in a coma or even death.[152]

E. *Penetrating TBI*

Penetrating TBIs involve open head wounds.[153] From a combat perspective, these may result from skull fractures and projectiles.[154] These

143. Ambrose, *supra* note 99, at 895; *see also 4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
144. Ambrose, *supra* note 99, at 894–95; *see also 4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
145. Ambrose, *supra* note 99, at 895.
146. *Traumatic Brain Injury*, *supra* note 140.
147. *Id.*
148. *See 4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
149. Ambrose, *supra* note 99, at 895.
150. *Id.*
151. *See id.*; *4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
152. *Sports-Related Head Injury*, *supra* note 98.
153. Ambrose, *supra* note 99, at 895.
154. *Id.* at 896.

types of injuries may be critical with many injuries leading to death and those who survive may not be able to return to their old lives.[155]

F. *Diagnosis and Treatment of TBIs*

Diagnoses of TBIs are no small feat.[156] Physicians employ various methods of determining the level and type of TBI an individual is suffering from, and one of the main methods is through the implication of the Glasgow Coma Scale.[157] This is "a [fifteen] point scale [that] estimat[es] and categoriz[es] the outcomes of the brain injury on the basis of overall social capability or dependence on others."[158] The test employed looks at three categories: Motor responses, verbal responses, and eye-opening responses.[159] Specific values per the scale are assigned based on the responses and the score from each category is then tallied together for an overall score.[160] The higher the score the better when looking at both survival and the degree to which an individual may return to a normal life.[161] When looking at the level of the TBI, the scores range as follows: Mild will range from thirteen to fifteen; moderate from nine to twelve; severe from three to eight; and anything below three is considered to be a vegetative state where the individual has "[s]leep wake cycles, [a]rousal, but no interaction with [the] environment; [and] [n]o localized response to pain."[162]

On the plus side, depending on the degree and severity of the TBI, there are treatment options available.[163] Initial treatment deals with stabilization immediately following the injury, and the Glasgow Coma Scale is applied to determine the state that the individual is in.[164] Following this, there are several more specific treatment options based on the individual's needs.[165] First, there is rehabilitative care which is designed to help restore the individual to daily life.[166] Second, there is an acute treatment that "is

155. *See 4 Types of Brain Injuries and 3 Levels of Severity*, *supra* note 33.
156. *See Glasgow Coma Scale*, TRAUMATICBRAININJURY.COM, http://www.traumaticbraininjury.com/symptoms-of-tbi/glasgow-coma-scale/ (last visited May 1, 2020).
157. *See id.*
158. *Id.*
159. *Id.*
160. *Id.*
161. *See Glasgow Coma Scale*, *supra* note 156.
162. *Id.*
163. *Treatments for TBI*, TRAUMATICBRAININJURY.COM, http://www.traumaticbraininjury.com/treatments-for-tbi/ (last visited May 1, 2020).
164. *Id.*; *Glasgow Coma Scale*, *supra* note 156.
165. *See Treatments for TBI*, *supra* note 163.
166. *Id.*

aimed at minimizing secondary injury and life support."[167] Finally, third, there are surgical treatment options available that "may be used to prevent secondary injury by helping to maintain blood flow and oxygen to the brain and minimize swelling and pressure."[168]

Looking past these treatment plans, it must be noted that the biggest challenges individuals face during the rehabilitative process are those dealing with cognitive and behavioral impacts.[169] Individuals may need to "relearn how to think, how to behave, how to control impulses and generally how to function appropriately and productively in life."[170] Unfortunately, these processes may never fully be relearned, even with ongoing therapy.[171]

A further concern for many individuals is the staggering costs related to treatment.[172] The Centers for Disease Control and Prevention ("CDC") estimated that in the year 2000, medical costs due to TBI totaled around $60,000,000,000.[173] An individual with a severe TBI could have suffered costs upwards of $1,875,000.[174] With the costs of inflation, that same individual would be looking at around $2,810,485 today.[175]

IV. CTE: A DIFFERENT TYPE OF TBI

CTE is essentially a subset of TBIs as it is a degenerative brain disease that is "caused by repetitive trauma to the brain."[176] Although not limited to professional athletes or veterans, it is in these groups of individuals that CTE tends to be most prolific.[177] The repeated trauma causes a protein called tau to form clumps that slowly buildup throughout the brain.[178] As tau spreads, brain cells die.[179] This is a very slow process with early symptoms usually first appearing in an individual's late twenties or early thirties.[180]

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167. *Id.*
168. *Id.*
169. Snodgrass & Justice, *supra* note 29, at 88.
170. *Id.*
171. *Id.*
172. *Id.* at 89.
173. *Id.*
174. Snodgrass & Justice, *supra* note 29, at 89.
175. *See Inflation Calculator*, US INFLATION CALCULATOR, http://www.usinflationcalculator.com/ (last visited May 5, 2020).
176. Korngold et al., *supra* note 111, at 430.
177. *Frequently Asked Questions About CTE*, BOS. U. RES.: CTE CTR., http://www.bu.edu/cte/about/frequently-asked-questions/ (last visited May 1, 2020); *What Is CTE?*, *supra* note 3.
178. *Frequently Asked Questions About CTE*, *supra* note 177; *What Is CTE?*, *supra* note 3.
179. *What Is CTE?*, *supra* note 3.
180. *Id.*

Side effects include increased aggression, depression, paranoia, and a high risk of suicide.[181] Further, it appears that CTE causes a decline in executive functioning which is seen by an individual's inability to make decisions, a lack of impulse control, and decreased memory and problem solving abilities.[182] It is thought that "CTE deprives [an individual] of the ability to handle disputes rationally . . . [which] may . . . equate to insanity."[183] As a result of CTE, many people with "no history of domestic violence . . . become dangerous to their families."[184]

In addition to the cognitive issues, CTE can also be linked to physical decline as well.[185] Four years prior to his death, NFL star Fred McNiell had a scan of his brain performed on an MRI.[186] Two years later, he began experiencing significant motor deficits such as an inability to tie his shoes or button his shirt and, eventually, he could no longer feed himself.[187] He died two years later, and his autopsy confirmed that he suffered from CTE.[188]

Evidence of CTE was first truly publicized by Dr. Bennet Omalu in 2005 when he published an article identifying American football hero Mike Webster with the disease.[189] This was a highly unpopular diagnosis, but as it turns out, CTE was known to exist in boxers since 1928.[190] At that time, the condition was known as punch drunk syndrome and was diagnosed antemortem.[191] However, the extent of the disease, its causes, and consequences were not known at that time.[192] Current data shows that "[t]he force of a professional boxer's fist is equivalent to being hit with a [thirteen] pound bowling ball traveling [at twenty] miles per hour, or about [fifty-two]

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181. *See Frequently Asked Questions About CTE*, *supra* note 177; Mohney, *supra* note 3; *What Is CTE?*, *supra* note 3.

182. Korngold et al., *supra* note 111, at 431–32.

183. Dillard & Tucker, *supra* note 16.

184. Michael O'Keeffe, *Boston University Study Finds Possible Link Between Traumatic Brain Injuries and Domestic Violence*, N.Y. DAILY NEWS (Oct. 18, 2014, 8:33 PM), http://www.nydailynews.com/sports/football/study-cte-linked-domestic-violence-article-1.1978936.

185. *See* Jacobo, *supra* note 21.

186. Andrew Freedman, *Doctors Detected CTE in a Living Football Player, Bringing Us Closer to Next Frontier in Treatment*, MASHABLE: SCI. (Nov. 16, 2017), http://www.mashable.com/2017/11/16/cte-study-diagnosis-living-nfl-player/.

187. *Id.*; Jacobo, *supra* note 21.

188. Freedman, *supra* note 186.

189. *What Is CTE?*, *supra* note 3.

190. *Id.*

191. *Id.*; *Frequently Asked Questions About CTE*, *supra* note 177.

192. *See Frequently Asked Questions About CTE*, *supra* note 177; *What Is CTE?*, *supra* note 3.

times the force of gravity."[193] At the present, it is believed that the type of head trauma required to produce CTE does not require the individual to experience symptoms such as concussions, but instead subconcussive impacts are the biggest factor.[194] Further, there is little evidence that only a few impacts are needed to cause the condition.[195] Instead, the majority of those diagnosed suffered from repetitive cranial impacts in the hundreds or thousands over many years.[196]

At the current time, CTE can only be diagnosed postmortem.[197] Pathologists perform a tissue analysis of the brain where they use special chemicals to expose tau.[198] They then analyze the sections of the brain where tau is present for specific patterns unique to CTE.[199] This is a lengthy process which can take months for a complete diagnosis.[200] Although the existing test has helped to provide an understanding of the disease—when considering the various ways in which the disease impacts an individual's cognitive and physical stability—the development of a viable test for a living individual is paramount to the search for a cure.[201]

Although in the very beginning stages, scientists have identified two potential ways to test for CTE antemortem.[202] The first potential test involves a new biomarker that may be used in identifying CTE.[203] This involves analyzing spinal fluid for a protein called CCL11 which is significantly elevated in those suffering from the disease.[204] Another nice feature of the CCL11 biomarker is that it can be used to differentiate between CTE and Alzheimer's disease, which presents similar cognitive symptoms.[205]

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193. *Sports-Related Head Injury*, *supra* note 98.
194. *What Is CTE?*, *supra* note 3.
195. *See id.*; *Frequently Asked Questions About CTE*, *supra* note 177.
196. *What Is CTE?*, *supra* note 3.
197. *Id.*
198. *Id.*
199. *Id.*
200. *Id.*
201. *See What Is CTE?*, *supra* note 3.
202. *See* Jonathan D. Cherry et al., *CCL11 Is Increased in the CNS in Chronic Traumatic Encephalopathy but Not in Alzheimer's Disease*, PLOS ONE, Sept. 26, 2017, at 1, 2–3; Bennet Omalu et al., *Postmortem Autopsy — Confirmation of Antemortem [F-18]FDDNP-PET Scans in a Football Player with Chronic Traumatic Encephalopathy*, 82 NEUROSURGERY 237, 238 (2018).
203. Freedman, *supra* note 186.
204. Maggie Fox, *Test Might Diagnose Brain Damage in Living Football Players*, NBC NEWS: HEALTH (Sept. 27, 2017, 12:40 PM), http://www.nbcnews.com/health/health-news/test-might-diagnose-brain-damage-living-football-players-n804916; *see also* Cherry et al., *supra* note 202, at 5, 7.
205. Cherry et al., *supra* note 202, at 5, 7.

Although the mere presence of one biomarker may not be enough for proper identification of CTE, it is a step in the right direction.[206]

The second potential test deals with Positron Emission Tomography ("PET") imaging.[207] Through the use of the PET scan, it may be possible to "identify the distinctive . . . topographic . . . distribution of brain tau pathology."[208] This may be a useful tool in diagnosing CTE because it can be used to identify the *fingerprint* signature of CTE and can be done in a relatively non-invasive way.[209] The combination of the PET scan with the CCL11 biomarker tests may pave the way to a living diagnosis.[210]

Although not available now, it is likely that at some point there will be a definitive test that will have the capability of confirming a CTE diagnosis in a live person.[211] If this occurs, there will be a potential defense to criminal activity based on the disease, just as there is the potential for a defense stemming from other forms of brain damage.[212] As with TBIs or other forms of brain damage, the defense would likely argue that the defendant suffered from diminished capacity, and, therefore, could not have had the necessary mens rea to establish criminal intent.[213] "Indeed, being afflicted with CTE may well equate to insanity."[214] Should the jury be given an instruction to consider CTE as a mitigating circumstance, there is the possibility that the jury would give the defendant the benefit of the doubt.[215] In a 2016 study, participants found that the criminal acts of an individual suffering from brain damage were somewhat excusable, and recommended reduced penalties as a result.[216]

V. CRIMINAL INTENT AND INSANITY DEFENSES

There are three main schools of thought for why society punishes individuals who commit criminal acts.[217] First there is *retribution*, where it

206. *See id.*
207. *Id.* at 10.
208. Omalu et al., *supra* note 202, at 242.
209. Jacobo, *supra* note 21.
210. Cherry et al., *supra* note 202, at 10.
211. *See id.* at 9; Omalu et al., *supra* note 202, at 237–38.
212. *See* Dillard & Tucker, *supra* note 16; *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, *supra* note 16.
213. *See* Dillard & Tucker, *supra* note 16; *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, *supra* note 16; discussion *infra* Part V.
214. Dillard & Tucker, *supra* note 16.
215. *See id.*; *Chronic Traumatic Encephalopathy (CTE) as a Criminal Defense*, *supra* note 16.
216. Bozelko, *supra* note 13.
217. *Punishment*, FREE DICTIONARY: LEGAL DICTIONARY, http://www.legal-dictionary.thefreedictionary.com/punishment (last visited May 1, 2020).

is "not primarily for the socially useful punishment, but for the just punishment, the punishment that the criminal—given his wrongdoing—deserves or merits, the punishment that the society has a right to inflict and the criminal a right to demand."[218] The second is *rehabilitation*, which has the goal of preventing future crime from existing offenders through the treatment of an individual's afflictions—such as mental illness or drug dependency—along with educational programs designed to increase knowledge and job skills.[219] Finally, there is *deterrence* which is designed to prevent other individuals from committing criminal acts.[220] This is accomplished by placing them on notice that a given behavior is considered criminal and, therefore, punishable.[221]

When looking at the most basic criminal law level, to be deemed guilty of a crime, an individual must normally have had the intent to commit the crime.[222] Intent is defined as a state of mind accompanied by an act.[223] The first element of intent is known as mens rea, which literally translates to *guilty mind*.[224] It is this state of mind that is required for most convictions.[225] A person suffering from frontal lobe damage should be carefully evaluated prior to sentencing to determine if the individual possessed "the requisite mens rea for the crimes with which [he or she is] being charged."[226] The second element, the act, is known as actus reus.[227] This is "[t]he wrongful deed that comprises the [elements] of a crime."[228] Further, to have the intent to commit a crime, one must have criminal capacity: "[T]he ability to understand right from wrong."[229]

Before transitioning to the insanity tests described below, the terms *insanity* and *mental illness* need to be clarified as they tend to be used both

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218. Mike C. Materni, *Criminal Punishment and the Pursuit of Justice*, 2 BRIT. J. AM. LEGAL STUD. 263, 277–78 (2013); Jeffrie G. Murphy, *Retributivism and the State's Interest in Punishment*, 27 AM. SOC'Y FOR POL. & LEGAL PHIL. 156, 158–59 (1985).

219. *See* Materni, *supra* note 218, at 291.

220. *Id.* at 289–90.

221. *Id.* at 290.

222. N. J. Schweitzer et al., *Neuroimages as Evidence in a Mens Rea Defense: No Impact*, 17 PSYCHOL. PUB. POL'Y & L. 357, 364 (2011); *Intent*, BLACK'S LAW DICTIONARY (11th ed. 2019).

223. *Intent*, *supra* note 222.

224. *Id.*; Schweitzer et al., *supra* note 222, at 364; *Mens Rea*, BLACK'S LAW DICTIONARY (11th ed. 2019).

225. *Mens Rea*, *supra* note 224.

226. Wood & Agharkar, *supra* note 35, at 418.

227. Schweitzer et al., *supra* note 222, at 364; *Actus Reus*, BLACK'S LAW DICTIONARY (11th ed. 2019); *Intent*, *supra* note 222.

228. *Actus Reus*, *supra* note 227.

229. *Criminal Capacity*, BLACK'S LAW DICTIONARY (11th ed. 2019).

incorrectly and interchangeably.[230] The problem arises because these terms reflect different standards.[231] *Insanity* is a legal term, whereas *mental illness* is a medical term referring to *psychosis or neurosis*.[232] Just because an individual suffers from a mental illness does not make that person automatically legally insane.[233] Due to the elements of the tests for insanity, an individual diagnosed with a mental illness may be perfectly sane from a legal standpoint.[234] However, when looking from a medical perspective, there is little difference in the behavior of an individual with a mental illness, and an individual deemed to be insane.[235] The big issue is in the way the law treats and sentences the two categories of offenders.[236] When looking at capital punishment, there is an exception for the insane, but not for the mentally ill.[237] The rift, created in disposition, should be a clear indicator that something needs to be done to correct the legal farce forged by the age-old argument between medicine and law.[238]

A. *M'Naghten Insanity Test*

Society has strong beliefs concerning guilt, innocence, and capacity.[239] One belief is that criminals should be punished for their misdeeds.[240] The second is that those with diminished capacity should be given help due to their illness.[241] The first real test concerning an individual's capacity came from *M'Naghten's Case*[242] in 1843.[243] In that case, Daniel M'Naghten believed that he was the victim of a conspiracy and accidently killed Edward Drummond while trying to murder British Prime Minister Robert Peel.[244] At trial, he pled insanity and was found not

230. *See* Michelle Armstrong, Note, *Addressing Defendants Who are "Crazy, but Not Crazy Enough": How* Hall v. Florida *Changes the Death Penalty for Mentally Ill Defendants*, 47 U. TOL. L. REV. 743, 750–51 (2016).
231. *Id.*
232. *Id.* at 750.
233. *Id.* at 750–51.
234. *Id.*
235. Armstrong, *supra* note 230, at 745.
236. *Id.*
237. *Id.*
238. *See id.*
239. *See Insanity Defense*, LEGAL INFO INST., http://www.law.cornell.edu/wex/insanity_defense (last visited May 1, 2020).
240. *See id.*
241. *See id.*; *Punishment*, *supra* note 217.
242. 8 Eng. Rep. 718.
243. M'Naghten's Case (1843) 8 Eng. Rep. 718, 718; *M'Naghten Rule*, *supra* note 34.
244. *M'Naghten's Case*, 8 Eng. Rep. at 719; *M'Naghten Rule*, *supra* note 34.

guilty.[245] Due to public outrage, the Lords of Justice of the Queen's Bench formulated what would become the M'Naghten test for insanity.[246] The test states that:

> [A]t the time of the committing of the act the party accused was laboring under such a defect of reason, from [a] disease of the mind, as not to know the nature and quality of the act he was doing, or if he did know it, that he did not know that what he was doing was wrong.[247]

This is a narrow test that helps those who, at the time of the crime, did not understand the nature of what they were doing or did not understand that what they were doing was wrong.[248]

B. *Irresistible Impulse Test*

Moving on, the Iowa Supreme Court in 1868 created a new test to determine insanity as a replacement for the M'Naghten test.[249] This test, known as the Irresistible Impulse Test, was further solidified into public policy via the Alabama Supreme Court in 1887.[250] The Irresistible Impulse Test looks at those who commit a crime "due to their inability to exercise behavioral control."[251] "Put simply, 'the irresistible impulse defense is available when "the accused's mind has become so impaired by disease that he is totally deprived of mental power to control or restrain his act."'"[252] Some states created a hybrid between this test and the M'Naghten Test where this test supplements that of M'Naghten.[253]

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245. *M'Naghten's Case*, 8 Eng. Rep. at 719–20; *M'Naghten Rule*, *supra* note 34.

246. *M'Naghten Rule*, *supra* note 34.

247. *M'Naghten's Case*, 8 Eng. Rep. at 719; *M'Naghten Rule*, *supra* note 34.

248. Redding, *supra* note 2, at 53; *see also M'Naghten's Case*, 8 Eng. Rep. at 719; *M'Naghten Rule*, *supra* note 34.

249. *See* State v. Felter, 25 Iowa 67, 82–83 (1868).

250. *Id.*; Parsons v. State, 2 So. 854, 866 (Ala. 1887); Redding, *supra* note 2, at 53.

251. Redding, *supra* note 2, at 53.

252. Russell Spivak, *Not Guilty by Reason of CTE: The Imminent Rise of Football's Foil as a Criminal Defense*, 54 CRIM. L. BULL. 1279, 1299–1300 (2018) (quoting Bennett v. Commonwealth, 511 S.E.2d 439, 447 (Va. Ct. App. 1999)); *see also* Godley v. Commonwealth, 343 S.E.2d 368, 370 (Va. Ct. App. 1986).

253. Spivak, *supra* note 252, at 1300.

C. *Model Penal Code Test*

In addition to both of these tests, there is one additional test of note.[254] The American Law Institute created the Model Penal Code ("MPC") in 1962 and subsequently updated it in 1981.[255] Although not law itself, many states have adopted the MPC as their criminal statutes.[256] The MPC rule for insanity states that "[a] person is not responsible for criminal conduct if at the time of such conduct as a result of mental disease or defect he lacks substantial capacity either to appreciate the criminality [wrongfulness] of his conduct or to conform his conduct to the requirements of law."[257] It is interesting that although the MPC has the affirmative defense of insanity, the authors chose not to define what the terms *mental disease* or *defect* mean for purposes of the rule.[258] Per the MPC's commentary, the authors did this intentionally in order to keep the rule open for *developing medical understanding*.[259]

D. *Insanity Defense Reform Act*

Since the M'Naghten Test was established in 1843, the concept of the insanity plea has been the subject of a great deal of controversy.[260] On one hand, society demands that criminals be punished for their crimes.[261] On the other, society wants to forgive and treat.[262] In light of the 1982 assassination attempt of President Ronald Reagan by John W. Hinckley Jr., and his successful use of the insanity defense, Congress passed the Insanity Defense Reform Act ("IDRA") in 1984.[263] Although not applicable in state

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254. *Id.* at 1301.

255. *Id.*; *see also* Model Penal Code § 4.01 (AM. LAW INST. 1962); Model Penal Code § 4.01 (AM. LAW INST. 1981).

256. Paul H. Robinson & Mark D. Dubber, *The American Model Penal Code: A Brief Overview*, 10 NEW CRIM. L. REV. 319, 326 (2007); *see also Model Penal Code*, A.L.I., http://www.ali.org/publications/show/model-penal-code/ (last visited May 1, 2020).

257. Model Penal Code § 4.01.

258. *Id.*; Spivak, *supra* note 252, at 1308.

259. Model Penal Code § 4.01(1); Spivak, *supra* note 252, at 1308.

260. *See* M'Naghten's Case (1843) 8 Eng. Rep. 718, 718; *M'Naghten Rule*, *supra* note 34.

261. *See* Nicola Lacey & Hanna Pickard, *To Blame or to Forgive? Reconciling Punishment and Forgiveness in Criminal Justice*, 35 OXFORD J. LEGAL STUD. 665, 666 (2015).

262. *Id.*

263. Insanity Defense Reform Act of 1984, Pub. L. No. 98-473, § 402, 98 Stat. 1837, 2057 (1984) (codified as amended at 18 U.S.C. § 17); *Insanity Defense Reform Act*, IRESEARCHNET, http://www.psychology.iresearchnet.com/forensic-psychology/criminal-responsibility/insanity-defense-reform-act/ (last visited May 1, 2020); *see also* 18 U.S.C. § 17 (2018).

courts, the purpose of the IDRA was to impose a uniform insanity standard to be used in all federal trials, in which the defense of insanity is raised.[264] Per IDRA:

> It is an affirmative defense to a prosecution under any federal statute that, at the time of the commission of the acts constituting the offense, the defendant, as a result of a severe mental disease or defect, was unable to appreciate the nature and quality or the wrongfulness of his acts. Mental disease or defect does not otherwise constitute a defense.[265]

Further, it shifted the burden of proof to the defense who must show by clear and convincing evidence that the individual was legally insane.[266]

VI. THE DAMAGED BRAIN AND CRIMINAL CULPABILITY

As previously discussed, there is evidence that brain abnormalities can both affect decision making and potentially trigger violent actions.[267] When considering criminal proceedings, having an understanding of how brain injuries affect criminal responsibility may have the effect of acting as mitigating factors or defenses in sentencing.[268] "The core principle of [our legal] system is that a person can be held criminally responsible if he performs a prohibited act intentionally and with a statutorily specified mental state, such as *purpose*, *knowledge*, *recklessness*, or *negligence*."[269] Research shows that when an individual suffers a TBI, the individual will suffer from a mental change.[270] The question lies in what happens if the injury-caused change has a profoundly negative effect on the individual's mental state that leads to criminal behavior.[271] Being able to show the court that, as a result of a TBI—or other brain injury—the defendant suffered a change in personality or behavior could have a significant impact in terms of sentencing.[272] It would be very helpful if, at some point, a method is developed that has the ability to show how a particular brain injury affected an individual's capacity to make good choices and exercise reasonable judgment.[273]

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264. *Insanity Defense Reform Act*, *supra* note 263; *see also* 18 U.S.C. § 17.
265. 18 U.S.C. § 17(a).
266. *Id.* § 17(b); *see also Insanity Defense Reform Act*, *supra* note 263.
267. Johnson, *supra* note 35, at 25; *see also supra* Part IV.
268. Johnson, *supra* note 35, at 25–26.
269. *Id.* at 30–31.
270. *Id.* at 31–32.
271. *See id.* at 25.
272. Wood & Agharkar, *supra* note 35, at 419–20.
273. *Id.*

Studies have shown that TBIs are common among criminal defendants and the overall jail and prison populations.[274] The CDC estimates that somewhere between twenty five and eighty seven percent of incarcerated individuals suffered from some form of TBI.[275] The CDC studies also show that prisoners who have suffered TBIs are at a high risk of reoffending post release.[276] As a result of their TBIs, many prisoners exhibit behaviors that are misinterpreted by prison staff as defiance or disciplinary problems while the reality is that these are the secondary effects of their TBIs.[277] Prisons are not mental health institutions and prisoners who exhibit these behaviors are more likely to receive some form of punishment, rather than receive the help they actually need.[278] Moreover, these behaviors may lead to increased problems with other inmates, which potentially may lead to the individual suffering further TBIs.[279]

VII. POTENTIAL EIGHTH AMENDMENT AVENUE FOR BRAIN DAMAGED DEFENDANTS

The Eighth Amendment of the United States Constitution prohibits the Government from exercising cruel and unusual punishments.[280] Justice Warren explained that "[t]he basic concept underlying the Eighth Amendment is nothing less than the dignity of man."[281] Depending on the circumstances, capital punishment can be deemed cruel and unusual.[282] Although capital punishment is not the focus of this Article, the cases addressed below will be used to show that there should be a similarity in the way brain damaged individuals are sentenced to those groups that American society deems *uniquely vulnerable*; specifically juveniles, and the intellectually disabled.[283]

Historically, common law prohibited criminal punishment for those individuals with intellectual disabilities.[284] During the eighteenth century, "it was understood that 'total idiocy . . . excuses from the guilt, and of course from the punishment, of any criminal action committed under such

274. *Id.* at 412–13.
275. *Id.*
276. *Id.* at 413.
277. Wood & Agharkar, *supra* note 35, at 413.
278. *Id.*
279. *Id.*
280. U.S. CONST. amend. VIII.
281. Trop v. Dulles, 356 U.S. 86, 100 (1958).
282. *See* U.S. CONST. amend. VIII; Atkins v. Virginia, 536 U.S. 304, 311 (2002); Snodgrass & Justice, *supra* note 29, at 83.
283. Armstrong, *supra* note 230, at 744.
284. *Id.* at 746.

deprivation of the senses.'"[285] Currently, the definition of who may be characterized as possessing an intellectual disability is a bit more politically correct as the requirement of *total idiocy* has been removed.[286] In its place, the current definition is "a disability characterized by significant limitations in both intellectual functioning and in adaptive behavior [and] originates before age [eighteen]."[287] Based on this definition, there is at least the appearance that an individual with a brain injury may qualify.[288] The following cases illustrate the direction that the Court has taken when considering the level of punishment appropriate for the intellectually disabled and juvenile offenders.[289]

A. *Atkins v. Virginia*

In 2002, the Supreme Court of the United States decided the case of *Atkins v. Virginia*[290] in a landmark decision that barred the intellectually disabled from receiving capital punishment.[291] "Petitioner, Daryl Atkins, was convicted of abduction, armed robbery, and capital murder [at which time he was] sentenced to death."[292] Prior to trial, Atkins was evaluated by a forensic psychologist who concluded that he was *mildly mentally retarded*.[293] This conclusion was reached based on a series of interviews with people Atkins knew, along with his school records and the administration of a standard intelligence test which showed that Atkins had an IQ of fifty-nine.[294] The State presented a rebuttal expert witness who expressed his belief that Atkins was not *retarded* but instead was of *average intelligence, at least*.[295] Atkins was sentenced to death and the Supreme Court of Virginia affirmed the imposition of the death penalty.[296] In their dissenting opinion, Justices Hassell and Koontz stated that "the imposition of the sentence of

285. *Id.* at 746–47 (quoting MARSHALL D. EWELL, BLACKSTONE'S COMMENTARIES 484 (1882)).
286. *See id.* at 746–47.
287. *Id.* at 747 (quoting *Definition of Intellectual Disability*, AM. ASS'N ON INTELL. & DEVELOPMENTAL DISABILITIES, http://www.aaidd.org/intellectual-disability/definition (last visited May 1, 2020).
288. *See* Armstrong, *supra* note 230, at 747.
289. Hall v. Florida, 134 S. Ct. 1986, 1990 (2014); Roper v. Simmons, 543 U.S. 551, 555–56 (2005); Atkins v. Virginia, 536 U.S. 304, 310 (2002); *see also* discussion *infra* Sections VII.A–C.
290. 536 U.S. 304 (2002).
291. *Id.* at 321.
292. *Id.* at 307.
293. *Id.* at 308.
294. *Id.* at 308–09.
295. *Atkins*, 536 U.S. at 309.
296. *Id.* at 309–10.

death upon a criminal defendant who has the mental age of [nine] and [twelve] is excessive [and] it is indefensible to conclude that individuals who are mentally retarded are not to some degree less culpable for their criminal acts."[297] They went on to point out that "[a] moral and civilized society diminishes itself if its system of justice does not afford recognition and consideration of those limitations in a meaningful way."[298]

In making its decision, the Court considered the dwindling number of states that still imposed the death penalty on the intellectually disabled.[299] By the time the case came before the Court, only five states remained.[300] The Court determined that, as a result of so few states willingly imposing the death penalty on the intellectually disabled, the national consensus showed this practice to be out of favor.[301] The Court then considered other societal reasons justifying the imposition of the death penalty—those of retribution and deterrence—and found that executing the intellectually disabled did nothing to further either justification.[302] The Court also reasoned that although the intellectually disabled generally understand the difference between right and wrong, their disabilities prevent them from employing proper reasoning and judgment.[303] Additionally, they tend to lack control of their impulses and do not understand the consequences of their actions.[304] Per Justice Stevens, "[t]heir deficiencies do not warrant an exemption from criminal sanctions, but they do diminish their personal culpability."[305]

B. *Hall v. Florida*

Twelve years following *Atkins*, *Hall v. Florida*[306] provided the Supreme Court of the United States with the opportunity to revisit the country's stance on executing the intellectually disabled.[307] Petitioner Freddy Lee Hall and his accomplice "kidnapped, beat, raped, and murdered Karol Hurst, a pregnant [twenty-one]-year-old newlywed."[308] They then

297. *Id.* at 310 (quoting Atkins v. Commonwealth, 534 S.E.2d 312, 321 (Va. 2000) (Hassell, J., concurring in part, dissenting in part)).

298. *Id.* at 310 (quoting *Atkins*, 534 S.E.2d at 396–97 (Hassell, J. & Koontz, J., concurring in part, dissenting in part)).

299. *Id.* at 316; Armstrong, *supra* note 230, at 751.

300. *Atkins*, 536 U.S. at 316 n.20; Armstrong, *supra* note 230, at 751.

301. *Atkins*, 536 U.S. at 316; Armstrong, *supra* note 230, at 751.

302. *Atkins*, 536 U.S. at 318–20; Armstrong, *supra* note 230, at 751–52.

303. *Atkins*, 536 U.S. at 306; Snodgrass & Justice, *supra* note 29, at 83.

304. *Atkins*, 536 U.S. at 306; Snodgrass & Justice, *supra* note 29, at 83.

305. *Atkins*, 536 U.S. at 305; Snodgrass & Justice, *supra* note 29, at 83.

306. 134 S. Ct. 1986 (2014).

307. *Id.* at 1990.

308. *Id.*

killed Lonnie Coburn, a sheriff's deputy who attempted to prevent them from robbing a convenience store.[309] Hall was sentenced to death.[310] He argued that he could not be sentenced to death due to being an intellectually disabled individual.[311] At the time he was sentenced, there was no federal or state prohibition on sentencing the intellectually disabled to death.[312] Hall was later resentenced after the Court held in *Hitchcock v. Dugger*,[313] "that capital defendants must be permitted to present non-statutory mitigating evidence in death penalty proceedings."[314] As evidence, Hall introduced school records that indicated that his teachers believed him to be *[m]entally retarded* and his lawyer from an earlier crime for which he was prosecuted stated that he "[could not] really understand anything [Hall] said."[315] His lawyer further compared Hall's mental faculties to his four-year-old daughter's when explaining that Hall could not assist in his own defense.[316] Moreover, medical professionals stated that Hall was *significantly retarded*.[317] As a result of *Atkins*, Hall filed a motion stating that he could not be executed due to his being intellectually disabled.[318] Five years later, the Supreme Court of Florida held that he was not intellectually disabled per the Florida Statutes because his IQ was seventy-one and the cutoff was seventy.[319] Hall challenged the constitutionality of the seventy-point cutoff.[320]

The Court began its analysis by restating its holding from *Atkins*.[321] The twist arose when the Court addressed that Florida law defined *intellectual disability* as requiring an IQ score of seventy or less.[322] The Court acknowledged the crucial role states have in "understanding how intellectual disability should be measured and assessed," however, "*Atkins* did not give the states unfettered discretion to define the full scope of the constitutional protection."[323] *Atkins* required the states to create their own

309. *Id.*
310. *Id.*
311. *Hall*, 134 S. Ct. at 1990.
312. *Id.*
313. 481 U.S. 393 (1987).
314. *Hall*, 134 S. Ct. at 1990; *see also* Hitchcock v. Dugger, 481 U.S. 393, 398–99 (1986).
315. *Hall*, 134 S. Ct. at 1990 (quoting Joint Appendix, Vol. II 480, 482–83, Hall v. Florida, 134 S. Ct. 1986 (2013) (No. 12-10882)).
316. *Id.* at 1990–91.
317. *Id.* at 1991 (quoting Joint Appendix, Vol. II 507, Hall v. Florida, 134 S. Ct. 1986 (2013) (No. 12-10882)).
318. *Id.* at 1991–92; *see also* Atkins v. Virginia, 536 U.S. 304, 321 (2002).
319. *Hall*, 134 S. Ct. at 1992.
320. *Id.*
321. *Id.* at 1993; *see also Atkins*, 536 U.S. at 320–21.
322. *Hall*, 134 S. Ct. at 1994.
323. *Id.* at 1998; *see also Atkins*, 536 U.S. at 317.

definition of the meaning of intellectually disabled after consultation with medical experts.[324]

The issue was the IQ score cutoff.[325] Due to the strictness of the cutoff, the sentencing courts had no wiggle-room to look at additional evidence pertaining to the claimed disability.[326] Meanwhile, the medical community accepts additional evidence due to its probative value for diagnosing an individual with an intellectual disability, even if the individual has an IQ score above seventy.[327] Further, every state legislature—other than Virginia—has taken a contrary position to that of Florida.[328] As such, the Court deemed the Florida statute unconstitutional.[329] In the end, *Hall* changed the playing field by requiring states to use the definition of intellectually disabled created by the medical experts themselves.[330]

C. *Roper v. Simmons*

The turn of the millennium brought important changes to the American view of who would suffer the penalty of execution.[331] *Atkins* was the seminal case that denied the execution of intellectually disabled offenders.[332] *Hall* went on to demonstrate the Court's resolve in seeing justice for the harmed while maintaining and clarifying its holding in *Atkins*.[333] In 2005's *Roper v. Simmons*,[334] the Court further solidified its stance on the prohibition of execution for mentally inculpable offenders when it reasoned that under the Eighth and Fourteenth Amendments of the United States Constitution, juvenile offenders have not reached the level of culpability present in adults.[335] To be more precise, the issue in this case was not whether juveniles as a whole are barred from execution.[336] Rather, the

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324. *Hall*, 134 S. Ct. at 1999–2000; Armstrong, *supra* note 230, at 753; *see also Atkins*, 536 U.S. at 317.

325. *Hall*, 134 S. Ct. at 1994.

326. *Id.*

327. *Id.*

328. *Id.* at 1998.

329. *Id.* at 2000; *see also* FLA. STAT. § 921.137(1) (2019), *declared unconstitutional by* Hall v. Florida, 572 U.S 701 (1986).

330. *Hall*, 134 S. Ct. at 1999–2000; Armstrong, *supra* note 230, at 753.

331. *See The Case Against the Death Penalty*, ACLU, http://www.aclu.org/other/case-against-death-penalty (last visited May 1, 2020).

332. Atkins v. Virginia, 536 U.S. 304, 321 (2002).

333. *See Hall*, 134 S. Ct. at 1998–99, 2001.

334. 543 U.S. 551 (2005).

335. *Id.* at 570, 578; *see also* U.S. CONST. amend. VIII; *id.* amend. XIV, § 1.

336. *Roper*, 543 U.S. at 555–56.

Court considered whether the Constitution bars capital punishment to offenders in the fifteen to seventeen age group.[337]

At the age of seventeen, Christopher Simmons kidnapped and murdered Shirley Crook, the woman with whom he had been involved in a car accident.[338] Simmons planned the murder with two adolescent friends and on the night of the murder, he broke into her home, bound her arms and face in duct tape, drove her to a state park, tied her hands and feet together using electrical wire, covered her face in a towel, which he then completely wrapped in duct tape, and threw her off a bridge into the waters of the Meramec River, where she subsequently drowned.[339] Prior to these events, he assured his accomplices that they would get away with the crimes due to all of them being minors and after the events, he bragged to his friends that he had killed a woman "because the bitch seen my face."[340] After his arrest, he was advised of his *Miranda* rights, waived his right to an attorney, confessed to the murder, and performed a reenactment of the crime scene that was videotaped.[341] He was subsequently found guilty of murder and sentenced to death.[342] At the time of his trial and sentencing, he was eighteen.[343]

As a result of *Atkins*, Simmons filed a new petition where he argued that the "Constitution prohibits the execution of a juvenile who was under [eighteen] when the crime was committed."[344] The Missouri Supreme Court agreed and re-sentenced him to life in prison "without eligibility for probation, parole, or release except by act of the Governor."[345] The Court granted certiorari and affirmed.[346] When considering the argument against the execution of juvenile offenders in this age group—and below for that matter—the Court identified three important differences between juveniles and adults.[347] First, there is "[a] lack of maturity and an underdeveloped sense of responsibility . . . found in youth more often than in adults and are more understandable among the young. These qualities often result in impetuous and ill-considered actions and decisions."[348] The Court further

337. *Id.*
338. *Id.* at 556.
339. *Id.* at 556–57.
340. *Id.*
341. *Roper*, 543 U.S. at 557.
342. *Id.* at 558.
343. *Id.* at 556.
344. *Id.* at 559; *see also* Atkins v. Virginia, 536 U.S. 304 (2002).
345. *Roper*, 543 U.S. at 560; State *ex rel.* Simmons v. Roper, 112 S.W.3d 397, 400 (Mo. 2003).
346. *Roper*, 543 U.S. at 560; *Roper*, 112 S.W.3d at 400.
347. *Roper*, 543 U.S. at 569.
348. *Id.* (quoting Johnson v. Texas, 509 U.S. 350, 367 (1993)).

pointed out that due to these factors, nearly every state prohibits individuals under the age of eighteen "from voting, serving on juries, or marrying without parental consent."[349] The second "difference is that juveniles are more vulnerable or susceptible to negative influences and outside pressures, including peer pressure."[350] The third "difference is that the character of a juvenile is not as well-formed as that of an adult. The personality traits of juveniles are more transitory, less fixed."[351]

The Court went on to explain that in terms of retribution, "[r]etribution is not proportional if the law's most severe penalty is imposed on one whose culpability or blameworthiness is diminished, to a substantial degree, by reason of youth and immaturity."[352] When looking at whether there is a deterrent effect for juvenile offenders, the Court quoted its language from *Thompson v. Oklahoma*[353] where it stated, "[t]he likelihood that the teenage offender has made the kind of cost-benefit analysis that attaches any weight to the possibility of execution is so remote as to be virtually nonexistent."[354] In its decision, the Court also pointed out that the United States was the only country that still permitted the execution of juveniles.[355] In the end, the Court determined that the sentencing of capital punishment to an individual that was a juvenile at the time the crime was committed is unconstitutional.[356]

VIII. INDIVIDUALS WITH BRAIN INJURIES

When comparing individuals with brain damage to both the intellectually disabled and juveniles, there are many similarities to the ways in which their minds either work or, more specifically, do not work.[357] Many TBIs "result in permanent cognitive, physical, emotional, and behavioral disabilities that will greatly impact [the individual's] lives."[358] How are these issues so different from the other groups?[359] When considering that the Supreme Court of the United States has deemed execution as too great of a punishment for the intellectually disabled or juveniles due to their levels of moral culpability as a result of their mental status, logically it would seem

349. *Id.* at 569.
350. *Id.*
351. *Id.* at 570.
352. *Roper*, 543 U.S. at 571.
353. 487 U.S. 815 (1988).
354. *Roper*, 543 U.S. at 572 (quoting *Thompson*, 487 U.S. at 837).
355. *Id.* at 575; Snodgrass & Justice, *supra* note 29, at 85.
356. *Roper*, 543 U.S. at 578.
357. *See* Snodgrass & Justice, *supra* note 29, at 82.
358. *Id.*
359. *See id.*

that the rationale of the cited cases should be granted to individuals with damaged brains.[360]

Looking outside of the court system, various leading organizations such as the American Bar Association and the American Psychiatric Association have recommended that individuals with certain mental disorders, including brain damage, be exempt from capital punishment.[361] Although brain injuries, intellectual disabilities, and being a juvenile are not the same thing, their respective similarities suggest that each of these categories of individuals should not be subject to execution for essentially the same reasons.[362]

When comparing individuals with brain damage to those with intellectual disabilities, the similarities between the groups are to such a degree that it boggles the mind that they would be given differing statuses and different treatments under the law.[363] The Supreme Court of the United States specifically pointed out in *Atkins* that individuals suffering from intellectual disabilities "have diminished capacities to understand and process information, to communicate, to abstract from mistakes and learn from experience, to engage in logical reasoning, to control impulses, and to understand the reactions of others."[364] It is odd that if these characteristics either remove or lower the culpability of an individual with an intellectual disability, it seems almost discriminatory that these same characteristics in persons with brain damage are considered any less important or consequential.[365]

When considering the similarities between individuals with brain injuries and juveniles, there are often times where their issues are one and the same.[366] "Impulsive behavior, failure to recognize the consequences of an action, and the exercise of poor judgment are all characteristics common to both juveniles" and brain-damaged individuals.[367] This is not to say that similar characteristics cannot be present in normal adults.[368] The difference is that individuals with brain damage and juveniles are not equipped to control such behaviors and are therefore less culpable for their actions.[369] There is a big difference between having the ingredients to bake a chocolate

360. *See id.*; *Roper*, 543 U.S. at 575, 578–79.
361. Snodgrass & Justice, *supra* note 29, at 84.
362. *Id.* at 82.
363. *See id.* at 89.
364. Atkins v. Virginia, 536 U.S. 304, 318 (2002); Snodgrass & Justice, *supra* note 29, at 89.
365. Snodgrass & Justice, *supra* note 29, at 89.
366. *Id.*
367. *Id.*
368. *See id.* at 90.
369. *Id.*

cake—but choosing or failing to put in the chocolate—and either not having the chocolate at all, or not possessing the capacity to understand why it should be used.*

IX. CAN THE DAMAGED BRAIN POSSESS PROPER COMPETENCY?

Looking past whether neurological damage led to the commission of a criminal act, there is the issue of whether that damage—in the interim between the crime and the trial—caused the brain of the accused to deteriorate to the point where the offender lacks competency to stand trial.[370] Competency is required to fulfill the Constitutional rights of due process under the Fifth and Fourteenth Amendments.[371] A person deemed not competent to stand trial cannot be convicted of a crime.[372] Looking back at *Atkins*, the Court noted that the intellectually disabled are at a severe disadvantage at trial because they are generally unable to provide counsel with any meaningful assistance and tend to make poor witnesses.[373] As explained, brain injuries are known to cause a steep cognitive decline.[374] "Cognitive symptoms such as an inability to learn new information, slowed information processing, and retrograde amnesia . . . can impact a defendant both pretrial and in court."[375] Should this be the case, the accused would likely have difficulty assisting counsel.[376] The accused's mind may not be in a state that can comprehend the facts of the case, let alone coherently respond to questions or even take in their surroundings.[377] In a 2016 decision, World Wrestling Federation star, Jimmy *Superfly* Snuka, was found "incompetent to stand trial for the 1983 homicide of his girlfriend."[378] For decades, he was *banged around . . . the ring*, thus causing dementia.[379] A forensic psychologist called him a *shell of a man*.[380] Considering the

370. *See* Wood & Agharkar, *supra* note 35, at 416.

371. *See* U.S. CONST. amend. V; *id.* amend. XIV, § 1.

372. *Competency to Stand Trial*, NOLO, http://www.nolo.com/legal-encyclopedia/competency-stand-trial.html (last visited May 1, 2020).

373. Atkins v. Virginia, 536 U.S. 304, 320–21 (2002); Snodgrass & Justice, *supra* note 29, at 84.

374. *See* Korngold et al., *supra* note 111, at 431.

375. Wood & Agharkar, *supra* note 35, at 416.

376. *Id.* at 417.

377. *See id.* at 416–17.

378. Doree Lewak, *Athletes Charged with Heinous Crimes May Try the* CTE Defense, N.Y. POST: NEWS (July 18, 2016, 1:33 PM), http://www.nypost.com/2016/07/18/athletes-charged-with-heinous-crimes-may-try-the-cte-defense/.

379. *Id.*

380. *Id.*

repeated concussive events throughout his career, it would come as little surprise if he later received a diagnosis of CTE, let alone TBI.[381]

Looking back at Aaron Hernandez, his brain was so damaged from his years on the football field that it resembled the innards of a crusty baguette.[382] Considering this level of brain damage, whether he had the requisite mens rea to form criminal intent must be asked.[383] Moreover, did he actually understand the nature of his actions or at least that the action of murdering Odin Lloyd was wrong?[384] Could and did he provide meaningful assistance to his counsel at trial?[385] At the time of his suicide, was he little more than a corporeal ghost?[386]

X. THERAPEUTIC JURISPRUDENCE: THE NEED FOR MENTAL HEALTH COURTS

"It is not controversial to say that our criminal law system is not aligned with an *ethic of care*, nor is it a surprise to learn that defendants feel they are often without voice in circumstances that are certainly not voluntary."[387] Depending on the circumstances, the law can have either a therapeutic effect or an anti-therapeutic effect.[388] The purpose of the therapeutic jurisprudence model is to look at the impact of case law and legislation from the standpoint of a therapeutic agent.[389] The goal is to craft legal rules and procedures that can enhance the therapeutic potential without subordinating due process principles.[390] The problem with the typical criminal justice model is that it looks "backward, finding fault, making accusations, and inflicting punishment."[391] The profound difference is that the therapeutic model looks at the future consequences for the individual and community after the case ends.[392] Individuals with mental health disorders—including brain damage—tend to go through a cycle within the criminal justice system where they commit an illegal act, are punished by the system,

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381. *See id.*; Wood & Agharkar, *supra* note 35, at 412.
382. *See* Associated Press, *supra* note 94; Freedman, *supra* note 186.
383. Wood & Agharkar, *supra* note 35, at 418; *see also* discussion *supra* Part V.
384. *See* Associated Press, *supra* note 94; Dillard & Tucker, *supra* note 16.
385. *See Competency to Stand Trial*, *supra* note 372.
386. *See* Associated Press, *supra* note 94.
387. Perlin & Lynch, *supra* note 126, at 358.
388. Perlin, *supra* note 38, at 957.
389. *Id.*
390. *Id.* at 957–58.
391. Risdon N. Slate, *Deinstitutionalization, Criminalization of Mental Illness, and the Principle of Therapeutic Jurisprudence*, 26 S. CAL. INTERDISC. L.J. 341, 353 (2017).
392. *Id.*

get out, and repeat.[393] Studies have shown that individuals with mental illness are twice as likely to violate their parole as those without mental illness and tend to return to their previous incarceration in under one year.[394] The goal of the therapeutic model is to help the individual by providing the treatment that is so desperately needed rather than submitting the individual to yet another blanket punishment which, in the end, serves no one; thus, ending the cycle.[395] Leading the way to therapeutic stabilization are the mental health courts.[396]

On June 6, 1997, Chief Judge Dale Ross of Broward County, Florida, signed the administrative order that created America's first mental health court.[397] "This order recognized the essential need for a new system of justice to focus on individuals with mental health disabilities . . . and the need for appropriate treatment in a therapeutic environment conducive to wellness [rather than punishment]."[398] Individuals permitted to access this court included those with "neurological and cognitive disorders such as [TBIs]" and access was to be on a voluntary basis.[399]

There are over 400 mental health courts in existence throughout the United States today.[400] However, not all mental health courts see the same types of cases or operate in the same manner.[401] Some mental health courts only see misdemeanors, some only see felonies, some see both, and others may only see nonviolent offenders.[402]

Mental health courts provide an important niche where historically stigmatized and ill-treated individuals can seek community-based treatment in lieu of criminal consequences.[403] Judges in the mental health court system are not restrained in the same ways as those who preside over regular criminal courts.[404] This allows a judge to be more malleable in sentencing, in that the judge can "negotiate the particulars of individual cases and inspire

393. *See id.*
394. Peterson & Heinz, *supra* note 14, at 539.
395. Slate, *supra* note 391, at 353.
396. *See id.* at 354.
397. *In re* Creation of Mental Health Court Subdivision within the Circuit Criminal Division, Fla. Admin. Order No. VI-97-I-1A (June 6, 1997) (on file with clerk, Fla. 17th Cir. Ct.); *see also* GINGER LERNER-WREN WITH REBECCA A. ECKLAND, A COURT OF REFUGE: STORIES FROM THE BENCH OF AMERICA'S FIRST MENTAL HEALTH COURT ix (2018).
398. LERNER-WREN WITH ECKLAND, *supra* note 397, at ix.
399. *Id.* at x.
400. E. Lea Johnston & Conor P. Flynn, *Mental Health Courts and Sentencing Disparities*, 62 VILL. L. REV. 685, 685–86 (2017).
401. *See* Perlin, *supra* note 38, at 946–47.
402. *See id.*
403. Castellano, *supra* note 29, at 398–99; *see also* Johnston & Flynn, *supra* note 400, at 689.
404. *See* Castellano, *supra* note 29, at 399.

offenders to adopt normative patterns of social behavior."[405] Unlike traditional criminal courts, mental health courts are able to help the individual not only receive the treatment they need, but also help with housing and employment assistance so that transitioning back into being productive members of society becomes both a realistic, and achievable goal and reality.[406] Judges in this role tend to shed the robe and work as a hybrid of judge, social worker, and probation officer.[407] The judges find ways to motivate, question, and defend mental health court participants.[408]

Generally, the judge works with a team who assesses each individual's specific needs, and formulates a plan together.[409] In a nice contrast to the typical criminal court setting, participants in the mental health courts generally interact with the judge personally, rather than sitting idly as their attorney speaks on their behalf.[410] This grants the individual the sense of dignity that they deserve, which would likely be withheld in a criminal court setting, where the individual may be treated as a second-class citizen.[411]

In order to maintain the effectiveness of a given program, an individual enrolled in a court-ordered treatment plan is required to submit reports to the court so that the judge can keep track of all progress along with treatment compliance.[412] Failure to comply will result in what will likely be an unpleasant chat with the judge.[413] Studies have shown that individuals who participate in mental health court programs utilize crisis or high-intensity services at lower rates, and often report decreases in substance abuse as well.[414]

Although the mental health court system is a definite step in the right direction, no program is without its faults.[415] There is criticism that the current mental health court model creates false success rates by limiting participants to those individuals deemed safe.[416] Granted, when the system was first created, this was likely the best direction to go since everything was new and untested.[417] However, twenty years have passed since that first

405. *Id.*
406. *Id.* at 399–400.
407. *Id.* at 400, 402.
408. *Id.* at 416.
409. Perlin, *supra* note 38, at 947–48.
410. *Id.* at 951.
411. *See id.* at 949–51.
412. *Id.* at 948.
413. *See* Castellano, *supra* note 29, at 409.
414. Perlin, *supra* note 38, at 953.
415. Amanda Joy Peters & Indira Azizi Lex, *Improving Insanity Aftercare*, 42 MITCHELL HAMLINE L. REV. 564, 596 (2016).
416. *Id.*
417. *See id.*

Broward County mental health court came into being, and perhaps the time has come to expand the system into accepting participants with more severe issues—even if this means taking on individuals who have committed violent, and even horrendous crimes.[418] When looking back at the difference between *mental illness* and *insanity*, it should be clear that they both connote virtually the same meaning with the key difference being medical versus legal perspective.[419] The reality is that brain damage can do terrible things to an individual's psyche and, in turn, the individual may do heinous actions that they never would have done, but for the neurological trauma.[420] These individuals need our help just as much as those the current system deems safe.[421] The mental health courts are an attempt to provide that help.[422]

XI. CONCLUSION

Brain damage robs people not only of their minds, but of their dignity and quality of life.[423] Just as the advent of DNA changed the criminal justice system, in time, diagnostic tools will improve, and where CTs and MRIs help with diagnoses of TBIs today, a live diagnosis of CTE will have a great impact as well.[424] As previously addressed, the prosecution is required to prove the elements of a crime beyond a reasonable doubt.[425] This is the highest burden of proof required in the United States.[426] In light of the developments in the diagnosis of various types of brain damage, this burden may become harder to prove.[427] This is especially true in cases where the mental health courts play a role in diverting brain-damaged individuals from prison to treatment.[428] It is through the trials and tribulations of the judges and staff of the mental health courts that true change can take place.[429]

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418. *See id.* at 595; *In re* Creation of a Mental Health Court Subdivision within the Circuit Criminal Division, Fla. Admin. Order No. VI-97-I-1A (June 6, 1997) (on file with Clerk, Fla. 17th Cir. Ct.).

419. Armstrong, *supra* note 230, at 750–51.

420. *See* Redding, *supra* note 2, at 52–53; Reed-Guy, *supra* note 41; discussion *supra* Part II.

421. *See* Peters & Lex, *supra* note 415, at 596.

422. *See id.* at 591.

423. *See* Korngold et al., *supra* note 111, at 431–32; Jacobo, *supra* note 21.

424. Lewak, *supra* note 378.

425. Patterson v. New York, 432 U.S. 197, 210 (1977).

426. *Evidentiary Standards and Burdens of Proof*, JUSTIA (May 2019), http://www.justia.com/trials-litigation/lawsuits-and-the-court-process/evidentiary-standards-and-burdens-of-proof/.

427. *See* Lewak, *supra* note 378.

428. Castellano, *supra* note 29, at 398–400; Johnston & Flynn, *supra* note 400, at 689.

429. Castellano, *supra* note 29, at 398–400.

Through their efforts, the retributive wall barring brain-damaged individuals from rehabilitative treatment will hopefully crumble.[430] As the saying goes, "[a] mind is a terrible thing to waste."[431] However, it is even more egregious to leave a damaged mind to shutter alone helplessly in the dark.*

430. *See* Redding, *supra* note 2, at 53.

431. Peter Carlson, *Thinking Outside the Box*, WASH. POST (Apr. 9, 2001), http://www.washingtonpost.com/archive/lifestyle/2001/04/09/thinking-outside-the-box/3dbc49c7-aee1-4cea-a397-d2a3c7c8c8d8/.


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