FUTURE OF PHARMACO-ELECTRONIC MEDICINE[1]

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[1] This article contains commentary, data and conclusions, some of which is original and other of which has been disseminated in the author's publications (a) JOSEPH R. CARVALKO, CONSERVING HUMANITY AT THE DAWN OF POST HUMAN TECHNOLOGY (2020); (b) JOSEPH CARVALKO, THE TECHNO-HUMAN SHELL: A JUMP IN THE EVOLUTIONARY GAP (Sunbury Press, 1st ed. 2012); (c) Joseph Carvalko, *Who Should Own In-The-Body Medical Data in the Age of Electronic Medicine?*, IEEE TECH. AND SOC'Y MAG., June 2, 2014, at 46; (d) Joseph R. Carvalko, *Pharmaco-Electronics Emerge*, IEEE TECH. AND SOC'Y MAG., Dec. 17, 2015, at 36.

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Abstract

Unlike prescription distribution by a pharmacy, electroceuticals wirelessly distribute prescriptions to patients through an implanted medical device.[2] This technology will administer treatment to the patient, and, in turn, sense and transmit information about a prescription's effectiveness.[3] As to the physician, it will permit access to a patient's response to therapy and allow for changes in prescription if warranted. As to the public health community, it will assist in the modelling of patient wellness and, thus, enable broad assessment of a treatment's efficacy, safety, and forecast epidemics. Wireless communication between a host computer and the patient's anatomy raises cybersecurity concerns. Data breaches may result in preventing a prescription from its intended therapy or be vulnerable to malware and/or a hacker intent on causing digital mayhem—such as holding a service provider hostage to a ransom.[4] Currently, the legal and regulatory framework appears to lag the technology, and the technology itself lags the protective measures that may be required to ensure patient welfare.[5] This last point calls for a critical assessment of the advisability of the widespread deployment of pharmaco-electronic enterprises that intimately connects expert systems, medical devices, and humans. We need to ensure that beyond the aim of providing beneficial diagnosis and therapy, we do no harm. This calls for a thorough analysis of the potentially unintended effects on a patient's physical, cognitive, and social capacity, as well as on society-at-large.

Keywords - Technology law, drug delivery, science policy, wireless, telemetry, biosensor, implanted computer, molecular computer, synthetic DNA, pharmacology, Big Data, system security, privacy, artificial intelligence, FDA, technology ethics.

[2] *Electroceutical* refers to the implanted device; *Pharmaco-electronics* refers to the larger system which includes electroceuticals' communication of information with a technology (IT) platform. *See id*.; Arizona State University School for the Future of Innovation in Society, *Public Interest Technology (PIT) Colloquium with Joseph Carvalko, Pharmaco-Electronics: The Future of Medicine*, YOUTUBE (Mar. 1, 2022), https://www.youtube.com/watch?v=fvznpLhOnFs&t=4265s.

[3] *Id*.

[4] *Id*.

[5] *Id*.

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Introduction

The technologies of Anatomically Embedded Computers, Internet of Medical Things, Smart Devices, Big Data, Information Systems, and Cloud Services are revolutionizing healthcare throughout the world. We experience much of this in our daily lives, but the next stage of this digital transformation in healthcare will bring forth diagnosis and treatment in the form of electronically transmitted data from one's physician directly to an implanted device. Advancements in wirelessly linking parts of the human anatomy to host computers for medical diagnosis and therapy has quietly, yet dramatically, risen during the past decade due to electronic miniaturization, telecommunication innovations, data collection, and artificial intelligence.[6]

Both the Federal Communications Commission (FCC) and the Food and Drug Administration (FDA) regulate aspects of biomedical telemetry or implanted medical wireless devices.[7] Separate from the electrical requirement to produce a stimulus or receive an impulse from an implanted sensor is the need to receive and transmit relevant data from outside the body to a remote host computer.[8] The FCC has established the allocation of conventional transmission frequency bands for transmission of medical data to remote computers, whereas the FDA has set forth wireless transmission requirements for the devices that are anatomically implanted.[9]

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[6] Telecommunications relates to telemetry, which is the collection and transmission of data from remote locations utilizing radio waves. In this article, we employ telemetry and wireless interchangeably as the bidirectional transfer of data to and from a device or individual subject. The FDA refers to these products as implantable radiofrequency transponder systems for patient identification and health information. *See* Kristoffer Famm et al., *Drug Discovery: A Jump-Start for Electroceuticals*, NATURE, Apr. 11, 2013, at 159-61.

[7] U.S. FOOD & DRUG ADMIN., U.S. FED. COMMC'N. COMM'N., JOINT STATEMENT ON WIRELESS MEDICAL DEVICES (July 26, 2010) (current as of Dec. 4, 2017), https://www.fda.gov/medical-devices/news-events-medical-devices/joint-statement-wireless-medical-devices-us-food-and-drug-administration-federal-communications.

[8] *See* U.S. FOOD & DRUG ADMIN., WIRELESS MEDICAL DEVICES, https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices#8.

[9] The Federal Communications Commission (FCC) established the Wireless Medical Telemetry Service (WMTS) by allocating specific frequency bands exclusively for wireless medical telemetry from any source. The WMTS set aside 14 MHz of spectrum in three defined frequency bands of: 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz for primary or co-primary use by eligible wireless medical telemetry users. Implanted devices, such as the pacemaker can establish

The viability of delivering prescriptions to treat illness and infirmity relates to the nature of anatomical organs to respond to, and produce, electrical and electrochemical impulses. [10] The reception from imbedded sensors and stimuli produced by imbedded transducers requires extremely low electrical energy. In-the-body electronic communication has limited power levels, producing no more than 25 microwatts power as measured outside of the body. [11] This relatively low power level ensures safe anatomical radiation levels and, for individuals in proximity and wearing medical devices, prevents potential electrical interference.[12] Until recently, this low power limitation did not permit electronic communication beyond a few meters. With the advent of Bluetooth-like technology serving as a bridge to a smartphone, low power transmission levels have ceased being a factor in mainstreaming electroceuticals.[13] To succeed as an effective means for treatment, implanted technology requires robust data science methodologies, and a greater acceptance of this technology delivery platform by a range of stakeholders. High on the stakeholder list would be the medical profession followed by regulators. The utilization of pharmaco-electronic prescriptions, as characteristic of all medically approved devices, requires that system performance, i.e., the embedded subsystems, telemetries, and the data processing component, meet medical-scientific standards for accuracy, reliability, efficacy, and safety.[14]

a bi-directional radio communication with a local computer, e.g., a smartphone, within the Medical Implant Communication Service frequency band between 402 MHz and 405 MHz. *Id*.

[10] *Pharmaco-electronics* is a word coined by the author as a sub-category of *mHealth*—a term coined by Robert Istepanian—and for which a definition emerged at the 2010 mHealth Summit of the Foundation for the National Institutes of Health as "the delivery of healthcare services via mobile communication devices." ROBERT ISTEPANIAN ET AL., M-HEALTH: EMERGING MOBILE HEALTH SYSTEMS (Robert Istepanian et al. eds., 1st ed. 2006); Carol Torgan, *The mHealth Summit: Local & Global Converge,* KINETICS (Nov. 6, 2009), https://caroltorgan.com/mhealth-summit/; ERIC R. KANDEL ET AL., PRINCIPLES OF NEURAL SCIENCE (5th ed. 2012).

[11] *See* Medical Implant Communications Service Frequency Table, CSGNETWORK, http://www.csgnetwork.com/micsfreqtable.html (last visited Jan. 17, 2022). The maximum power transmission of 25 microwatts provides a range of a few meters. The maximum bandwidth of 300 kHz limits these devices to low bitrates compared with Wi-Fi or Bluetooth. *Id*.

[12] *See id.*

[13] *Bluetooth-like* refers to any short-range wireless technology standard used for exchanging data between fixed and mobile devices over short distances.

[14] *See id*.

What follows describes a novel combination of sensors, computers, and large data bases, which communicate with implanted technology to respond to a doctor's orders or orders directed by an expert system ("ES").[15] A closed system linking doctors, an ES, and the patient, allows for seamless administration via electronic signaling of drugs or other stimuli, without the usual intervention of a medical service provider.[16] The information processing components of a pharmaco-electronics platform have the potential to analyze data, utilize artificial intelligence, and achieve greater levels of treatment efficacy.[17] In a disaggregated fashion, we already depend on automated intelligent systems to keep us well, but pharmaco-electronics takes the medical model to a new level—not only as to the individual, but to the population generally.

We have reached a threshold where electronic medicine requires policymakers to fashion regulations. This will ensure that the integration of a collection of disparate technologies, as described, protects the health and welfare of its intended patients. Below, we discuss but a few of the issues and complexities that surround pharmaco-electronics. As will become clear, implementation of a system of this magnitude calls for solutions built from a great breadth and depth of knowledge, expertise, and perspective. By bringing together scholars, policymakers, and practitioners—experienced in the fields of medicine, engineering, data science, law, and ethics—we better ensure that as pharmaco-electronics infiltrates our lives, we limit to manageable proportions any unintended consequences related to liberty interests, privacy, security, and the well-being of future generations.

I. Forces Behind the Innovation

During the past decade, a steady turn toward proactive patient care, known under the rubric "P4," has improved levels of disease predictability and prevention, both on a personalized and

[15] *See id*.
[16] *See id*.
[17] *See id*.

participatory basis.[18] To fulfill this objective successfully requires steady progress in precision medicine—now advantaged by the availability of ubiquitous data sources—such as wearable and implanted medical devices outfitted with sensors, smartphones, IoMT (Internet of Medical Things), along with AI machine learning, and large-scale data analytics.[19] To this end, due to rapid scientific and technological advances, patient-centered care has also made considerable headway. Thanks to innovations in omics science, data science, and artificial intelligence—along with the development of faster computers housed in consumer-friendly forms and the growing necessity for access to high-speed telecommunications—patients are now able to easily connect with their healthcare professionals.[20,] Determining the pace with which a P4 healthcare regimen might reach its goal depends in part on first overcoming the forces that potentially stand between physicians and patients, such as government regulations, insurance company interests, and the pharmaceutical industry. [21] A direct line between patient and doctor, and facilitated through technology, can serve to reduce the friction extant in the current system.

Until now, modern healthcare has relied on laboratories and their role in producing the analytical data determinative of a patient's health.[22] But change is underway as innovative medicine moves to systems of embedded sensors that not only manage to treat pain or lend vital support to a dysfunctional organ—such as the heart, brain, pancreas, or bladder—but in real-time transmit information relevant to one's physical condition.[23] An analysis of the received data by an ES will result in dispensing a feedback-controlled prescription—such as a traditional pharmaceutical, insulin, or therapies—which transmit

18 *See* Scott A. Waldman & Andre Terzic, *Health Care Evolves from Reactive to Proactive*, 105 CLINICAL PHARMACOLOGY & THERAPEUTICS 10 (2019); *See* Francesco Schiavone & Marco Ferretti, *The FutureS of Healthcare*, 134 FUTURES 102849 (2021).

19 *See id*.

20 *Omics* refers to various disciplines in biology; the suffix which ends in *-omics*, such as genomics, proteomics, and metabolomics. *Omics*, WIKIPEDIA, https://en.wikipedia.org/w/index.php?title=Omics&oldid=1071973303 (last modified Feb. 15, 2022).

21 *Id*.; *See Stratified, Personalised or P4 Medicine: A New Direction for Placing the Patient at the Centre of Healthcare and Health Education,* ACAD. OF MED. SCI. 4 (May 12, 2015).

22 *See id*.; *see also* ROCCO PALUMBO, THE BRIGHT SIDE AND THE DARK SIDE OF PATIENT EMPOWERMENT: CO-CREATION AND CO-DESTRUCTION OF VALUE IN THE HEALTHCARE ENVIRONMENT (2017).

23 *See id*.

control codes and data to embedded sub-systems, and electrical currents, or mechanical forces directly to transducers, as required.[24]

An offshoot of the communication connection between a patient and a host computer will be the rich accumulation of data by an ES. The ES utilizes data-science, including artificial intelligence, to effectuate machine learning, which will lead to advances in medical diagnostic science.[25] Today, medical ES has shown to improve accuracy and speed of diagnosis while reducing costs.[26]

The application of anatomically embedded technology is well-established within the current state of medical arts in the form of implanted medical devices (IMDs)—such as defibrillators, pacemakers, deep brain stimulators, retinal and cochlear implants—each of which serve a restorative function. Other applications of this technology, such as body area networks (BANs) and body sensor networks (BSNs), serve as diagnostic tools and prosthetic devices that restore an impaired or lost neurological function or limb.[27] Most prosthetic devices relate primarily to electromechanical motor control of one's musculoskeletal system.[28] Technology, referred to as neuroprosthetic devices, now interfaces computers to the neurological system, to excite, inhibit, or tune the activities of peripheral nerves, cortical

[24] *See id*.

[25] *Expert System* (ES) is software designed to reason and think as a human trained, educated, and skilled in a subject domain using rules. R.E Imhanlahimi & Adetokubo MacGregor John-Otumu, *Application of Expert System for Diagnosing Medical Conditions: A Methodological Review*, 7 EUR. J. OF COMPUT. SCI. AND INFO. TECH. 12 (2019); *See* S. J. Gath & R. V. Kulkarni, *A Review: Expert System for Diagnosis of Myocardial Infarction*, 3 INT'L J. OF COMPUT. SCI. AND INFO. TECH. 5315 (2012); Rimpy Nohria, *Medical Expert System: A Comprehensive Review*, 130 INT'L J. OF COMPUT. APPLICATIONS 44 (2015); P.K. Patra, Dipti Prava Sahu, and Indrajit Mandal, *An Expert System for Diagnosis of Human Diseases*, 1 INT'L J. OF COMPUT. APPLICATIONS 71 (2010); R.A. Soltan, M. Rashad, and B. El-Desouky, *Diagnosis of Some Diseases in Medicine via Computerized Experts System*, 5 INT'L J. OF COMPUT. SCI. AND INFO. TECH. 79 (2013); Hambali Moshood Abiola, Akinyemi Adesina Alaba, and Luka Joy D., 15 *Expert System for Lassa Fever Diagnosis Using Rule Based Approach*, 15 ANNALS COMPUT. SCI. SERIES 68 (2017); Aytürk Keleş, *Expert Doctor Verdis: Integrated Medical Expert System*, 22 TURKISH J. OF ELEC. ENG'G & COMPUT. SCI. 1032 (2014).

[26] *See* Bassem S. Abu-Nasser, *Medical Expert Systems Survey*, 1 INT'L J. OF ENG'G AND INFO. SYS. 218 (2017); *See* P. Santosh Kumar Patra et al., *An Expert System for Diagnosis of Human Diseases*, 1 INT'L J. OF COMPUT. APPLICATIONS 71, 71-73 (2010); *See* R.A. Soltan et al., *Diagnosis of Some Diseases in Medicine via Computerized Experts System*, 5 INT'L J. OF COMPUT. SCI. AND INFO. TECH. 79 (2013).

[27] *See* Xiaochen Lai et al., *A Survey of Body Sensor Networks*, 13 SENSORS 5406 (2013); *see also* Jerry J. Shih et al., *Brain-Computer Interfaces in Medicine*, 87 MAYO CLINIC PROC. 268 (2012).

[28] *See* Shih et al., *supra* note 27.

neurons, or entire neural networks in the brain to produce beneficial effects.[29] These therapies reduce chronic pain, movement disorders, epilepsy, psychiatric disease, hearing, and visual loss.[30]

The word 'implant' refers to a device surgically affixed within the anatomy. But other devices—in pill-like form, for example—may also provide the communicative functionality discussed here. Still, other devices may attach to the body in the form of belts applied to the torso, but more frequently the wrist.[31] Devices worn on the wrist typically acquire and report one's temperature, heart, or pulse rate.[32] Any of these devices are equipped to send physiological data to the cloud so that "examinations" can proceed in real time.[33] Only implanted devices and electronic pill-like forms supply direct access to internal organs and provide the technological sophistication required to bidirectionally communicate status to a host computer as the prescription fulfils the treatment or prosthetic objective.[34] Pharmaco-electronics aided by processors embedded in a smartphone working with processors implanted in the anatomy will virtually decouple the individual from the age-old doctor-patient model for treatment.[35]

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[29] *See* MATTHEW E. GLADDEN, THE HANDBOOK OF INFORMATION SECURITY FOR ADVANCED NEUROPROSTHETICS 25-41 (Synthypnion Academic., 2nd ed. 2017).

[30] *See* DAMIANOS E. SAKAS ET AL., OPERATIVE NEUROMODULATION 3-13 (2007).

[31] More than 500,000 Americans are living with artificial pacemakers. *See* Chris Woolston, *Pacemakers,* CONSUMER HEALTH NEWS (Dec. 31, 2020), https://consumer.healthday.com/encyclopedia/heart-health-22/misc-stroke-related-heart-news-360/pacemakers-645670.html.

[32] *See id*.

[33] In the brief time that Smartphones have been in existence, pacemaker recipients can connect their device wirelessly to their Smartphones via Bluetooth. An APP under the Medtronic, Inc. brand MyCareLink Smart™, automatically connects a pacemaker to a remote data base that receives information about the status of the heart presently and over the course of many months. A healthcare worker then inspects the data and the patient is informed if any anomalies present issues that a doctor needs to address. *See Acute Device Management*, MEDTRONIC (Feb. 2020), https://www.medtronic.com/us-en/healthcare-professionals/products/cardiac-rhythm/managing-patients/acute-device-management.html.

[34] *See id*.

[35] Nick Flaherty, *Apple's M1 Pro has 57bn transistors with 58 processor, GPU and AI cores built in a 5nm process by TSMC*, EENEWS EUROPE (Oct. 19, 2021), https://www.eenewseurope.com/en/apple-launches-5nm-chip-with-57bn-transistors/.

Today's silicon-based microprocessor use 22 nanometer transistor technology, assembled as six-core hyper- threaded chips running at roughly 3.3 gigahertz. Since each core executes two threads, the theoretical processing speed is 40 billion flops. Although a general-purpose microprocessor may measure 90mm^2 and contain several billion transistors, application specific processors (ASICs) can be constructed employing fractions of the number of transistor and remain computationally powerful while reaching down into the sub-micron (smaller than blood cells) range for special processes. This paper focusses on in-the-body processing and the processors used would

II. The Technology

To summarize the new paradigm, the self-contained hardware first delivers therapy, measures biophysical properties, and transmits measurements—either for processing in an application specific smartphone environment or forwarded to a more powerful computer that may deal with wide-area data bases.[36] An individual's processing system takes the form of wearable and embedded computer/transmitters, sensors, or electrodes, all of which connect to stimulators, actuators, and pumps.[37] Second, telecommunications interconnect the local device, both within the body and to the outer world.[38] The latest embedded medical gear usually connects through Bluetooth, or other technology, to both local and remote computers—this includes smartphones and local general purpose internet modems that transmit data to host sites where it can be analyzed and configured to respond to medically significant events.[39]

The biomedical implantable device era had its practical beginnings in the late 1950s with the invention of the pacemaker—when transistor technology became available.[40] Until the invention of the transistor, control devices depended on large electron tube technology, which employed dangerously high voltages.[41] Errant high voltages and currents had lethal consequences, and the circuits were too

reflect a measurably smaller and less computation power. In central site applications, where large data processing occurs will utilize processors such as AMD's 64-core, with 128 threads, Ryzen ThreadRipper 3990X desktop PC processor was considered the world's fastest CPU in 2021.

36 IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY, *Pharm-Electronics Emerge*, TECH. AND SOC'Y (June 29, 2017), https://technologyandsociety.org/pharmaco-electronics-emerge/.

37 *Id*.

38 *Id*.

39 The Medtronic CareLink® Network for pacemakers allows patients to have their devices checked remotely by telephone rather than requiring a doctor's office visit. The test includes: a full parameter summary, battery voltage and longevity, lead impedance between the heart and the device, automatic capture thresholds, the record of heartbeat episodes, the percent utilization or pacing, histograms, real-time and magnet EGMs, stored EGMs, and an arrhythmia summary with mode switch duration. *See Acute Device Management*, *supra* note 33; *see also* V. Thulasi Bai & S.K. Srivatsa, *Portable telecardiac system for arrhythmia monitoring and alerting*, INT'L. J. OF HEALTHCARE TECH. AND MGMT. 517, 517-25 (2008) (reporting on a system that detects an arrhythmia and informs the patient's condition by automatically sending an alerting SMS to the mobile phone of the doctor and caretaker).

40 *See* O. Aquilina, *A Brief History of Cardiac Pacing*, 8 IMAGES IN PAEDIATRIC CARDIOL. 17 (2006).

41 *See id*.

large to operate within the body.[42] Implants were only made feasible with the invention of the transistor during the mid-50's, with its small size—comparable to that of an aspirin—and low power requirements that made the biomedical implantable device possible.[43] Today, an implantable package that once contained a few transistors now contains millions.[44]

Digital technology—as found in every corner of 21st Century life—has spawned an abundance of lifesaving products, mainstreamed—in large part—because of the exponential accumulation of scientific knowledge and ever-increasing computationally sophisticated computers, software, and analytical data science methodologies. Within only the last decade, we have witnessed: (1) computer processors reaching an astounding 4.3 gigahertz clock rate; (2) the launch of 5G communications networks rates of transmission in the realm of a gigabit (10^9) per second; (3) robust networking infrastructure, and (4) high-speed relays that provide the medium over which the innovation of smartphones can, on one end, connect to anatomically deep-seated application specific processors, and, on the other end, directly to the cloud.[45]

Central to the feasibility of in-the-body devices has been the miniaturization of computer transistors—currently smaller than a 5-7 nanometers size range—employing materials such as wafer-thin graphene (carbon) and MoS_2 (molybdenum disulfide) that measure a few atoms wide.[46] The rate of progress will, in-part, depend on the continued success of semiconductor miniaturization—which appears to be slowing—as transistor size reaches into the single digit nanometer domain.[47] Intel claims its Intel Stratix 10 FPGAs are capable of 10 trillion arithmetic operations per second, referred to by programmers

42 *See id*.

43 *See id*.

44 *See id*.

45 *See generally* MOBILE TECHNOLOGY, WIKIPEDIA, https://en.wikipedia.org/wiki/Mobile_technology (last updated Mar. 11, 2022).

46 Anh Tuan Hoang et al., *Epitaxial Growth of Wafer-Scale Molybdenum Disulfide/Graphene Heterostructures by Metal-Organic Vapor-Phase Epitaxy and Their Application in Photodetectors*, 12 ACS APPLIED MATERIALS INTERFACES 44335 (2020).

47 *See* Ian Cutress, *Intel's Manufacturing Roadmap from 2019 to 2029: Back Porting, 7nm, 5nm, 3nm, 2nm, and 1.4 nm*, ANANDTECH (Dec. 11, 2019), https://www.anandtech.com/show/15217/intels-manufacturing-roadmap-from-2019-to-2029.

as 10 teraflops (10^{12}) and containing about 30 billion transistors. [48] Semiconductor technology soon will commonly use 11 nm, and then, in short order, shrink to below 2 nm technology.[49] Semiconductors, but a few atoms wide, will populate state-of-the art microprocessors housing upwards of 13 billion transistors.[50] These new microprocessors will configure upwards of fifty-cores of computing power, allowing 100 simultaneous hyper- threads to process trillions of flops of data.[51]

These newer processors will be used in host systems, smartphones, and adjuncts to smart phones, when required. However, due to their high electrical power requirements which, as a result, generate enormous heat, these newer processors will not be installed in the anatomy. Nonetheless, sensor technology which produces little heat and small computers—such as Pentium vintage processors—are used, and these, in combination with smartphones, prove sufficient for an effective pharmaco-electronics system.

Another limitation of embedded electronics concerns the maximum bandwidth of transmission, currently regulated at 300 kHz. This limits the data rate at which information is capable of being processed. Because a device can maintain an open channel with a nearby computer, such as a smartphone, it can broadcast continually as required. Therefore, this relatively low bandwidth should not prove to be a material limitation in the transfer of information—either to, or from, the device.

As computing power increases in processors—just as we witness occurring in smartphone technology—it points developers toward

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[48] *Flop* refers to program cycles or operations occurring per second, which translates into one arithmetic operation (add, subtract, multiply, divide) per second. Mark Tyson, *Intel Boasts of an FPGA Chip Capable of 10 TFLOPS*, HEXUS (Apr. 19, 2018), https://hexus.net/tech/news/cpu/117380-intel-boasts-fpga-chip-capable-10-tflops/; INTEL NEWSROOM, *Intel Chip Performs 10 Trillion Calculations Per Second* (Apr. 18, 2018), https://newsroom.intel.com/news/intel-chip-performs-10-trillion-calculations-per-second/#gs.wk4gim.

[49] *See* Michael Irving, *IBM's New 2-nm Chips Have Transistors Smaller than a Strand of DNA*, NEW ATLAS (May 6, 2021), https://newatlas.com/computers/ibm-2-nm-chips-transistors/.

[50] *See* Usman Pirzada, *IBM Unveils the World's First '2nm' Technology with Nanosheets – But Don't Let That 2nm Tag Fool You*, WCCF TECH (May 6, 2021), https://wccftech.com/ibm-unveils-the-worlds-first-2nm-technology-with-nanosheets-but-dont-let-that-2nm-tag-fool-you/.

[51] *See generally* Daniel Horowitz, *CPU Cores: How Many Do I Need?*, HEWLETT-PACKARD (Aug. 24, 2020), https://www.hp.com/us-en/shop/tech-takes/cpu-cores-how-many-do-i-need.

utilizing these devices to undertake the complexities of personalizing therapies at the patient level. For example, today's iPhone chip, the A15 Bionic with 5 graphic processing units or GPUs, runs 15 trillion arithmetic operations per second.[52] By comparison, in 1961 the state-of-the-art IBM 7090 computer system performed 100,000 instructions per second.[53]

Much of this computing power will service to advance the capabilities of an integrated pharmaco-electronic platform, one that would eventually be required to process increasing volumes of data as an influx of patients were to come online. Data science technology, in combination with artificial intelligence, will drive these platforms into autonomous operation. Social media platforms work similarly, and—as discussed below—present concerns in the administration of healthcare.

III. An Overview of Technology Specific to Electroceuticals

Biological cells express physical properties that engineers recognize as electric charge, viscosity, modulus of elasticity, and volumetric density. These are all measurable properties which, when detected by and coupled through sensors, can be fed into a computer for analysis. The convergence of computing and biology—i.e., a microprocessor embedded into our physiology at various sites— in the future, will form elements of a computing network where cell molecular properties can be analyzed, predict disease, and afford better regulation of the biological function to which it is assigned.

Electronic devices, such as sensors, supply physiological data measurements that transmit to the outer world via the internet.[54] By the end of 2018, an estimated 22 billion identifiable objects were

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[52] APPLE A15, WIKIPEDIA, https://en.wikipedia.org/wiki/Apple_A15 (last updated Apr. 8, 2022).

[53] *See* Matthew Smith & Rodney Brooks, *Gizmo: Myth and Machine*, 59 IEEE SPECTRUM 22, 22-23 (2022).

[54] *See* Nigel H. Lovell et al., *Biological-Machine Systems Integration: Engineering the Neural Interface*, 98 PROC. OF IEEE 418 (2010). (Products range from relatively simple devices—such as containing medical history that is injected under the skin—to more complex devices connected to the brain). *See also* Tal Shany et al., *Sensors-Based Wearable Systems for Monitoring of Human Movement and Falls*, 12 IEEE SENSORS J. 658 (2012).

connected to the internet and referred to as the "internet of things" (IoT) throughout the world.[55] Many identifiable objects were related to healthcare delivery in the form of sensors at the point of care in hospitals and also as installed in home treatment devices.[56]

The emergence of sensors and transducers—i.e., stimulators telecommunicating—have varying degrees of sophistication: (a) to monitor the wellness of otherwise symptom free individuals who desire to have their health monitored; (b) to track the occurrence of illnesses extant within a population; (c) to diagnose, for example, the onset of a heart attack; (d) to diagnose the state of the electronic device, e.g., the functioning of the battery life for a pacemaker or a prosthetic; (e) to adjust an anatomical process, e.g., to alleviate pain, depression or neurological diseases such as Parkinson's disease; and (f) to transmit physiological data, such as obtained from electrocardiograms, and ultrasonic devices at the point-of-emergency with telecommunication to transmit injuries. [57]

As a system, diagnostic/therapeutic devices use sensors, transducers, and computers which are tailored to a range of patient centered requirements, such as stimulators, pumps, or artificial organs.[58] Specialized clinical situations—such as home care, retirement home care, hospitals, the battlefield, and portable applications—may exist.[59] In 2015, ResearchKit launched by Apple addressed challenges facing

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[55] Lionel Sujay Vailshery, *Number of Internet Things (IOT) Connected Devices Worldwide in 2018, 2025, and 2030 (in billions)* (Jan. 22, 2021), https://www.statista.com/statistics/802690/worldwide-connected-devices-by-access-technology/#:~:text=Industry-specific%20and%20extensively%20researched%20technical%20data%20%28partially%20from,%28IoT%29%20connected%20devices%20in%20use%20around%20the%20world; *see also IEEE Sensors Registry*, IEEE STANDARDS ASS'N (Growth in the sensors market is expected to exceed USD 345 billion at a CAGR of 8.9% by 2028), https://standards.ieee.org/products-programs/icap/programs/sensors/.

[56] *Recommended Medical Alert Systems*, TOP 5 MEDICAL ALERT SYSTEMS (Feb. 2022), https://top5-medicalalertsystems.com/?utm_medium=cpc&utm_source=bing&gclid=fb256c7c8c861af16d5b0d9644e8a184 (Emergency alert systems use detectors with medical alert buttons connected to an emergency response system to notify first responders if a user needs immediate attention).

[57] IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY, *supra* note 36. *See generally* Carvalko, et al. Remote controlled telemedical ultrasonic diagnostic device and method for diagnosis injury using an ultrasonic glove for forming three dimensional anatomical images and transmitting the images to a remote location. U.S. Patent Application No. 20140180111A1 (filed Dec. 17, 2013)

[58] IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY *supra* note 36.

[59] *Id*.

medical research.[60] By using apps installed on a smartphone, researchers could collect physiological data for the purpose of informing users of their progress in controlling a medical disease, such as diabetes.[61] The potential exists for sending data directly to hospitals, insurance companies, and doctors, which can update, in real-time, an individual's medical prescription or record.[62] The success of these systems to achieve the intended purpose of improving healthcare begins with sensor and transducer technology.[63]

The pacemaker represents the most widely deployed example of an implantable/telecommunicating medical device that utilizes a computer, a transmitter, sensors, and transducers.[64] Doctors install the conventional product beneath the epidermis—above the outer chest—with electrical wires that affix to the inner heart wall.[65] The device paces the heart and may be combined with a cardioverter or defibrillator.[66] A recent innovation passes unimpeded through the femoral artery leading to the heart's cavity, thus obviating the need for surgical implantation.[67] The device lodges onto the inner heart via a "grappling hook" where it stimulates the heart.[68]

Neurological stimulators, bone growth stimulators, and drug delivery systems for insulin or pain medication are now available and are in the family of pacemaker like devices.[69] One type of neurological stimulator provides for "deep brain stimulation," to treat depression and bradykinesia (slow movement) associated with Parkinson's

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60 *Id*.

61 *Id*.

62 *Id*.; Brian Dolan, *Samsung Reveals 24 Digital Health Partners Including Aetna, Cigna, Humana, Welldoc*, MOBI HEALTH NEWS (Nov. 13, 2014, 7:21 AM), https://www.mobihealthnews.com/38252/samsung-reveals-24-digital-health-partners-including-aetna-cigna-humana-welldoc (Samsung's commercial partners for digital health currently include: Nike, Aetna, Cigna, Cleveland Clinic, dacadoo, Edamam, Humana, Fitbug, Lark, Merck, Preventice, Skimble, WellDoc. Samsung's research partners include UCSF, IMEC, Bloom Technologies, EarlySense, Elfi Tech, Stanford University, LifeBeam, Sensifree, SleepRate).

63 IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY *supra* note 36.

64 *Id*.

65 *Id*.

66 *Id*.

67 *Id*.

68 *Id*.

69 *Id*.; Medtronics, Inc., developed the IsoMed Constant-Flow Infusion System for bodily implantation that provides intrathecal infusion of morphine sulfate solution in the treatment of chronic intractable pain, or the intravascular infusion of floxuridine for the treatment of primary or metastatic cancer.

disease, where electrodes are implanted in the subthalamic region of the brain.[70] The wire ends are placed beneath the scalp and an impulse generator is placed in the chest.[71] These treatments reduce tremors, rigidity, slow movement, stiffness, and walking abnormalities.[72] Medical technicians can adjust the device parameters remotely, via a telecom link.[73]

In 1973, the first communication between a human and a computer, which employed electrical encephalograph (EEG) signals from a patient's brain, occurred.[74] Today, gross motor control devices use neuroprostheses to assist individuals who otherwise would be unable to mobilize a limb without the ability to move prosthesis based on their intention as sensed within their brains.[75] In May 2012, Cathy Hutchinson, a 58-year-old woman, who'd been paralyzed by a stroke and unable to move her own arms or legs, sipped a latte with the assist of a brain implanted sensor the size of an 80 mg aspirin and a mind-controlled robotic arm.[76]

In these types of applications, a motor neuroprosthetic detects and interprets a patient's thoughts.[77] In other applications, they have been effective in steering a wheelchair or guide a computer screen cursor.[78] In this same vein, these innovations now service patients who are paralyzed but conscious, including those suffering from ALS, stroke, or traumatic brain injury, to communicate via a computer-aided device, that can interpret their thoughts.[79]

According to an international consortium led by researchers at U.C. Berkeley and the U.S. Institute for Molecular Manufacturing,

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[70] *Id*.

[71] *Id*.

[72] *Id*.

[73] *Id*.

[74] Jacques J. Vidal, *Toward Direct Brain-Computer Communication*, ANNU. REV. OF BIOPHYS. AND BIOENG 157, 161-62 (1973).

[75] *See* IMPLANTABLE NEUROPROSTHESES FOR RESTORING FUNCTION (Kevin Kilgore ed., 2015)

[76] Katie Moisse, *Paralyzed Woman Moves Robotic Arm With Her Mind*, ABC NEWS (May 15, 2012, 5:46 PM), https://abcnews.go.com/Health/w_MindBodyNews/paralyzed-woman-moves-robotic-arm-mind/story?id=16353993.

[77] *See generally* CHRISTOPH GUGER ET AL., BRAIN-COMPUTER INTERFACE RESEARCH: A STATE-OF-THE-ART-SUMMARY (2013).

[78] *Id*. at 57.

[79] Emmanuel Donchin & Yael Arbel, *P300 Based Brain Computer Interfaces: A Progress Report*, DEP'T OF PSYCH. 724, 724 (2009).

developments of a "Human Brain/Cloud Interface" (B/CI) currently underway will connect brain cells to cloud-computing networks in real-time.[80] The means by which electronic prescription can be administered is now available.[81] Research moves apace as to the dispensing, efficacy, and safety of the signals, i.e., the specific locations within the brain and a better understanding of electric potentials, as modulated by different kinds of electrical signaling (sinusoidal, pulsed, or triangular), repetition rates, signal frequencies, all which will influence the neuronal activities over a range of infirmities and illnesses associated with the brain.[82]

Medical treatments that require on-demand, localized release of drugs in controlled amounts represent ideal candidates for electronic release methodologies and technologies.[83] These therapies typically treat hormone imbalances, malignant cancers, osteoporosis, and diabetic conditions.[84] In addition, the stage of a disease progression also may dictate different drug release amounts and rates. In many instances, the therapy depends on a well-controlled drug release.[85] For

[80] Nuno R. B. Martins et al., *Human Brain/Cloud Interface*, 13 FRONTIERS IN NEUROSCI. 1, 1 (2019); *see also* Anthony Cuthbertson, *Elon Musk's Brain Chip Startup Prepares for First Ever Human Trials*, YAHOO FINANCE (Jan. 21, 2022), https://finance.yahoo.com/news/elon-musk-brain-chip-startup-185702068.html?fr=sycsrp (In January 2022, Elon Musk's brain chip startup announced preparation for its first human trials of its brain computer interface. Its trademarked product, Neuralink reportedly had been used in trials on pigs and monkeys, and an experiment involving a nine-year-old macaque, which capably played video games using only its thoughts).

[81] Martins et al., *supra* note 80.

[82] *Id*.

[83] *See* APPLICATIONS OF NANOMATERIALS: ADVANCES AND KEY TECHNOLOGIES (Sneha Mohan Bhagyaraj et al. eds., 2018).

[84] *See id*. U.S. Patent No. 20210322212 (filed Aug. 30, 2018). The patent is designed for implantation in the ciliary sulcus during a cataract extraction. *Id*. It claims that some patients will have an implanted sensor in one or both eyes, such as an intraocular pressure sensor, for patients with pre-existing glaucoma, or diabetic retinopathy. *Id*. ("intraocular drug delivery has been under development worldwide over the last 46 years, beginning with the introduction of pilocarpine containing Ocusert, a conjunctival device for sustained release of pilocarpine for management of glaucoma … electronically actuated drug delivery systems for intraocular applications are less common and their development has had to wait for realization of wireless supply of electrical energy to the implant"). *Id*. For example, an electronically controlled drug delivery system employing a novel electrochemical pump was disclosed in 2007. Since drug delivery systems are now, in some instances, being designed to operate for more than three years, stability of the drug formulation becomes crucially important, as well as their sterility. Recent studies show that ophthalmic pharmaceutical formulations can be stable for two years or more." *Id*.

[85] *See generally* Earl E. Bakken & Kenneth Heruth, *Temporal Control of Drugs: An Engineering Perspective*, ANN. N.Y. ACAD. SCI. 422, 422-27 (1991).

example, distinct stages of cancer evolution demand different drug release rates, and, thus, a programmed release control can improve therapeutic efficacy while reducing side effects, such as cardio-toxicity[86] and congestive heart failure.[87]

Intelligent medicines, or chip-in-the-pill technology, are roughly the size of a grain of sand and offer yet another family of devices.[88] In the early 1960s, patients ingested the Konigsberg telemetry pill to record their temperature and transmit the data to a receiver for analysis.[89] In 1991, Jerome Schentag invented a pill that when swallowed could be tracked as it progressed through the alimentary tract.[90] When the pill reached a specific site, a trigger remotely dispensed the medication.[91]

The IntelliCap® device, first reported in 2014, is a swallowable electronic device approximately 27×11 mm, which can be filled with 0.3 ml of a drug liquid formulation[92] The body of the pill contains a microcomputer, a temperature and pH sensor, a wireless data exchange, and stepper motor.[93] Combining the control of the stepper motor with a variable timer allows any drug release, as profiled, over time.[94] Timing and control can be either programmed or controlled from a laptop.[95]

In 2012, Farra reported the first clinical trial of a subcutaneously implanted microchip containing a drug wirelessly delivered into eight postmenopausal women with osteoporosis.[96]

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86 T.M. Allen & P.R. Cullis, *Drug Delivery Systems: Entering the Mainstream*, 303 DRUG DISCOVERY 1818, 1820 (2004).

87 Yechezkel Barenholz, *Doxil−The First FDA-Approved Nano-Drug: Lessons Learned*, 160 J. OF CONTROLLED RELEASE 117, 119 (2012).

88 IEEE SOCIETY ON SOCIAL IMPLICATIONS OF TECHNOLOGY, *Pharm-Electronics Emerge*, *supra* note 36.

89 *Id*.

90 *Id*.

91 *Id*.

92 *See* Dieter Becker et al., *Novel Orally Swallowable IntelliCap Device to Quantify Regional Drug Absorption in Human GI Tract Using Diltiazem as Model Drug,* 15 AAPS PHARMSCITECH 1490, 1491 (2014).

93 *Id*.

94 *Id*.

95 *Id*.

96 Robert Farra et al., *First-in-Human Testing of a Wirelessly Controlled Drug Delivery Microchip*, 4 SCI. TRANS. MED. 1, 1 (2012).

In 2015, Lee reported on the treatment of tumor cells by wirelessly dispensing doxorubicin in treating cancer. [97] In addition to the transmission of wireless control, the invention also included a bioresorption of the residual of the device following a prescribed functional period, thereby eliminating a subsequent surgical extraction.[98]

IV. Data Science

Bidirectional communication between the application of patient's therapy and it's host, such as a smartphone or laptop computer that connects to ES, further differentiates the new technology and devices which merely report a status extant in the semiconductor memory of a device.[99] An ES employs complex analytical methods, including artificial intelligence comprised of fuzzy based logic, artificial neural networks, or hybrid approaches, such as neuro-fuzzy, all which support an inference engine.[100] ES has the power draw upon associations and other service decision support systems (DSS) that can lead to valuable insights, which otherwise might escape a researcher or diagnostician.[101] For example, a small study of twelve type 1 diabetic patients, using AI and DSS, resulted in quicker changes in therapy than would have occurred at their next scheduled healthcare appointment.[102]

At one end of the spectrum of medical informatic platforms are national or international data gathering systems; and at the other end are platforms that operate as closed systems servicing one or more medical centers. In this latter category, Pathinarupothi developed a platform that collects data from patient monitoring devices that,

97 Chi Hwan Lee et al., *Biological Lipid Membranes for On-Demand Wireless Drug Delivery From Thin, Bioresorbable Electronic Implants*, NPG ASIA MATER 9 (2015). *See generally* Amy C. Richards Grayson et al., *Multi-Purpose Drug Delivery from a Resorbable Polymeric Microchip Device*, 2 NATURE MATERIALS 767, 767-72 (2003).

98 Chi Hwan Lee et al., *supra* note 97.

99 *See generally* R. E. Imhanlahimi & A.M. John-Otumu, *Application of Expert System For Diagnosing Medical Conditions: A Methodological Review*, 7 EUROPEAN J. OF COMPUT. SCI. AND INFO. TECH. 12, 12-25 (2019).

100 *Id.* at 12.

101 *See* Carmen Pérez-Gandia et al., *Decision Support in Diabetes Care: The Challenge of Supporting Patients in Their Daily Living Using a Mobile Glucose Predictor*, 12 J. OF DIABETES SCI. AND TECH. 243, 249 (2018).

102 *Id*. at 243, 250.

among other measurements, provided blood pressure, blood glucose, oxygen saturation, and electro cardiographs, and, if needed, transmitted the data to tertiary care hospitals that, in turn, were anticipated to respond with timely interventions.[103] This was referred to as a 3P approach: personalized patient monitoring, precision diagnostics, and preventive criticality alerts.[104] In part, the system transforms multisensor time series data into patient/disease specific trends in steps of progressive precision "as demanded by the doctor for patient's personalized condition . . . [and] predictively alerting the onset of critical conditions."[105]

At the other end of the medical informatic systems spectrum "Big Data," comprises an array of systems that employ user behavior, predictive analytics, and other advanced analytical methods, utilizing rule-based, fuzzy logic, artificial neural networks and intelligent hybrid models to extract and interpret relevant medical information from interconnected data sources.[106] The information associated with Big Data, ranges from omic, medical research and treatment, to how this information factors into diagnoses, prognoses, and prescriptive directives to treat patient illnesses, injuries, and wellness. The volume of data has increased, with the collection rate doubling every 40 months since the 1980s.[107] United Nations Global Working Group on Big Data was created under the UN Statistical Commission in 2014 to create a global statistical community for data sharing and economic benefit.[108]

In summary, Big Data combined with anatomically embedded or wearable processors outfitted with bi-directional communications comprise the essential elements of an ES for diagnosing disease, offering treatment options, and—apropos to our discussion here—

103 Rahul Krishnan Pathinarupothi et al., *Data to Diagnosis in Global Health: A 3P Approach,* BMC MED. INFO. AND DECISION MAKING 1, 1 (2018).

104 *Id*.

105 *Id*.

106 *See generally* Mary Mallappallilet al., *A Review of Big Data and Medical Research*, 8 SAGE (2020); See, European Journal of Computer Science and Information Technology, Vol.7, No.2, pp.12-25, April 2019. Also see, Arvind Kumar Yadav et al., Machine Learning in Expert Systems for Disease Diagnostics in Humanhealthcare, in MACHINE LEARNING, BIG DATA, AND IOT FOR MEDICAL INFORMATICS 179 (Pardeep Kumar et al. eds., 1st ed. 2021).

107 *Id*. at 1.

108 UNBIGDATA, https://unstats.un.org/bigdata/ (last visited Apr. 5, 2019).

personalizing electronic prescriptions.[109] The heart of these systems depends on the acquisition of real time information about the physical status of patients.[110] Information acquired directly from patients will be used to update charts, and may also be used to alert health officials of impending pandemics, and to assist in the identification of individuals that pose public health threats.[111]

V. Privacy and Security Concerns

Pharmaco-electronic medicine is in the grasp of a new healthcare era, but not without concern about its misuse from hackers, especially its inability to withstand instances of privacy leakage from the use of IoMT technology. .[112] A sizable consensus exists that, by itself, Big Data, presents an enormous challenge regarding data security, especially in the management of large volumes of personal health data.[113] In the absence of early regulatory intervention, the fears raised by a robust pharmaco-electronics platform security system stem more immediately from intrusions into personal liberty, security, and privacy, such as the exfiltration of medical data.[114] It's been reported that from 2005 to 2019, 249.09 million healthcare breaches occurred, and, of these, 157.40 million individuals were affected between 2014 and 2019.[115]

The U.S. HIPAA Privacy Rule applies to health plans, healthcare clearinghouses, and those healthcare providers that conduct

[109] Pathinarupothi et al. BMC Medical Informatics and DecisionMaking (2018) 18:78 https://doi.org/10.1186/s12911-018-0658-y

[110] *Id.*

[111] Ribeiro-Navarrete, et al., *Towards a new era of mass data collection: Assessing pandemic surveillance technologies to preserve user privacy,* Technological Forecasting and Social Change, Vol. 167,
2021, https://doi.org/10.1016/j.techfore.2021.120681.

[112] Xiaofan Wang, X., et al., Privacy-aware efficient fine-grained data access control in Internet of medical things based fog computing. (2018). IEEE Access 6, 47657–47665. https://doi.org/10.1109/access.2018.2856896.

[113] Xiaoming Wang et al., *Big Data Management Challenges in Health Research-a Literature Review*, 20 BRIEFINGS IN BIOINFORMATICS 156, 156 (2017).

[114] *See generally id*.

[115] Adil Hussain Seh et al., *Healthcare Data Breaches: Insights and* Implications, 8 HEALTHCARE 1, 2 (2020) (comprehensive analysis of the severity of the problem).

healthcare transactions electronically.[116] HIPPA applies to pharmaco-electronic platforms, such as the Medtronic service MyCareLink Smart™, which automatically connects a pacemaker to a remote data base that receives information about the status of the heart.[117] But HIPAA imposes rules and requirement for protection of patient information once it comes into possession of an entity within the sphere of providing healthcare or servicing healthcare, such as insurance providers.[118] It does not protect against a breached pharmaco-electronics system.[119] And it does not protect against the possibility that pharmaco-electronics platforms will function both according to fixed rules as established by developers, and rules that may be invented by the AI component itself, independent of system developers or users.[120] These systems will depend significantly on Big Data to collect information, and AI will use this information in guiding treatments developing algorithms as it logically determines fit and do so quite autonomously.[121]

It would not seem unreasonable to assume that patient information should be shuddered to protect it from unauthorized disclosure, whether through misfeasance, but malfeasance as well. These will require independent risk assessments, especially because they pose the threat of unleashing a force that might be impossible to contain once the technology roots itself into the mainstream of medical care. In 2012, the Obama administration proposed a data privacy

116 45 C.F.R. § 160 (2022), 45 C.F.R. § 164 (2022) (any pharmaco-electronics platform would be subject to the Health Insurance Portability and Accountability Act of 1996, PubLNo. 104-191, Stat 1028 (1996). ("HIPAA"), and as to privacy, particularly, The Privacy Rule. The Privacy Rule establishes national standards for the protection of certain health information).

117 *Available Monitors Remote Monitoring: MyCareLink Heart Mobile App*, MEDTRONIC, https://www.medtronic.com/us-en/patients/treatments-therapies/remote-monitoring/available-monitors.html.

118 *See* U.S. DEP'T OF HEALTH & HUM. SERV., HEALTH INFORMATION PRIVACY: THE HIPAA PRIVACY RULE, https://www.hhs.gov/hipaa/for-professionals/privacy/index.html#:~:text=The%20HIPAA%20Privacy%20Rule%20establishes,care%20providers%20that%20conduct%20certain; *see also* U.S. DEP'T OF HEALTH & HUM. SERV., HEALTH INFORMATION PRIVACY: SUMMARY OF THE HIPAA PRIVACY RULE, https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#:~:text=The%20Privacy%20Rule%20covers%20a,do%20so%20on%20its%20behalf..

119 *See id*.

120 *See id*.

121 *See* Adam Bohr & Kaveh Memarzadeh, *The Rise of Artificial Intelligence in Healthcare Applications*, *in* ARTIFICIAL INTELLIGENCE IN HEALTHCARE 25 (2020).

framework for commercial networks, which in principle, especially as to FTC digital privacy enforcement, could be incorporated into a pharmaco-electronics network.[122] Although, below, we discuss unintended consequences, we do not have a full accounting of what might go wrong. It is instructive to acknowledge that social media's unintended consequences are legion, to wit, its inability to control malicious postings, ones that incite violence or disseminate falsities, all apparently impossible to remediate. The enormity of these systems makes them unmanageable as to key structural features.

We must also consider security, not breached by outside malefactors or operational system failures, but as it might relate to the administration of care. Two primary medical ethics directives relate to maintenance of patient autonomy and avoiding maleficence in the manner of treatment. Together, these serve as the basis for the right to privacy and to one's liberty interest or agency. But there are tradeoffs, which most would deem acceptable. For example, an electronic prosthesis controlled telemetrically may increase the freedom of movement for a recipient patient, while restricting an otherwise normally autonomous mode of freedom of movement. However, the ability to communicate between a host computer and a patient allows the potential for a malefactor to wrestle control over a host, where it might manipulate the information content regarding movement as transmitted to the patient. [123] An adversary who had access to, or intercepted, a prescription deploying computer, could compromise hardware or software by commandeering the device and the prosthetic to behave against the patient's interest.[124] In the conventional doctor/pharmacist/patient relationship, there have been reported instances where a patient's prescription was purposely altered with the intent to treat, or in some cases, *harm*, the patient or diminish the

[122] *See*, Consumer data privacy in a networked world: A framework for protecting privacy and promoting innovation in the global digital economy (2012). https://obamawhitehouse.archives.gov/sites/default/files/privacy-final.pdf. Note, FTC Act § 5, 15 U.S.C. § 45 arguably may be extended to protect a patient's digital privacy here, as in addition to using its Section 5 authority to protect consumer data privacy, the FTC has brought cases under sector-specific statutes, such as the Children's Online Privacy Protection Act.

[123] MATTHEW GLADDEN, AN ONTOLOGY OF NEUROPROTHESIS AS INSTRUMENTS OF 'CYBORGIZATION': PORTALS TO THE EXPERIENCE OF POSTHUMANIZED DIGITAL-PHYSICAL WORLDS, 118 (Synthypion Acad. 2017).

[124] MATTHEW E. GLADDEN, *supra* note 29, at 37.

patient's agency.[125] We live in an age where the transmission of harmful data has become routine, ranging in significance from nuisance to life threatening. One could imagine ample opportunities to interfere with one's motor control, other neurologically based prosthesis, or drug prescription.

In an era of pharma-electronics, the difference between medical data and medical information is more than semantic. With every new stream of medical data to and from a patient, we need to guard against its unrestricted access or we run the risk of surveillance and ultimate control over otherwise lifesaving treatment. The electronic signals in electroceuticals represent the prescription and thus constitute medical data. Although one might advance valid arguments as to a doctor's right to own a patient's medical record, we draw attention to medical data particularly because it further differentiates information based on the seriousness of the harm that may occur in its misuse. Medical data, as contrasted to medical information, consists of electronic data representations directly related to a patient (e.g., heartbeats or doses of a prescription) as acquired through a sensing device (e.g., pacemaker) or controlled through a transducer (insulin pump). Medical data at the patient level may include transmission protocols, such as device addresses, packet control data, hash codes, and encryption keys. Additionally, the data may be parsed, so it exists in various places where medical professionals can obtain access. These include charts, and, as authored by a doctor, likely will remain medico-legal records, as typically "owned" by the medical professional.[126] Medical data's integrity, privacy, and security is often instantiated in the electronic data transmission protocols themselves, which, if compromised, should offer the patient a private right of action. One solution might be to place ownership of these kinds of artifacts into a patient's hands, providing them with the power to legally redress a breach.

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125 Shaheen E. Lakhan & Annette Kirchgessner, *Prescription Stimulants in Individuals With and Without Attention Deficit Hyperactivity Disorder: Misuse, Cognitive Impact, and Adverse Effects*. 2(5) BRAIN AND BEHAVIOR 661, 664 (2012). Prescription stimulants treat attention deficit hyperactivity disorder (ADHD), e.g., methylphenidate (Ritalin, Concerta), dextroamphetamine (Dexedrine), and dextroamphetamine-amphetamine (Adderall) help ADHD patients focus. Misuse of stimulants has increased over recent years for a variety of reasons. *Id*.

126 Medical providers typically have claimed to own the information because they created it, use it, store it, and control it. As this information goes to the "cloud," and both storage and control belong to a third party, with potentially liability for its release increasing, medical professionals may not want to "own" those records.

A pharmaco-electronic system's failure to reliably perform as intended puts patients at risk on several levels, thus requiring that every element of hardware, software, communication channel, and the devices it communicates with, possess greater than commercially reasonable or conventional reliability standards. Each element requires extra safety functionalities—such as fail-safe or fault-tolerant performance features—to maintain a safe state, especially where engineers and programmers can foresee that failure of the device or system could lead directly to personal injury or death.[127] Often, these include secondary or redundant systems that come into operation to prevent breakdown or operate as a backup in the event of a malfunction.[128]

Privacy by Design (PbD) relates to a practice that Europe, Canada, and the U.S. have widely adopted.[129] The PbD practice has seven foundational principles which should be adopted pursuant to any information technology system, especially those that have significant impacts on society and its need for privacy.[130] The practice had been codified in-part into laws both in North American and Europe.[131] The PbD practice includes the following: (1) designers should be proactive not reactive; (2) designers should prevent not remediate, where privacy serves as the default setting; (3) privacy must be embedded into each design; (4) designers must recognize that full functionality relates to a positive-sum, not zero-sum; (5) designers must strive for end-to-end security—full lifecycle protection; (6) designs visibility should remain transparent and open; and (7) designers must maintain respect for user privacy and keep it "user-centric."[132]

Ann Cavoukian, Ontario's Information and Privacy Commissioner in the 1990s, first proposed PbB as a response to the growing

127 *See* HIGH RISK SYSTEM DEFINITION, LAW INSIDER, https://www.lawinsider.com/dictionary/high-risk-system.

128 *See id*.

129 PRIVACY BY DESIGN: INFO. & PRIV. COMM'R OF ONTARIO (revised Sept. 2013); Ann Cavoukian, PRIVACY BY DESIGN: THE 7 FOUNDATIONAL PRINCIPLES, INFO. & PRIV. COMM'R OF ONTARIO, (revised Jan. 2011).

130 *Id*.

131 *Id*. "Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)". Commission Regulation (EU) No 28/2012.

132 Cavoukian, *supra* note 129; PRIVACY BY DESIGN: INFO. & PRIV. COMM'R OF ONTARIO, *supra* note 129.

threats of online privacy.[133] In 2012, The U.S. Federal Trade Commission ("FTC") recognized PbD as one of its recommended practices for protecting online privacy and included it as one of the pillars in its *Final Commissioner Report on Protecting Consumer Privacy*.[134] Whether PbD can serve as a privacy or security solution to a wide-ranging pharmaco-electronics system remains unknown. However, without a central authority managing the development of such a system, it might prove impossible to marshal and manage every subsupplier to the design, development, and deployment of a pharmaco-electronic system.

VI. AI: A Future Rife with Unintended Consequences

Relying on artificial intelligence as a mainstay of diagnosis and treatment of illness may produce outcomes antithetical to patient health and welfare. Much of the recent commentary about the dangers from AI are discussed in the context of artificial general intelligence (AGI) technology, expected sometime within the next 10 to 30 years.[135] But even at the level of simple AI that presently exists, it raises a possibility for human health risks from what scientists refer to as the capability claim and the value claim.[136] First, risk may occur based on the premise that AI can reach a capability to inflict major damage to our well-being. Second, risk may occur based on the premise that AI may act according to values that do not align with humanity's values, resulting in unspecified harm. AI, in its present form and as used in a pharmaco-electronic applications, would collect information at the anatomical level and administer prescriptions based on expert system analysis. AI at its present level of sophistication can help automate the diagnosing and dispensing function related to health. But, as with all huge IT systems, it is not possible to predict in advance what might go wrong. Query – what threats might we

133 *Id.*

134 FED. TRADE COMM'N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE 23 (2012); *FTC Issues Final Commission Report on Protecting Consumer Privacy*, FED. TRADE COMM'N (Mar. 26, 2012), https://www.ftc.gov/news-events/press-releases/2012/03/ftc-issues-final-commission-report-protecting-consumer-privacy.

135 NICK BOSTROM, SUPERINTELLIGENCE: PATHS, DANGERS, STRATEGIES 129 (1st ed. 2014).

136 *Id.*

anticipate if the AI attains and exercises powers to achieve its own technological end, whether that be efficiency, efficacy, reliability, or control over its subjects? As Wendell Wallach writes, "technological development is at the risk of becoming a juggernaut beyond human control."[137]

Physicians cannot process the enormous data sets that a rival ES can.[138] ES processing power depends on such technology as neural networks and the facility with which they can process multivariate data streams. Moreover, a neural network may not merely condition or operationalize the anatomically engaged sensor technology and consider the efficacy of a therapy, but also deal with disparate objectives, such as may be present by design, notably built-in economic objectives.

The unregulated development of a pharmaco-electronics ES, especially when we empower program developers to determine limits to a range of competing aims, risk putting populations of patients in harm's way.[139] Analogous to social media, an AI diagnosing and therapeutic application can lead to obscuring the boundaries between a platform and its users—in this case, the patients that it serves.[140] A platform does not sense humans, it senses technology.

We might consider AI as a self-contained paradigmatic process where algorithmic operations, used in machine learning, or artificial neural networks weave logical connections on their way to achieving a well-defined outcome. But many instances have been recorded where an AI calculation resulted in a completely unexpected and unintended outcome. Often, we accept how this happens by rationalizing that those algorithms—designed by humans with their built-in biases— are addressed and fixed when discovered. But often, a programmer creates an algorithm based on a specification that

[137] WENDELL WALLACH, A DANGEROUS MASTER: HOW TO KEEP TECHNOLOGY FROM SLIPPING BEYOND OUR CONTROL 21-22 (2015).

[138] Arvind Kumar Yadav et al., Machine Learning in Expert Systems for Disease Diagnostics in Humanhealthcare, in MACHINE LEARNING, BIG DATA, AND IOT FOR MEDICAL INFORMATICS 179 (Pardeep Kumar et al. eds., 1st ed. 2021).

[139] Stephan Vladimir Bugaj & Ben Goertzel, *Five Ethical Imperatives and their Implications for Human-AGI Interaction*, DYNAPSYCH (2007), https://goertzel.org/dynapsyc/2007/Five_Ethical_Imperatives_svbedit.htm.

[140] *Id*.

includes reaching a goal based on built-in incentives or biases that go well beyond the system's main purpose.

In systems that deal with an array of variables and algorithms having competing objectives, a neural network can be programmed to actualize its intended goal through an iterative trial-and-error reinforcement learning process that can lead to the eventual maximization of a distinct parameter.[141] It takes no imagination to see that if the healthcare platform strives to minimize costs while maximizing growth and revenues, it may not be optimized for medical treatment.

In addition to the economic incentives, some which may be antithetical to best practices medical care, other problems may surface that have noneconomic effects, e.g., resulting in changes in one's sapience, autonomy, and volitionality.[142] Consider that our thoughts, as well as other sensory output from individuals utilizing BCI integration or neural implants, will create a new kind of knowledge space, one that includes emotionality and cognitive biases, within which an AI function has access.[143]

It is not science fiction to suggest that overtime AI driven pharmaco-electronic systems will be central to health care decision making. Such decisions may be partly based on human interactions between a patient, a patient's family, the physician(s), or medical orders such as "do not resuscitate" and partly based on machine judgment. AI by definition has the potential to autonomously decide matters of consequence unless initiatives are pursued to regulate its influence.[144] Without regulation medically judgmental outcomes effectively become undisclosed autonomous agencies operating in the background.

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141 Bob Suh, *5 Rules to Manage AI's Unintended Consequences*, HARV. BUS. REV. (May 21, 2021), https://hbr.org/2021/05/5-rules-to-manage-ais-unintended-consequences.

142 MATTHEW GLADDEN, *The Deepening Fusion of Human Personnel and Electronic Information Systems: Implications of Neuroprosthetic Augmentation for Enterprise Architecture*, *in* NEUROPROSTHETIC SUPERSYSTEMS ARCHITECTURE 210, 210-52 (2017).

143 *Id*. at 213.

144 H.R.6216 - National Artificial Intelligence Initiative Act of 2020 became law on January 1, 2021, providing for a coordinated program across the entire Federal government to accelerate AI research and application for the Nation's economic prosperity and national security. SEC. 3. DEFINITIONS define: ARTIFICIAL INTELLIGENCE as ". . . a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to— (A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action."

The built-in independence of AI systems to achieve a technically specified goal points to the very danger these entities pose. Query, who, if any institution or governmental agency, will regulate the implementation and use of a pharmaco-electronic method for delivering healthcare? This remains an open question.

VII. Side Stepping Spin Offs

We distribute medical technologies based on need, for example, pacemakers for victims of heart block or arrhythmias, artificial limbs for amputees, and cochlear implants for the deaf. But technologies, as discussed, have the potential for enhancing otherwise normal performance. Under elective circumstances, these products might be applicable in those patients that can afford an enhancing prosthetic. Once implantable technology goes beyond medicine and into the realm of physiological enhancement (e.g., increased physical and mental agility), it may find demand in those who maintain standing in a community of peers, based on an enhancement feature. This demand would raise issues affecting equal opportunity, because an enhanced enabled individual may present the more qualified candidate for employment. In addition, questions will be raised as to whom and under what conditions, outside of medical necessity, should anyone have the right to upgrade a cognitive or physical characteristic.

The nootropic (smart) drug market presently flourishes to improve cognitive performance. Nearly 10 years ago, modafinil, considered a smart drug, was approved by the U.S. Air Force as a "go pill" for fatigue management.[145] These not-too-distant spin-offs of pharmaco-electronic technology portend to go beyond any requirement driven by medical necessity.

In 2021, the Defense Advanced Research Projects Agency (DARPA) announced that a team of engineers at Northwestern University aims to develop a wirelessly controlled bioelectronic implant that reduces the time needed to adapt to new time zones or drastic

[145] Debbie Gregory, *Is Using Smart Drugs to Help the Military a Good Idea?*, MIL. CONNECTION (Aug. 19, 2018), https://militaryconnection.com/blog/using-smart-drugs-help-military-good-idea/.

changes in schedules by releasing peptide-based therapies to harmonize the warfighter's central and peripheral circadian clocks.[146]

Consider that these systems will shorten the arrival time for enhancing the physical and mental capacities of individuals, at least those who might regard a physiological extension within the right of self-determination.[147]

In addition to drugs as a prescription to alter states of mind, physicians may employ neuroprostheses to suppress fear and anxiety. Researchers have hypothesized that these devices may be activated "when a soldier, aircraft pilot, or surgeon is about to perform some highly dangerous and sensitive maneuver, in order to allow him or her to act without any psychological and physical disruptions caused by nervousness," and at other times deactivated "from performing actions that are reckless and inappropriate in everyday life."[148]

Government agencies, including the FDA, must consider regulating applications beyond safe operation in a technical sense. Agencies must begin to explore requirements pertaining to suppliers, medical device software, and software updates. Likewise, agencies must evaluate requirement for deciding action when insurance or a health administering software subscription runs out. These matters invariably implicate insurance, healthcare, patents, copyrights, licensing, product safety, and other consumer laws. In the future, Congress may consider empowering a new federal office to police viruses, bots, spam, ransomware, and other evils and ills that befall the computer user today. Clearly, in the future, denial-of-service, potentially, may cause death.

[146] DARPA Announces Researchers to Tackle Common Travelers' Issues that Impact Force Readinesshttps://www.darpa.mil/news-events/2021-05-10. Also, see, D. Young, "This Implant Could One Day Control Your Sleep and Wake Cycles", Smithsonian Magazine, June 18, 2021, https://www.smithsonianmag.com/innovation/this-implant-could-one-day-control-your-sleep-wake-cycles-180977983/

[147] We are referring to the transhuman or posthuman movement, where it considers one who orients his/her thinking towards the future to prepare for coming changes and who seeks out and takes advantage of opportunities for self-advancement.

[148] GLADDEN, *supra* note 123, at 122.

VIII. Standards, Legal and Ethical

Although it is impossible within the allowable space to discuss the full panoply of rights, duties, obligations, and liabilities associated with pharmaco-electronic prescriptions, the compendium of torts, actions in contract, including medical malpractice, and product liability for pharmaceuticals and medical devices apply to implanted medical devices.[149]

As a population becomes increasingly dependent on electronic medicine for its state of health, ownership and control of the pharmaco-electronic technology and prescriptions will need fresh consideration. For example, who will decide availability, price, performance/warranty, safety, personal security, and ownership of data? And who will control the intellectual property, such as patent/copyright licensing, which may affect access for upgrading device hardware/software or repair? Although these issues currently run through pharmaceuticals and medical devices, many of them—such as ownership of data, security, and software updates—will raise issues unique to pharmaco-electronic prescriptions. Again, by analogy, we experience these forms of inconveniences when a licensor of computer operating systems decides to abandon an earlier version or requires an upgrade that proves inoperable.

Pharmaco-electronic devices span a spectrum of designs from simple circuits to those that register at the complexity of computer processors.[150] Professional associations, such as the IEEE, set design standards for architectures and communication protocols related to point-of-care medical devices to ensure the exchange of data and protect personal safety and privacy considered in controlling networked devices.[151]

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[149] For example, in January 2007, Medtronic a developer of pacemaker technology reported five patient deaths. At that time the U.S. FDA had 599 reports of malfunctions and injuries associated with fractured leads. Suits followed and Medtronic settled most of the cases.

[150] *See* CENTRAL PROCESSING UNIT, WIKIPEDIA, https://en.wikipedia.org/wiki/Central_processing_unit (last updated Mar. 24, 2022).

[151] *See generally* IEEE, HEALTH INFORMATICS – DEVICE INTEROPERABILITY – PART 20701: POINT-OF-CARE MEDICAL DEVICE COMMUNICATION – SERVICE ORIENTED MEDICAL DEVICE EXCHANGE ARCHITECTURE AND PROTOCOL BINDING (1st ed. 2020); Shahanawaj Ahamad, *Contemporary Research Challenges and Applications of Service Oriented Architecture*, INT'L. J. OF SCI. RSCH. IN COMPUT. SCI., ENG'G AND INFO. TECH. 1143, 1143 (2020).

Simple circuits may serve as peripherals, such as sensing mechanisms, that have little to no ability for wireless communication.[152] Most of these circuits remain insulated from outside assaults by hackers.[153] However, computers accessible via wireless communications include operating system, application specific programs, and associated databases, individually or collectively, are potentially vulnerable to adversarial intrusion.[154] Pharmaco-electronics raises the stakes; intercepting a transmission, hacking into data bases, or seeking ransom via a hack, can put a patient's life at risk.[155] Although these types of breaches squarely fall within the ambit of federal law, these laws do not offer any guarantees that they will, or are not, the object of disreputable intrusions.[156]

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq*. (Medical Device Amendments of 1976 ("MDA")), requires FDA approval for new drugs and medical devices.[157] Electronic medicine relates to pharmacology generally, and more directly to medical devices, included those with wireless capability.[158]

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[152] *See* Patricia AH Williams & Andrew J. Woodward, *Cybersecurity Vulnerabilities in Medical Devices: A Complex Environment and Multifaceted Problem*, 8 MED. DEVICES: EVIDENCE AND RSCH. 305 (2015).

[153] *See id*.

[154] *See id*.

[155] Russell L. Jones & Sheryl Coughlin, *Networked Medical Device Cybersecurity and Patient Safety: Perspectives of Health Care Information Cybersecurity Executives*, DELOITTE CTR. FOR HEALTH SOL. 13 (2013); U.S. GOV'T ACCOUNTABILITY OFF., *Medical Devices: FDA Should Expand Its Consideration of Information Security for Certain Types of Devices* (Aug. 31, 2012), https://www.gao.gov/products/gao-12-816.

[156] In 1986, Congress passed the Computer Fraud and Abuse Act (CFAA), now codified under 18 U.S.C. § 1030. This law makes it a federal crime to either obtain information (otherwise known as "hacking") or transmit harmful information subject to a fine, imprisonment for up to ten years, or both.

[157] The Food and Drug Administration (FDA) defines a medical device in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: —recognized in the official National Formulary, or the United States Pharmacopoeia, or supplement to them;—intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or—intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h).

[158] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF: CLASS II SPECIAL CONTROLS GUIDANCE DOCUMENT: IMPLANTABLE RADIOFREQUENCY TRANSPONDER

The FDA monitors recalls on products that contain errant components, including software, but few instances have been reported of Internet and software related willful misconduct or malfeasance resulting in bodily injury or death.[159] Criminal activity, through the use of computers—including the Internet—takes many forms that will be applicable to implanted/telemetry devices and systems.[160] Unlike most computer hacking, which generally invades privacy or wrecks economic damage, hacking an implanted device may lead to potentially lethal results, such as, slowing down or halting a pacemaker, or commanding a defibrillator to deliver a 800-volt deadly shock from a mobile device several feet away.[161] However, as to other breaches, we currently witness weak enforcement (state or federal), of

SYSTEM FOR PATIENT IDENTIFICATION AND HEALTH INFORMATION, 1-2 (Dec. 10, 2004), https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/implantable-radiofrequency-transponder-system-patient-identification-and-health-information-class-ii.

[159] *See* CTR. FOR DISEASE CONTROL AND PREVENTION, FATAL INJURY AND VIOLENCE DATA, https://www.cdc.gov/injury/wisqars/fatal.html (last visited Jan. 29, 2022); There are numerous recalls related to malfunctions in medical devices with software for example, on March 6, 2013, the FDA Medical Recall Division, recalled the Alaris PC Unit (Model 8015) with Software Version 9.12 manufactured by CareFusion Corporation. The Alaris PC unit (model 8015) is part of the Alaris electronic infusion pump. An electronic infusion pump delivers controlled amounts of medications or other fluids to patients through intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration. The reason for the recall was that the company received reports of a communication error on the Alaris PC unit (model 8015) with software version 9.12 when the Alaris $EtCO_2$ module or Alaris SpO_2 module is attached. It reported that the use of the product may cause serious adverse health consequences, including death. U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE RECALLS (current as of Aug. 9, 2021), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls.

[160] No Electronic Theft Act, 18 U.S.C. § 506; Identity Theft and Assumption Deterrence Act of 1998, 18 U.S.C. § 1028A; Fraud and Related Activity in Connection with Access Devices, 18 U.S.C. § 1029; Fraud and Related Activity in Connection with Computers, 18 U.S.C. § 1030; Wire Fraud, 18 U.S.C. § 1343; Communication Lines, Stations, or Systems, 18 U.S.C. § 1362; Interception and Disclosure of Wire, Oral, or Electronic Communications Prohibited, 18 U.S.C. § 2511; Unlawful Access to Stored Communications, 18 U.S.C. § 2701; Disclosure of Contents, 18 U.S.C. § 2702; Requirements for Governmental Access, 18 U.S.C. § 2703.

[161] Daniel Halperin, *Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses*, 68 UNIV. OF MASS. AMHERST, COMPUT. SCI. DEP'T FAC. PUBL'N SERIES 2 (2008); Selena Frye, *Black Hat demo shows vulnerability of insulin pumps to remote attack*, TECHREPUBLIC (Aug. 5, 2011), https://www.techrepublic.com/article/black-hat-demo-shows-vulnerability-of-insulin-pumps-to-remote-attack/; Jeremy Kirk, *Pacemaker hack can deliver deadly 830-volt jolt*, COMPUT. WORLD (Oct. 17, 2012), http://www.computerworld.com/article/2492453/malware-vulnerabilities/pacemaker-hack-can-deliver-deadly-830-volt-jolt.html.

computer crimes, e.g., software piracy, knockoffs, unlawful upgrades, hacking, ransom, or virus transmission.[162]

In 2008, the Supreme Court considered whether the pre-emption clause enacted in §360k of the MDA prohibited common-law claims challenging the safety and effectiveness of a medical device after premarket approval by the FDA.[163] The Court held that state common law claims of negligence, strict liability, and breach of implied warranty, against a device's manufacturer, were preempted by the MDA and that states cannot establish requirements which are different from, or add to, any federal requirement applicable to the device.[164] The Court indicated that "State tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[165] Plaintiff's claims were preempted because they attempted to establish state requirements for safety that were "different from, or in addition to" the federal requirements, although the Court indicated that the federal law "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements."[166]

In modern life, values take form from institutional authority, whether legislated or through professional organizations. At the governmental level, this manifests in enforceable regulations, which control the extent to which conventions or modifications will prevail, or how far an institution, such as a corporation, might be allowed to control the operation, distribution, and use of a know-how or its product. Accordingly, pharmaco-electronic systems, presumably widely deployed and lifechanging, should be accompanied by scrutiny from responsible agencies. Agencies must ensure that newly acquired technological tools do not fall into the hands of irresponsible or

162 The Failure of the Computer Fraud and Abuse Act: Time to Take an Administrative Approach to Regulating Computer Crime, Ric Simmons, THE GEORGE WASHINGTON LAW REVIEW, December 2016 Vol. 84 No. 6.

163 Riegel v. Medtronic, Inc., 552 U.S. 315, 327-28 (2008).

164 *Id.*

165 *Id.* at 325.

166 *Id.* at 330.

disreputable agents. After all, we are dealing with innovations that will affect the health of virtually everyone.

Going forward, policy advisors drawn together by government or professional organizations should push initiatives to develop model legislation to operationalize pharmaco-medical fiduciaries to assure governance. For example, advisors might propose a community-centric governance, rather than governance managed by a private corporation. Policy advisors might work in collaboration with persons or agencies responsible for creating the framework to identify, examine, and resolve how the field appropriately manages ethical issues in pharmaco-electronics. For example, advisors could consider transparency and auditability of the artificial intelligence component (the machine learning features of a system). Similarly, governance might address establishing standards for promoting human values in the design, development, and deployment of devices through a pharmaco-electronics system. Such design would have consequences far beyond medical treatment, such as a brain-machine interface might.

Conclusion

Every day, scientists discover new cures for humankind's most intractable diseases—cancer**,** heart disease**,** mental illness**,** and, recently, a variety of SARS-COVID viruses. Additionally, technologists continue to invent the future, providing life saving devices and greater efficiencies in the delivery of healthcare. We should celebrate this collective contribution to a world which, on the surface, at least, appears to move millions of us into an ever-enlightened future and healthier lives. Yet, human history reflects its true achievements, not based on technology, but by its passion for embodying the virtues of responsible stewardship of our humanity. These achievements include preserving life and engaging in universal social justice. If, through common neglect, we irreversibly apply technology that does not serve this aim, then we destroy any semblance of a moral legacy for the future of humanity.

When it comes to solving the hard problems, our success depends not solely on science and engineering**,** but significantly consensus within the population-at-large. We need not look far to find examples in American life where scientific and technological progress alone

cannot reverse climate change, reduce the prevalence of gun violence, change attitudes about social or criminal justice. Instead, we find ourselves stalemated for reasons of political affiliation, fealty toward forms of cultural solidarity, or among other reasons, such as a poorly informed populace or one lacking faith in science, even among those considered affluent and seemingly well-educated in other spheres of knowledge.

When it comes to the well-documented benefits, risks, or hazards associated with scientifically proven medical undertaking, non-believers come from all demographics. This past year especially**,** we witnessed how values and beliefs played out in deadly ways**,** where in the U.S.**,** despite the best medical advice**,** huge numbers of citizens refused to wear masks, reduce human contact, and vaccinate—steps that would mitigate Covid-19's potentially deadly consequences. Those behaving in this manner cannot lay blame on science and technology; instead, non-belief points to limitations in our powers of persuasion, rationality, and foreseeability.

The practices of medicine and engineering are quite different, but both are social enterprises which must consider who or what will be affected by their actions. Each undertaking begins with understanding the problem to be solved and its constraints, whether social, i.e., who, what, when and why, or the how, i.e., technology. Engineers think about "how" in terms of a product—notably, feasibility given the state-of-the-art—and what one needs to overcome to achieve a desirable form, fit, or function.

But understanding the social part, beliefs, desires, including laws or even marketplace realizability, come later in the development, often after launching a product engineers may have poured their souls into. We need only consider social media and the host of problems that have emerged to remind us how devastating an impact a new product can deliver without forethought. Other examples further back in time are legion—the invention and use of the cotton gin, combustion engine, the atomic bomb, asbestos, lead battery production. Those who design pharmaco-electronic medical systems must not merely consider technological feasibility, but what society desires to conserve: its cherished human values.

We must not fall back on the excuse that we did not have the luxury of time to evaluate what new assortment of problems we might

face or what time-honored social tenets we might overlook as we dash into the future. Social scientists, policymakers, legislators, regulators, ethicists, and lawyers should convene to address this inevitable technological evolution, and put forth policy prescriptions, ethical mandates, and model laws that address liability, privacy, security, and the preservation of liberty interests.

We must remember that as pharmaco-electronics advances toward becoming an accepted medical treatment regime—one that extends lifetimes and enhances mental well-being—it may fail as the proverbial silver bullet for fixing the hard problems**,** a significant, but partial, list which includes, overpopulation, famine, and the persistent lack of healthcare throughout much of the world. We need not go far before we see signs that human-centered technology fails to reach many throughout the world.

On this last point we end with a question. In those corners of the world now coming into the age of the Internet, those corners where people have been historically deprived of modern healthcare, will they now discover an accessible upgrading of care brought about by a responsible pharmaco-electronic paradigm, Internet-like, one with the power to change lives for the better?