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Instrumental and Transformative Medical Technology

Nicole Huberfeld*

ABSTRACT

This Article considers how medical technologies impact universality in health care. The universality principle, as embodied in the Patient Protection and Affordable Care Act (ACA), eliminated widespread discriminatory practices and provided financial assistance to those otherwise unable to become insured—a democratizing federal act that was intended to stabilize health care policy nationwide. This Article posits that medical technology, as with all of medicine, can be universalizing or exclusionary and that this status roughly correlates to its being “instrumental technology” or “transformative technology.” Instrumental technology acts as a tool of medicine and often serves an existing aspect of health care; in contrast, transformative technology is pioneering, meaning it creates a new form of care or otherwise is novel. Instrumental and transformative medical technologies provide end points on a continuum, which provides a lens through which to examine whether medical technology has greater potential to facilitate universality or exclusion. The Article first examines where technologies fit on the instrumental-transformative continuum and then considers measures more specific to universality, namely improving the quality of medical care, access to care, or the cost of care. These considerations help to pinpoint the moment at which a technology may have a universalizing effect, if at all. The Article concludes with preliminary thoughts regarding whether the instrumental-transformative continuum helps to determine whether certain technologies should be adopted or supported publically or allowed to develop (or fail) organically.

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TABLE OF CONTENTS

I. INTRODUCTION 268

II. A CONCEPT OF INSTRUMENTAL AND TRANSFORMATIVE TECHNOLOGIES..... 272

III. UNIVERSALITY AND MEDICAL TECHNOLOGY..... 279

IV. CONCLUSION..... 282

I. INTRODUCTION

Technology can have a democratizing effect,¹ increasing access to information, demystifying knowledge or goods that were unobtainable, and facilitating societal, vocational, and other advances for both individuals and the collective.² But technology also can be costly and power entrenching and, thus, inequitable and elitist.³ Like technology, American health care contains dichotomous tensions: on one hand, having a long history of excluding the poor and those who could not pursue private contracts with doctors;⁴ and on the other, achieving some balance through inclusive acts of charity or public programs that have facilitated health care access for those who could

1. The basic definition of “democratize” includes the following: “to make (something) available to all people: to make it possible for all people to understand (something).” *Democratize*, MERRIAM WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/democratize> [<https://perma.cc/2N58-HRPA>] (last visited Jan. 12, 2017). The Internet has been described as democratizing within the context of communication and, more specifically, communication that leads to political participation and change. *See, e.g.*, MATTHEW HINDMAN, THE MYTH OF DIGITAL DEMOCRACY 5–6 (2008) (attempting to define normatively and descriptively what it means for the internet to be democratizing and refuting the assumption that the internet is inherently a positive political element).

2. *See generally* ANDREW FEENBERG, QUESTIONING TECHNOLOGY (1999).

3. *See id.* One popular theory holds that technology has power to “disrupt” medicine and revolutionize it in a positive way. *See generally* CLAYTON M. CHRISTENSEN, JEROME H. GROSSMAN & JASON HWANG, THE INNOVATOR’S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE (2009) [hereinafter THE INNOVATOR’S PRESCRIPTION] (asserting that technology will “disrupt” traditional medical care, building on the theories delineated in Clayton M. Christensen’s *The Innovator’s Dilemma*). This Author does not adopt this viewpoint, in part because Christensen’s theory holds that market disrupters are usually rival, low cost, low quality “technologies” that displace existing higher quality products. In medicine, new medical technology is often high tech—costly, experimental in nature, and new, and it is often inaccessible or impractical for most daily medical needs. In other words, it is outside of Christensen’s business model. For a pithy, scathing review of *The Innovator’s Prescription*, see J.D. Kleinke, *Perfection in Power Point*, 28 HEALTH AFF. 1223 (2009). (Thanks to Frank Pasquale for the pointer).

4. Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL’Y L. & ETHICS 67, 70–71 (2015) (detailing the fragmented and exclusionary nature of health care in the United States).

not afford it.⁵ The conflicting forces in technology, in many ways, mirror conflicts within healthcare itself; medical technology can facilitate universality or exclusion, democratization or inequity.

Medical technologies are wildly varied and can be found in every aspect of medical practice, biomedical research, and public health—touching healthcare finance, individual and collective care, and engaging with laws throughout our federalist scheme. From a treatment perspective, doctors and medical institutions regularly use medical technologies in the curative setting.⁶ From a governance and finance perspective, the federal government has established support for medical technologies through various executive⁷ and legislative⁸ mechanisms. In addition, states regularly employ medical technologies ranging from mundane tasks, such as enrolling Medicaid-eligible citizens,⁹ to significant tasks, such as collecting and assessing data for statewide medical trends.¹⁰

5. See, e.g., Medicaid Act, 42 U.S.C. § 1396 (2012) (providing a system of federally funded medical assistance for low income individuals); Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd (2012) (requiring screening and treatment or appropriate transfer for any individual who seeks care at an emergency department regardless of ability to pay).

6. See, e.g., Neda Ratanawongsa et al., *Association Between Clinician Computer Use and Communication with Patients in Safety-Net Clinics*, JAMA INTERNAL MED. (Nov. 15, 2015), <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2473628> [<https://perma.cc/3V8F-VSEY>] (discussing the use of computers during patient interactions as negatively impacting patients' perceptions of the quality of their care).

7. Robert Pear, *U.S. to Collect Genetic Data to Hone Care*, N.Y. TIMES (Jan. 30, 2015), http://www.nytimes.com/2015/01/31/us/obama-to-unveil-research-initiative-aiming-to-develop-tailored-medical-treatments.html?_r=0 [<https://perma.cc/9A4J-F525>] (describing President Obama's "precision medicine initiative").

8. See, e.g., Medicare Access and CHIP Reauthorization Act, Pub. L. No. 114-10, 129 Stat. 87, 97 (2015) (encouraging the use of telehealth to share patient information by deeming it a "clinical practice improvement activity"); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (deeming telehealth the equivalent of face-to-face encounters with physicians throughout the statute); see also Health Information Technology for Economic and Clinical Health Act, Title VIII of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 3011, 4101, 13001, 123 Stat. 115 (2009) (supporting adoption of EMR). The ACA codified support for telemedicine in particular. See, e.g., 42 U.S.C. § 254c-18(a) (2012) ("The Secretary may make grants to State professional licensing boards to carry out programs under which such licensing boards of various States cooperate to develop and implement State policies that will reduce statutory and regulatory barriers to telemedicine."); see also DEP'T OF HEALTH AND HUMAN SERV., 2001 TELEMEDICINE REPORT TO CONGRESS (2001), http://armtelemed.org/resources/24-US_DHHS_TM_report-to-congress_2001.pdf [<https://perma.cc/PKB5-YP5H>].

9. See, e.g., Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems, 80 Fed. Reg. 75817 (Dec. 4, 2015), <http://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30591.pdf> (increasing and making permanent federal funding for states to use information technology to administer Medicaid eligibility and enrollment); *Optimizing Medicaid Enrollment: Spotlight on Technology*, HENRY J. KAISER FAM. FOUND. (July 30, 2010), <http://kff.org/health-reform/report/optimizing-medicaid-enrollment-spotlight-on-technology/> [<https://perma.cc/9TFF-VLYB>] (observing that the ACA increased pressure for administrative

Given medical technologies' diversity and pervasiveness, it is challenging to articulate one satisfying answer to questions posed by this symposium, which assumed that technology must have a positive impact on medicine ("Prognosis Positive: The Revolutionary Impact of Technology on Healthcare").¹¹ Technology is not, however, always a positive force in medicine or anywhere else.

Thus, this Article will address a topic adjacent to the writing of medical technology experts.¹² Rather than address the value of medical technology on its own terms, this Article considers whether medical technologies facilitate or hinder the new principle of universality in health care. The norm of universality was enacted as federal policy through the Patient Protection and Affordable Care Act (ACA),¹³ and it is an especially important principle for low-income Americans, whose interests historically were not well represented in medicine, health care law, or health care policy.¹⁴ The universality principle presented a new trajectory that made all Americans insurable and able to obtain insurance.¹⁵ Universality ended reliance on individual qualifiers, such as individual risk rating, parental status, and income, and is grounded by leveling concepts, such as required community rating in private insurance and open eligibility for Medicaid in public insurance.¹⁶ The ACA eliminated widespread discriminatory practices and provided financial assistance to those otherwise unable to become insured—a democratizing federal act that was intended to set the tone for health care policy nationwide.¹⁷

This Article posits that medical technology can be universalizing or exclusionary and that this status roughly correlates to being called "instrumental technology" or "transformative

simplicity and streamlining in Medicaid enrollment and providing links to states' experiments using technology to improve enrollment efforts).

10. See *Interactive State Report Map*, APCD COUNCIL, <https://www.apcdouncil.org/state/map> [https://perma.cc/6EU8-FS6S] (last visited Dec. 3, 2015). Whether this type of data collection can be required of all health insurers, including self-insured employers, was decided by the Supreme Court. See *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 947 (2016) (states' all-payer claims databases are preempted by ERISA when self-insured employers are required to submit information like any other insurer).

11. Symposium, *Prognosis Positive: The Revolutionary Impact of Technology on Healthcare*, 19 VAND. J. ENT. & TECH. 101 (2016).

12. This Author would like to convey that she is not a medical technology expert.

13. Patient Protection and Affordable Care Act, 124 Stat. 119; see Huberfeld, *supra* note 4, at 68.

14. See Huberfeld, *supra* note 4, at 68.

15. See *id.*

16. See *id.* at 68; Nicole Huberfeld & Jessica Roberts, *Health Care and the Myth of Self-Reliance*, 57 B.C. L. REV. 1 (2016) (discussing the leveling aspects of the ACA).

17. See Huberfeld, *supra* note 4, at 69, 73.

technology,”¹⁸ which this Article explains for the first time. This Article defines instrumental technology as technology that acts as a tool of medicine and often serves an existing aspect of health care. Instrumental technology can generally be thought of as a means to an end. In contrast, this Article defines transformative technology as technology that is radical or pioneering, meaning it creates a new service or device or otherwise is novel in approach or in reach.¹⁹ Instrumental and transformative medical technologies provide two end points on a continuum rather than opposing sides of a bright line, reflecting the changeable quality of technology itself.

This spectrum provides a lens through which to examine whether medical technology has greater potential to facilitate universality or exclusion in health care. Given the strong principle of universality now underlying health care finance and access, the question is what role medical technologies play relative to the rest of health care in a post-ACA world. Arguably, the most common form of government support for medical care is funding, which can facilitate new technologies and the dispersal of established technologies.²⁰ The ACA indicates that both private and public insurance now cover all lives, but this also means making harder choices in terms of supporting more expensive or experimental technologies through health care finance.²¹ Regulatory schemes can also direct medical

18. Professor Christensen uses the terms “disruptive innovation” and “sustaining innovation” to describe the effect of breakthroughs in the business world that “disrupt” the market of existing, successful businesses. This Author is not interested in invoking that distinction, which does not get at the heart of this Article. Here, the Author is interested in what medical technology does as it organically morphs from transformative to instrumental and whether it makes medicine more or less democratic. This Author does not agree with the assertions in *The Innovator’s Prescription* that the market will cure all medical delivery and accessibility issues if only innovation is allowed to disrupt the overly regulated marketplace. See generally, THE INNOVATOR’S PRESCRIPTION, *supra* note 3.

19. This is a broader concept than transformative drugs, which seems to mean “offering substantial improvements in patient outcomes over existing therapeutics.” Shuai Xu & Aaron S. Kesselheim, *Medical Innovation Then and Now: Perspectives of Innovators Responsible for Transformative Drugs*, 42 J.L. MED. & ETHICS 564 (2014).

20. Unsurprisingly, when Medicare decides to pay for a new item or service, private insurers often follow that lead, which in turn increases access to that new technology. See, e.g., Julia Adler-Milstein, Joseph Kvedar & David W. Bates, *Telehealth Among US Hospitals: Several Factors, Including State Reimbursement and Licensure Policies, Influence Adoption*, 33 HEALTH AFF. 207 (2014), <http://content.healthaffairs.org/content/33/2/207.short>.

21. See JAMES C. ROBINSON, PURCHASING MEDICAL INNOVATION: THE RIGHT TECHNOLOGY FOR THE RIGHT PATIENT, AT THE RIGHT PRICE 14 (2015) (suggesting that insurers should rely more on physician discretion, and that they should err on the side of encouraging “conservative rather than aggressive use” of new technologies in medicine).

technology by shuttling it into a distribution path, which in turn can impact access.²²

In Part I, this Article will examine where technologies fit on the instrumental-transformative continuum. Part II will consider measures more specific to universality, namely improving the quality of medical care, access to care, or the cost of care. These bedrock considerations for improving health care help to pinpoint the moment at which a technology may have a universalizing effect, if at all. Part III concludes with preliminary thoughts on how the instrumental-transformative continuum may help to determine whether certain technologies should be adopted or supported publicly or allowed to develop organically in more Darwinian private markets.

II. A CONCEPT OF INSTRUMENTAL AND TRANSFORMATIVE TECHNOLOGIES

Instrumental and transformative technologies exist throughout the health care industry and include numerous items and services. These include telemedicine,²³ electronic medical records (EMR),

22. For example, categorizing a new drug as available only by prescription limits access to the drug, and typically increases its cost, but classifying it as over-the-counter increases access and decreases cost (thanks to Nicolas P. Terry for the example).

23. The Centers for Medicare and Medicaid Services (CMS) defines telemedicine thus:

For purposes of Medicaid, telemedicine seeks to improve a patient's health by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site. This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and video equipment. Telemedicine is viewed as a cost-effective alternative to the more traditional face-to-face way of providing medical care (e.g., face-to-face consultations or examinations between provider and patient) that states can choose to cover under Medicaid. This definition is modeled on Medicare's definition of telehealth services (42 C.F.R. § 410.78). Note that the federal Medicaid statute does not recognize telemedicine as a distinct service.

Telemedicine, MEDICAID.GOV, <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html> [<https://perma.cc/AW9X-KHL3>] (last visited Dec. 1, 2016).

CMS distinguishes telehealth:

Telehealth (or Telemonitoring) is the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance.

Telehealth includes such technologies as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices, which are used to collect and transmit patient data for monitoring and interpretation. While they do not meet the Medicaid definition of telemedicine they are often considered under the broad umbrella of telehealth services. Even though such technologies are not considered "telemedicine," they may nevertheless be covered and reimbursed as part of a Medicaid coverable service, such as laboratory service, x-ray service or physician services...

electronic health records (EHR),²⁴ and other health information technology (HIT).²⁵ Other common technologies include mobile health,²⁶ health insurance exchanges (HIX),²⁷ big data,²⁸ and diagnostic and therapeutic technologies, including medical devices, biologics, cell therapies, and other alterations to the human body or its components.²⁹ This diverse inventory reflects medical technologies' quick infiltration of the health care industry in recent history.

Many of the items and services listed in the prior paragraph started as transformative and have become instrumental over time. Transformative technologies, given their novelty, are likely to be

Id.; see also Bill Marino, Roshen Prasad & Amar Gupta, *A Case for Federal Regulation of Telemedicine in the Wake of the Affordable Care Act*, 16 COLUM. SCI. & TECH. L. REV. 274, 277 (2015) (defining telemedicine as "the treatment of patients by doctors remotely, with the aid of technology" and advocating for federal law to facilitate its uniform growth).

24. According to the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC), EMR is a narrower concept than EHR. See Peter Garrett & Joshua Seidman, *EMR vs EHR – What Is the Difference?*, HEALTHITBUZZ (Jan. 4, 2011), <http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/> [<https://perma.cc/68UX-QN3V>] (defining EMR as the patient's medical record, the same information that physicians have always logged upon evaluating a patient but electronic rather than paper, whereas EHR embodies a broader concept of record keeping and sharing). For simplicity's sake, this Author will use the term EHR in this Article to refer to both EMR and EHR.

25. Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information*, 72 MD. L. REV. 682, 687 (2013) (calling for a new field of health information law to develop); see also Mark A. Rothstein & Gil Siegal, *Health Information Technology and Physicians' Duty to Notify Patients of New Medical Developments*, 12 HOUS. J. HEALTH L. & POL'Y 93, 103–06 (2012) (discussing forms of HIT and how HIT can make the physician's duty to warn more readily executable); Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7, 8 (2013) (describing EMR as a facet of HIT); Nicolas P. Terry, *Information Technology's Failure to Disrupt Health Care*, 13 NEV. L.J. 722, 723 (2013) (analyzing why health information technology and technology in general have been slow to catch on in medicine).

26. Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1173 (2014) (describing the phenomenon of mobile health, sounding a cautionary note, and calling for greater oversight).

27. See, e.g., 78 Fed. Reg. 8538 (Feb. 6, 2013) (publishing notice of new system of "records titled, 'Health Insurance Exchanges (HIX) Program,' to support the CMS Health Insurance Exchanges Program established under provisions of the Affordable Care Act . . .").

28. See John D. Halamka, *Early Experiences with Big Data at an Academic Medical Center*, 33 HEALTH AFF. 1132 (2014) (defining big data as "a large collection of disparate data sets that, taken together, can be analyzed to find unusual trends"); see also Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 77 (2011) (considering the propertization of data and weighing individual against collective interests in big data); John G. Francis & Leslie Francis, *Introduction: Technology and New Challenges for Privacy*, 45 J. SOC. PHIL. 291 (2014) (discussing privacy and confidentiality issues that arise in collecting large sets of data from patients and advocating for the ethical principle of justice to be incorporated into big data collection and use); Mark A. Rothstein, *Ethical Issues in Big Data Research*, 43 J.L. MED. & ETHICS 425 (2015) (building on this definition of big data to draw an ethical analogy to traditional biomedical research).

29. See generally W. Nicholson Price, II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419 (2015) (discussing the high technology advances in medicine that allow personalization).

expensive and available only to the privileged.³⁰ The more pervasive a medical technology becomes, the greater access it may both experience and create, indicating that a relationship exists between the instrumentalization of a technology and its democratization. In other words, technologies that begin as transformative and exclusive can become instrumental and universalizing.

Consider examples from the aforementioned medical technologies to illustrate the above point. When telemedicine was introduced, it was radical in concept and in execution. Video conferencing was the stuff of science fiction; it was expensive and unobtainable except for those with the best computers and related equipment, including connected video cameras and relatively fast forms of early Internet connections. Monitoring patients' vital signs from afar was nearly impossible. Medical images, such as ultrasounds or x-rays, could only be seen in person, typically on film, and sharing images meant mailing a hard copy from one office or hospital to another. Now, in contrast, video conferencing is regularly used in homes and businesses across the nation and the world, frequently through inexpensive or free conferencing services.³¹ Most mobile phones and computers contain a built-in camera as a standard feature, and wireless connection to the internet is freely available in many public spaces and is relatively cheap in homes and businesses. Medical images are digitized and often transmitted from one computer terminal, tablet, or mobile device to another; the "internet of things" increases and extends this connectivity.³²

Each of these technological advances facilitated the three most common uses of telemedicine: teleconferencing as a form of office visit, monitoring chronic conditions and medical compliance, and transmitting images or data.³³ Each of these actions is a common

30. See, e.g., Daniel Callahan, *Health Care Costs and Medical Technology*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 79–82 (Mary Crowley ed., 2008) (explaining why medical technology increases medical costs); R. Krishna Kumar, *Technology and Healthcare Costs*, 4 ANNALS OF PEDIATRIC CARDIOLOGY 84 (2011) (arguing that technology increases health care costs and is not accessible to many patients).

31. See *What About Telemedicine?*, AM. TELEMEDICINE ASS'N, <http://www.americantelemed.org/about/about-telemedicine> [<https://perma.cc/2K3E-SSWQ>] (last visited Oct. 26, 2016).

32. See Daniel Burrus, *The Internet of Things Is Far Bigger Than Anyone Realizes*, WIRED, <http://www.wired.com/insights/2014/11/the-internet-of-things-bigger/> [<https://perma.cc/R6X8-9MPJ>] (last visited Oct. 26, 2016) (discussing how the "internet of things" works and how extensive its connections and uses could be).

33. See Lisa Schmitz Mazur & Amy Gordon, *Is Telemedicine the Potential Solution to the Looming 'Cadillac Tax' and to Improving Employee Health?*, 24 BNA HEALTH L. REP. 1682 (2015) (discussing employer use of the three aspects of telemedicine to keep costs lower than the "Cadillac tax" trigger point).

medical service, extended by the instrument of telemedicine. Telemedicine enhances a doctor or nurse's reach and is a provider's tool for offering skills and services; it is widely available throughout the nation, reimbursed by public and private insurers, and inexpensive to use.³⁴ The most common telemedicine services are reimbursed by Medicare and Medicaid, a fact that offers indirect evidence of common acceptance in medical practice and supports the notion that telemedicine has transitioned from a transformative to an instrumental technology.³⁵

Consider a second example, EHR, which has an arc similar to telemedicine's. HIPAA is thought of as a privacy law, but its original objective was to construct national standards for portability of health insurance from one job to the next and electronic exchange of health insurance forms.³⁶ In 1996, the technology to create electronic exchange of health insurance forms was expensive and largely elusive: email was not routine, computers were not pervasive, and Internet connectivity was slow or unavailable. Fast forward to 2016, when the equipment has become commonplace. Virtually all businesses and many homes contain computers, and many doctors and hospitals use computers or tablets for tracking patient data and accessing reference materials.³⁷ In 2009, Congress created new

34. See, e.g., Steff Deschenes, *Five Ways Telemedicine Is Driving Down Healthcare Costs*, HEALTHCAREITNEWS (July 16, 2012, 10:29 AM), <http://www.healthcareitnews.com/news/5-ways-telemedicine-driving-down-healthcare-costs> [<https://perma.cc/XXJ3-2LLD>]; Laurence C. Baker et al., *Integrated Telehealth and Care Management Program for Medicare Beneficiaries with Chronic Disease Linked to Savings*, 30 HEALTH AFF. 1689 (2011).

35. See 42 C.F.R. § 410.78 (defining telehealth services that Medicare will reimburse); Centers for Medicare and Medicaid Services, *Telemedicine*, MEDICAID.GOV, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html> [<https://perma.cc/LJ8M-BWTC>] (last visited Jan. 15, 2016) (explaining telehealth and Medicaid's reliance on Medicare's definitions of telehealth). CMS states, "Note that the federal Medicaid statute does not recognize telemedicine as a distinct service." *Id.* CMS considers telemedicine and telehealth to be related but different services.

36. Health Insurance Portability and Accountability Act, Pub. L. No. 104-91 (1996); 45 C.F.R. §§ 164.500-164.534 (2009); Nicolas P. Terry, *What's Wrong with Health Privacy?*, 5 J. HEALTH & BIOMEDICAL L. 1 (2009) (detailing HIPAA's history and attendant problems).

37. An important exception is low-income individuals; research shows that people earning the least are also the least likely to have access to the Internet or to own home computers, a phenomenon called the "digital divide." See Kathryn Zickuhr & Aaron Smith, *Digital Differences*, PEW RES. CTR. (Apr. 13, 2012), <http://www.pewinternet.org/2012/04/13/digital-differences/> [<https://perma.cc/53DJ-HP92>]. That report noted that the digital divide is changing because internet access is not tied to computer ownership like it was fifteen years ago. The report stated internet access is no longer synonymous with going online with a desktop computer:

- Currently, 88 percent of American adults have a cell phone, 57 percent have a laptop, 19 percent own an e-book reader, and 19 percent have a tablet computer; about six in ten adults (63 percent) go online wirelessly with one of those devices. Gadget ownership is generally correlated with age, education, and household income, although some devices—notably e-book

financial incentives to encourage EHR adoption and interoperability standards, implicitly recognizing that the technology that facilitates EHR has moved from transformative to instrumental over the last twenty years.³⁸

Telemedicine and EHR sit on the instrumental end of the medical technology spectrum. They exhibit key features: they are not experimental, not radical, and not expensive to execute. They are common technologies that are easily accessed or easily constructed for those who want to use them. They contain some start-up costs, but their costs typically dissipate on a short time horizon. They facilitate access to health care and communication between and among health care providers and patients.

Consider a third example that sits closer to the middle of the spectrum: the federal and state HIX created by the ACA. HIX are similar to travel websites that search airlines for a particular flight path or hotels for open rooms on certain dates and times, but the industry underlying HIX is more complex and highly regulated.³⁹ HIX are not typically considered medical technology. Given their use of computer technology to create and facilitate access to health insurance through digital clearinghouses, however, HIX fit under the medical technology umbrella as a form of modern technology that has the power to increase health insurance enrollment, which in turn could improve access to care.

The task of building the HIX was substantial, and it cost the federal government hundreds of millions of dollars to implement its own exchange and to encourage states to create theirs.⁴⁰ Some states

readers and tablets—are as popular or even more popular with adults in their thirties and forties than young adults ages 18–29.

- The rise of mobile is changing the story. Groups that have traditionally been on the other side of the digital divide in basic internet access are using wireless connections to go online. Among smartphone owners, young adults, minorities, those with no college experience, and those with lower household income levels are more likely than other groups to say that their phone is their main source of internet access.
- Even beyond smartphones, both African Americans and English-speaking Latinos are as likely as whites to own any sort of mobile phone and are more likely to use their phones for a wider range of activities.

Id.

38. Health Information Technology for Economic and Clinical Health Act, Title XIII of American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5.

39. See HEALTHCARE.GOV, <https://www.healthcare.gov> (last visited Oct. 26, 2016). Common examples include EXPEDIA, <https://www.expedia.com> (last visited Oct. 26, 2016) and TRAVELOCITY, <https://travelocity.com> (last visited Oct. 26, 2016).

40. The cost of the federal exchange is difficult to pin down, but one source indicates \$834 million as of February 2014. See *Testimony of Sylvia M. Burwell, Nominee for Secretary of United States Department of Health and Human Services: Hearing on the Nomination of the Secretary of Health and Human Services-Designate, Sylvia Matthews Burwell Before the S.*

failed, and some did not choose to create their own exchanges.⁴¹ The difficult start was not because the technology itself was transformative—this kind of database was transformative a decade ago when Massachusetts originated statewide universal health insurance coverage and created the “Connector,” a predecessor to HIX.⁴² Rather, the work was substantial because the elements of the HIX existed in one state under that state’s particular regulatory regime, and other governmental actors had not created this type of database with federal regulatory elements before the ACA.⁴³ Gathering and compiling the qualified health plans in one place, on-line, meeting all regulatory standards and being able to screen all purchasers for their individual qualifications (i.e., eligibility for tax credits or for Medicaid), was a large task, but transformative only in terms of purchasing health insurance. The philosophy behind creating HIX, allowing direct governmental intervention in private insurance markets, could be deemed transformative, but that is a function of the law rather than technology. In other words, the technology *itself* was not transformative. HIX is instrumental technology that enables universal health insurance coverage, which is a transformative health policy concept, but not transformative medical technology. It is a tool for health insurance regulatory and purchasing mechanisms, not a novel technology that alters medical items or services.

The three prior examples illustrate elements of instrumental medical technology. An example of transformative technology aids in finding the other end of the spectrum. Consider gene therapy, a highly specialized, complex procedure that provides individualized treatment and has the potential to treat diseases deemed incurable by

Comm. on Health, Educ., Labor and Pensions, 113th Cong. (2014) (testimony of Sylvia Matthews Burwell, Nominee for Secretary United States Department of Health and Human Services).

41. The federal government offered states grants to create their own exchanges, and some states floundered at the opening of their exchanges for January 1, 2014 implementation of the ACA’s insurance precepts. See, e.g., Kyle Cheney & Jennifer Haberkorn, *\$474M for 4 Failed ACA Exchanges*, POLITICO (May 30, 2014), <http://www.politico.com/story/2014/05/obamacare-cost-failed-exchanges-106535> [<https://perma.cc/X5KJ-6B7W>] (discussing the failed opening of the Massachusetts, Oregon, Nevada and Maryland exchanges; Oregon has switched to the federal exchange, but the other states made their exchanges work).

42. See *History: Massachusetts: The Model for National Health Care Reform*, MASS. HEALTH CONNECTOR, <https://www.mahealthconnector.org/about/policy-center/history> [<https://perma.cc/XS6U-TSME>] (last visited Oct. 26, 2016); see also *State Marketplace Profiles: Massachusetts*, HENRY J. KAISER FAM. FOUND., <http://kff.org/health-reform/state-profile/state-exchange-profiles-massachusetts> [<https://perma.cc/9FBL-VQ7D>] (last visited Oct. 26, 2016) (describing the Massachusetts Connector as the model for the federal HIX).

43. The Massachusetts Health Connector was established by Massachusetts law in 2006. See *History: Massachusetts: The Model for National Health Care Reform*, *supra* note 42.

altering mutated genes in an individual.⁴⁴ Gene therapy suffered biomedical and ethical setbacks in its earliest stages.⁴⁵ Despite nearly two decades of research, gene therapy remains far from being a real treatment option for most of the population and is still considered experimental.⁴⁶ It is prohibitively expensive; only patients with the best, most advanced care and the greatest ability to pay for medical expenses can obtain it, unless patients are willing to participate as subjects in a research trial.⁴⁷ Companies that own the rights to gene therapies are setting the price for treatment as high as one million dollars.⁴⁸ Even if payments were spread over time, the average American could not afford it. Health insurers tend to plan on short timelines assuming that most enrollees will be in a new plan within a few years, classically called the “revolving door” of health insurance.⁴⁹ This mindset would bar payment for such costly, individualized treatments, even if an insurer is paying hundreds of thousands of dollars for other forms of care for chronically ill individuals. Medicare and Medicaid may pay for some genetic testing, if related to determining the best course of treatment for, say, a person with genetically inherited cancer, but public health care programs do not reimburse gene therapy.⁵⁰

Though a somewhat extreme example, gene therapy helps to tease out features of transformative medical technologies. Such features include: the technology is radically different from existing therapies, drugs, or other medical items and services; it may treat inherited orphan diseases (such as thalassemia) or otherwise untreatable inherited diseases or conditions (such as hemophilia or

44. See *What Is Gene Therapy?*, NAT'L INST. OF HEALTH NAT'L LIBR. OF MED., <https://ghr.nlm.nih.gov/primer/therapy/genetherapy> [<https://perma.cc/QUS4-YKQK>] (last visited Oct. 25, 2016).

45. See, e.g., Carolyn Y. Johnson & Brady Dennis, *Gene Therapies Offer Dramatic Promise but Shocking Costs*, WASH. POST (Nov. 11, 2015), https://www.washingtonpost.com/business/economy/gene-therapies-offer-dramatic-promise-but-shocking-costs/2015/11/11/01f11cf0-824b-11e5-9afb-0c971f713d0c_story.html?hpid=hp_rhp-more-top-stories_no-name%3Ahomepage%2Fstory [<https://perma.cc/FWQ6-CNJM>] (reporting some gene therapies could cost in the millions of dollars).

46. *What Is Gene Therapy?*, *supra* note 44.

47. See Johnson & Dennis, *supra* note 45.

48. Chris Morrison, *\$1-Million Price Tag Set for Glybera Gene Therapy*, NATURE.COM (Mar. 3, 2015, 12:32 AM), <http://blogs.nature.com/tradesecrets/2015/03/03/1-million-price-tag-set-for-glybera-gene-therapy> [<https://perma.cc/6QFZ-4T7D>] (discussing prices being set for new gene therapies).

49. See, e.g., R.O. Morgan et al., *The Medicare-HMO Revolving Door--The Healthy Go in and the Sick Go Out*, 337 NEW ENG. J. MED. 169 (1997).

50. See STUART WRIGHT, COVERAGE AND PAYMENT FOR GENETIC LABORATORY TESTS, OEI-07-11-00011, at 2 (2012), <http://oig.hhs.gov/oei/reports/oei-07-11-00011.pdf> [<https://perma.cc/2K95-KZFL>].

certain cancers); or it may facilitate understanding medical information that was indecipherable before the technology existed (big data). The cost of transformative medical therapies is generally high, and insurers almost certainly consider them experimental and thus excluded from coverage.

One way to think about medical technologies' role in universal health coverage is to place them on the instrumental-transformative continuum. This brief discussion highlighted the potential for transformative technologies to become instrumental and the difference between the two. It also indicated that instrumental technologies are more likely to be universalizing because they are easy to access, inexpensive, and facilitate better care. In short, instrumental technologies tend to facilitate universality, while transformative technologies tend to be exclusionary by virtue of their cost, complexity, and general inaccessibility. The hardest question may be when the tipping point occurs between the two.

III. UNIVERSALITY AND MEDICAL TECHNOLOGY

Universality can emerge through different dimensions of health care, such as improving the quality of medical care, expanding access to medical care, or decreasing the cost of care for large portions of the population. The ACA attempts all of these improvements to American health care, though arguably the greatest effort is spent on increasing access to care through universal insurance coverage.⁵¹ Medical technologies could fit within this set of measures by decreasing the invasiveness of a widely used treatment, preventing or treating conditions that affect wide swaths of the population, improving quality of life for individuals with chronic conditions, or improving access for those with difficulty finding medical care in a geographic location.

The question is whether to encourage or support medical technologies given that cost is always a concern in health care—and perhaps even more so in the era of universal coverage.⁵² If technologies should be encouraged, a straightforward mechanism for policy entrenchment exists in the Spending Power, one of Congress's

51. See Huberfeld & Roberts, *supra* note 16, at 3.

52. See generally Ann Marie Marciarille & J. Bradford DeLong, *Bending the Health Cost Curve: The Promise and Peril of the Independent Payment Advisory Board*, 22 HEALTH MATRIX: J.L. & MED. 75 (2012) (discussing the fact that the cost of health care is a longstanding policy concern in the United States); see also Reed Abelson, *Cost, Not Choice, Is Top Concern of Health Insurance Customers*, N.Y. TIMES (Aug. 12, 2016), http://www.nytimes.com/2016/08/13/business/cost-not-choice-is-top-concern-of-health-insurance-customers.html?_r=0 [<https://perma.cc/FKY5-BDTK>].

most powerful tools for encouraging implementation of federal policy goals.⁵³ Wielding this power, Congress has created public insurance like Medicare and Medicaid,⁵⁴ facilitated employer-sponsored health insurance coverage through tax policy,⁵⁵ encouraged development of new drugs by providing grants for clinical research,⁵⁶ facilitated family planning through grants to clinics and health care providers,⁵⁷ and other far-reaching medical policies. The states, too, can encourage developments in medical policy. For example, some states have chosen to fund stem cell research when presidential policies dictated otherwise.⁵⁸ But the ACA encourages thinking broadly and nationally about medical policy, and federal spending legislation is a principal mechanism for such policymaking.⁵⁹

A harder question is where in the transition from transformative to instrumental funding should be wielded to support technologies, if at all. One possibility is to evaluate the chances that the transformative technology will become an instrumental technology through existing channels without regulatory or financial encouragement and to adopt such technologies when they are least expensive and most useful to patients. Theranos, the tech start-up that attempted to design a simplified and cheaper blood testing mechanism, provides a recent example for considering whether supporting transformative medical technologies holds potential for furthering universality.

Theranos sought to create a blood test that could be conducted at home, with a pinprick's amount of blood, that would cost a fraction

53. U.S. CONST. art. I, § 8, cl. 1.

54. 42 U.S.C. § 1395 (2012) (Medicare); 42 U.S.C. § 1396 (2012) (Medicaid).

55. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

56. See *Funding*, NAT'L INSTS. OF HEALTH, <http://grants.nih.gov/funding/index.htm> [<https://perma.cc/2WX4-AS5D>] (last visited Mar. 23, 2016).

57. Title X of the Public Health Service Act, Population Research and Voluntary Family Planning Programs, Pub. L. 91-572 (1970). As HHS states, "Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services." *History of Title X*, DEP'T. OF HEALTH AND HUM. SERVS., <http://www.hhs.gov/opa/title-x-family-planning/> [<https://perma.cc/8VWP-YG65>] (last visited Oct. 25, 2016).

58. JUDITH A. JOHNSON & ERIN D. WILLIAMS, STEM CELL RESEARCH: STATE INITIATIVES 2 (2006), <https://stemcells.nih.gov/staticresources/research/GW-State-Funding.pdf>.

59. This is true even after *National Federation of Independent Business v. Sebelius*, in which the Supreme Court, by a plurality, recognized a constitutional doctrine of coercion. 132 S. Ct. 2566, 2602 (2012). In fact, the Court cited approvingly prior precedent upholding the conditional spending power and delineating how it can be used. See *id.* Though the spending power may be limited in other ways after *NFIB v. Sebelius*, it does not appear to be limited for the policymaking purposes discussed herein. See generally Nicole Huberfeld, Elizabeth Weeks Leonard & Kevin Outterson, *Plunging into Endless Difficulties: Medicaid and Coercion in National Federation of Independent Business v. Sebelius*, 93 B.U. L. REV. 1 (2013).

of current blood tests.⁶⁰ If Theranos had achieved this mission, the technology would have been transformative. No medical device exists that can take a few drops of blood (as opposed to many vials) to run the full range of laboratory diagnostics.⁶¹ Though the Theranos technology remains elusive, and the company got into regulatory trouble, if successful, it would have transformed the field of blood testing, which is the lucrative backbone of most diagnostic work.⁶² It would have made field testing much easier and cheaper (especially important in the event of an epidemic), and it could have made such private matters as testing for sexually transmitted infections easier to perform in the privacy of the home. These would be transformative steps in diagnostic medical technology.

Theranos also provides a cautionary tale of a transformative technology that crashed into regulatory hurdles designed to prevent fraud on unsuspecting consumers of medical products. The company allegedly neglected Food and Drug Administration regulations pertaining to medical devices, and its testing system seems to run inaccurate laboratory results.⁶³ The company's loose approach to regulatory superstructure led the Centers for Medicare and Medicaid Services to sanction Theranos.⁶⁴ These details are headline grabbing, but the larger question is whether existing finance mechanisms and regulatory regimes can position technology like this to safely transition from transformative to instrumental and thus to be democratized.

In other words, we could ask whether the Theranos technology will improve medical care, or access to care, or payment for care. The answer to all three questions is yes, but only if it is assumed that

60. THERANOS, <https://www.theranos.com> (last visited Oct. 5, 2016).

61. Robert Parloff, *This CEO Is out for Blood*, FORTUNE (June 12, 2014), <http://fortune.com/2014/06/12/theranos-blood-holmes/> [<https://perma.cc/7S79-USSA>].

62. Reed Abelson & Julie Creswell, *Theranos Founder Faces a Test of Technology, and Reputation*, N.Y. TIMES (Dec. 19, 2015), <http://www.nytimes.com/2015/12/20/business/theranos-founder-faces-a-test-of-technology-and-reputation.html> [<https://perma.cc/NBU4-GFKR>] (detailing the rise of Theranos and its technology's setbacks). In fact, lab testing is so lucrative that physicians started to own clinical laboratories and refer their patients to them; concern over such self-referrals led to passage of the Ethics in Patient Referrals Act, known commonly as the "Stark Law." 42 U.S.C. § 1395nn (2012).

63. John Carreyrou, *Hot Startup Theranos Has Struggled with Its Blood-Test Technology*, WALL ST. J. (Oct. 16, 2015, 3:20 PM), <http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901> [<https://perma.cc/9QSN-74EA>].

64. See *Theranos and Its CEO Slapped with CMS Sanctions*, GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS (July 8, 2016), <http://www.genengnews.com/gen-news-highlights/theranos-and-its-ceo-slapped-with-cms-sanctions/81252928/> [<https://perma.cc/D9FZ-5Y89>]; Beth Jones Sanborn, *Theranos Appeals Sanctions Imposed by Centers for Medicare and Medicaid Services*, HEALTH CARE FIN. (Aug. 26, 2016), <http://www.healthcarefinancenews.com/news/theranos-appeals-sanctions-imposed-centers-medicare-and-medicaid-services> [<https://perma.cc/5ZT6-5DEB>].

Theranos's assertions are true. The Theranos website proclaims: "The lab test, reinvented. We believe the future of health care lies in greater access for the individual. So we built a better lab experience with access in mind, making it easier than ever for you to engage with your health early and at the time it matters most"65 If accurate, this would have provided an example of transformative technology that could and should quickly become instrumental, which would push toward government supports at the moment where the technology can make that transition.

The reason for contemplating public support through funding is that this is the type of transformative medical technology that facilitates universality. This Article does not endorse any medical technology specifically, but rather, considers the model of transformative technology that such companies represent. A transformative technology that changes a fundamental aspect of basic medical diagnostics—making it easier on the patient in terms of pain, time, and cost, less expensive for payors, and easier for doctors to obtain key diagnostic information—is the kind of transformative technology that could quickly become instrumental and would serve the goals of universality.

Knowing whether a medical technology is transformative or instrumental can offer an indicator as to whether certain technologies are worthy of support through finance, regulatory mechanisms, or other forms of adoption through payment or encouragement for innovation. An inquiry into whether the technology could improve medical care, access to care, or payment for care helps a technology to be more fully analyzed for its universalizing effect, which in turn could trigger an understanding of desirable regulatory or financial supports.⁶⁶

IV. CONCLUSION

Technologically improved health care often comes at a high cost that only increases over time;⁶⁷ to be wary of medical technology is to

65. THERANOS, *supra* note 60.

66. See ROBINSON, *supra* note 21, at 9 (encouraging growth of medical technology and innovation through four stages of value-based purchasing, "regulatory market access, insurance coverage, care delivery, and patient engagement"). One possible model for this is the National Institute for Health and Care Excellence, part of the British National Health Service (NHS), which uses complex algorithms for determining whether medical technologies will be adopted by NHS. See *Guide to the Processes of Technology Appraisal*, NAT'L INST. FOR HEALTH AND CARE EXCELLENCE (Sept. 2, 2014), <https://www.nice.org.uk/article/pmg19/chapter/1-introductionPMG19> [<https://perma.cc/8JKC-5Z3W>].

67. *Snapshots: How Changes in Medical Technology Affect Health Care Costs*, HENRY J. KAISER FAM. FOUND. (Mar. 2, 2007), <http://kff.org/health-costs/issue-brief/snapshots-how->

recognize the low benefit that many new technologies present to most patients.⁶⁸ Yet, as technology becomes more integral to health care, the instrumental-transformative continuum may help dissect choices about whether certain technologies should be adopted or supported publically, or allowed to develop organically in more Darwinian private markets. The substance of those technologies and the effect they will have on quality of care, access to care, and cost of care are important characteristics in placing technologies on the continuum and then considering whether they can improve universal access to or distribution of medical care in a system with limited resources and an increased sense of broad-based policymaking.

changes-in-medical-technology-affect/ [https://perma.cc/YE5S-UQE2] (discussing the tendency of medical technology to drive costs up rather than down); Daniel Callahan, *Health Care Costs and Medical Technology*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 79–82 (Mary Crowley, ed. 2008), http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/health%20care%20costs%20chapter.pdf (ascribing steadily increasing costs of medical care to medical technology); Corinna Sorenson, Michael Drummond & Beena Bhuiyan Khan, *Medical Technology as a Key Driver of Rising Health Expenditure: Disentangling the Relationship*, CLINICOECONOMICS AND OUTCOMES RES. 223–34 (2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3686328/pdf/ceor-5-223.pdf> [https://perma.cc/86XA-WRC9] (refuting that all technology increases the cost of medical care and calling for a textured consideration of the costs of medical technology).

68. See ROBINSON, *supra* note 21, at 2 (describing “new drugs, devices, diagnostics, and procedures” as the root of increasing health care costs, even as they improve the quality of care).

