INFORMATION TECHNOLOGY'S FAILURE TO DISRUPT HEALTH CARE*

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I. INTRODUCTION

In 2001, the Institute of Medicine cut to the chase. Its canonical *Crossing the Quality Chasm* argued that information technologies (IT) "must play a central role in the redesign of the health care system if a substantial improvement in health care quality is to be achieved during the coming decade."[1] Three years later, President Bush made his optimistic commitment that, "[w]ithin 10 years, every American must have a personal electronic medical record."[2] In 2005, an oft-cited RAND study estimated that $80 billion per year would be saved with a ninety-percent adoption of electronic medical records (EMRs).[3] Yet, faced with a pitiful single-digit adoption rate for EMRs,[4] the Obama Administration

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[1] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 165 (2001).

[2] *Bush Announces New HHS Post to Facilitate Electronic Health Records*, AHA NEWS (Apr. 26, 2004), http://www.ahanews.com/ahanews/jsp/display.jsp?dcrpath=AHANEWS/AHANewsNowArticle/data/ann_040426_Bush&domain=AHANEWS.

[3] Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFF. 1103, 1107 (2005).

[4] Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1631 (2009) (finding that 1.5% of hospitals had a comprehensive electronic-records system and 7.6% had a basic electronic-records system).

found itself embarking on a $30 billion subsidy program designed to encourage providers to implement EMRs and other health care information technologies.[5]

Positive public relations material from the federal government argues that HIT (health information technology) adoption has reached a tipping point.[6] However, HIT still appears to be a large rock that only a few dedicated converts are pushing up a steep and expensive hill. A long tail of less than eager stragglers follows these converts with many of them making the journey solely in pursuit of government largesse.[7] In contrast, consumer-grade IT seems to surround and excite us. Consumers rightfully view IT-enabled or derived products and services, from smartphones and search engines to online banking and stock trading, as having transformed their lives.

Why has IT made only modest, non-disruptive inroads into health care? This question deserves careful scrutiny. There is every indication that U.S. health care is overdue for transformative disruption. After all, it is widely criticized for delivering mediocre care and quality to a shrinking percentage of the population with costs that are reaching crisis levels. Yet, at the same time, our largest industry is viewed as underutilizing IT.

This Article takes the position that the HIT space either shares or reflects the market failures of health care and that the modest attempts to correct HIT market failure, such as EMR subsidies, still leave us short of the inflection point. Leveraging Clayton Christensen's terminology, it suggests that today's health care technologies should be classified as the "sustaining technologies" of incumbents rather than examples of "disruptive technologies" that have upended incumbents in other domains.[8] It follows that in the absence of disruptive innovation, there will likely be continued build-out of sustaining technologies that may improve the quality of care but is unlikely to have any positive impact on the cost of or access to health care in the near future.

This Article examines four possible explanations for the difficulties faced by HIT in disrupting health care. First, while it is widely recognized that health care suffers from chronic market failure, the extent to which that phenomenon also applies to HIT may not be so widely appreciated. Second, HIT is not a good match for the current generation of health care that favors episodic rather than process-based care. HIT may be waiting for some major structural corrections to health care organizations (such as accountable care organizations) and remuneration. Third, IT's transformative abilities depend on its ability to innovate regarding the collection, processing, and sharing of data. However, health care lacks an amenable data standard. Fourth, the Article suggests that a truly disruptive HIT has yet to emerge. More optimistically, however, it goes on to

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[5] *See* Suzanne Felt-Lisk et al., *Toward Understanding EHR Use in Small Physician Practices*, 31 HEALTH CARE FINANCING REV. 11, 11 (2009).

[6] *See generally* David J. Brailer, *David Brailer and Farzad Mostashari: Two National Health IT Czars Compare Notes*, 31 HEALTH AFF. 475 (2012) (reviewing ten-year EMR adoption plan).

[7] Molly Merrill, *Survey Reveals Docs' Perceptions of EHRs as Potential Buyers, Users*, HEALTHCARE IT NEWS (Aug. 8, 2011), http://www.healthcareitnews.com/news/survey-reveals-docs-perceptions-ehrs-potential-buyers-users.

[8] CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL xv (1997).

argue that personal health technologies, exemplified by mobile platforms and their mobile medical apps, could develop to fill such a role.

Parts II, III, and IV explore the concept of disruption and Christensen's work, the promise and limitations of health care technologies, and the market failures that constrict the progress of health care and HIT. Part V examines the "waiting" phenomenon, inquiring whether the long-predicted HIT revolution is dependent on fundamental shifts in health care financing or delivery. Part VI examines whether the root cause of HIT failure may be our health care data model and draws a critical link between the iconoclastic 2010 report of the President's Council of Advisors on Science and Technology (PCAST)[9] on HIT failures and the demise of *Google Health*. Part VII, the final section of the Article, suggests that intrinsically disruptive mobile devices and mobile medical applications (apps) may turn out to be the first major success story of health care disruption by IT because they can disorder the high friction, embedded cost of location-specific medicine with a new model of "health care everywhere."

II. INCUMBENTS AND SUSTAINING TECHNOLOGIES

It is hard to find an analysis of U.S. health care that does not plead for transformation. Unfortunately, this makeover has proven to be a Herculean task. The Affordable Care Act contained just about every possible fix for our system, except the most politically difficult (such as the public insurance option[10]) or politically impossible (a single payer model[11]). Nevertheless, it proved to be a particularly divisive bundle of initiatives that barely survived a politicized challenge before the Supreme Court.[12]

Technology has long been viewed as having the potential to improve access to care. "Telemedicine" began in the early twentieth-century with what we would now call remote imaging or PACS (picture archiving and communications systems). By the 1950s, there were audio educational teleconferences, and by the 1960s, rudimentary telemedicine networks had added video, leading to the first remote consultations.[13] Tele-homecare has been awaited for almost a century as suggested in April 1924's *Radio News* cover story entitled, "The Radio Doctor—Maybe!"[14] Almost a century later, HIT routinely is hailed as transformative not only of access but also health care quality. Recently the

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[9] PRESIDENT'S COUNCIL OF ADVISORS ON SCI. AND TECH., REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD (2010), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf [hereinafter PCAST].

[10] *See, e.g.*, Paul Krugman, *Why the Public Option Matters*, N.Y. TIMES (Sept. 8, 2009, 4:56 PM), http://krugman.blogs.nytimes.com/2009/09/08/why-the-public-option-matters/.

[11] *See, e.g.*, William C. Hsiao, *State-Based Single-Payer Health Care—A Solution for the United States?*, 364 NEW ENG. J. MED. 1188, 1188 (2011).

[12] *See generally* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

[13] Travis Wheeler, *In the Beginning . . . Telemedicine and Telepsychiatry*, 2 TELEMEDICINE TODAY 2, 2, 4 (1994).

[14] INST. OF MED., *Evolution and Current Applications of Telemedicine*, *in* TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS IN HEALTH CARE 34, 36 (Marilyn J. Field ed., 1996), *available at* http://www.nap.edu/openbook.php?record_id=5296&page=R1; *see also The Radio Doctor—Maybe!*, RADIO NEWS, Apr. 1924, at 1406.

Institute of Medicine has argued: "Just as the information revolution has transformed many other fields, growing stores of data and computational abilities hold the same promise for improving clinical research, clinical practice, and clinical decision making."[15] Unfortunately, when there is great pressure for change, the potential for exaggerated claims and the likelihood of disappointed stakeholders also increase.

Health care fascinates technology experts and entrepreneurs because IT is generally well suited to solve problems of scale, complexity, and waste. For example, *The New New Thing* tells the story of Internet entrepreneur Jim Clark's *Healtheon*.[16] Clark's vision was to position *Healtheon* at the center of all health care transactions, eliminate paperwork (and hence waste), and extract profit from the savings.[17] As described by author Michael Lewis: "To [Clark's] way of thinking there were health care professionals who clearly served a purpose. They were called doctors. And there were people who clearly needed health care. They were called patients. Everyone else in between—the hundreds of billions in paperwork and bullshit—could go."[18] In the end Clark's vision was somewhat preempted by HIPAA's transactional makeover[19] and *Healtheon* was merged with the health portal WebMD.[20]

In summary, *Healtheon* failed to "disrupt" health care transactions. That term alludes to what Bower and Christensen labeled "disruptive technologies."[21] Such innovation is operationalized through disruptive technologies, which are not limited to IT and may include better processes, models, etc. In examining the concept of "disruptive innovation," the Christensen-led literature contrasts disruptive and sustaining technologies.[22] Disruptive technologies and resultant innovation "bring to a market a very different value proposition than had been available previously."[23] The disruptive innovation "theory holds that existing companies have a high probability of beating entrant attackers when the contest is about *sustaining* innovations."[24] However, "established compa-

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[15] INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA S-9 (Mark Smith et al. eds., 2012), *available at* http://www.iom.edu/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx.

[16] MICHAEL LEWIS, THE NEW NEW THING: A SILICON VALLEY STORY 19, 169 (2000). Clark was one of the founders of Netscape. *Id.* at 20.

[17] *See id.* at 99.

[18] *Id.* at 169.

[19] *See* AMA, UNDERSTANDING THE HIPAA STANDARD TRANSACTIONS: THE HIPAA TRANSACTIONS AND CODE SET RULE 2 (2009), *available at* http://www.ama-assn.org/resources/doc/psa/hipaa-tcs.pdf. *See also Transactions & Code Sets Standards*, CMS.GOV (Apr. 17, 2013, 8:18 PM), http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/TransactionCodeSetsStands/index.html?redirect=/transactioncodesetsstands/.

[20] Kim Girard, *Healtheon Shares Jump on WebMD Deal*, CNET NEWS (May 20, 1999, 3:15 PM), http://news.cnet.com/Healtheon-shares-jump-on-WebMD-deal/2100-1017_3-226108.html.

[21] Joseph L. Bower & Clayton M. Christensen, *Disruptive Technologies: Catching the Wave*, HARV. BUS. REV., Jan.–Feb. 1995, at 43, 45, *available at* http://hbr.org/product/disruptive-technologies-catching-the-wave/an/95103-PDF-ENG.

[22] *Id.*

[23] CHRISTENSEN, s*upra* note 8, at xv.

[24] CLAYTON M. CHRISTENSEN, SCOTT D. ANTHONY & ERIK A. ROTH, SEEING WHAT'S NEXT: USING THE THEORIES OF INNOVATION TO PREDICT INDUSTRY CHANGE xv (2004).

nies almost always lose to attackers armed with *disruptive* innovations."[25] Initially, disruptive technologies tend to underperform (or undershoot), but they "are typically cheaper, simpler, smaller, and, frequently, more convenient to use" than existing mainstream products.[26] In *The Innovator's Dilemma*, Christensen further explained the somewhat ironic indeterminacy inherent in disruption because "[p]roducts that do not appear to be useful to our customers today (that is, disruptive technologies) may squarely address their needs tomorrow."[27] In contrast, "sustaining technologies" "improve the performance of established products, along the dimensions of performance that mainstream customers in major markets have historically valued."[28]

So understood, disruptive technology seems omnipresent. Indeed, the success of Apple, Inc.,[29] is generally ascribed to its disruption of incumbent businesses (such as cell phones and music distribution). Small personal computers known as smartphones, such as the *iPhone*, have disrupted the mobile phone industry while tablets, such as the *iPad*, have disrupted PC markets. Video streaming services have disrupted movie rentals stores. E-reader devices have disrupted book publishing. Web services such as *Craigslist* and *Angie's List* have disrupted newspaper advertising (and so newspapers) and the Yellow Pages. *Wikipedia* has disrupted *Encyclopedia Britannica*'s print editions.[30]

Disruption can be serial. Digital cameras that once disrupted film, film cameras, and film processing markets are now themselves disrupted by smartphones with camera apps, onboard editing, and online sharing. Disruption has extended beyond individual products or product categories to entire industries. For example, "big box" electronic and book stores that disrupted small retailers and department stores now are suffering at the hands of online stores

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[25] *Id.*

[26] CHRISTENSEN, *supra* note 8, at xv.

[27] *Id.* at 226.

[28] *Id.* at xv. Christensen's adaptation of his theories to health care, *The Innovator's Prescription: A Disruptive Solution For Health Care* was published in 2009. CLAYTON M. CHRISTENSEN, JEROME H. GROSSMAN & JASON HWANG, THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE (2009). Surprisingly it makes few references to HIT. The first claim the book makes for IT is it will be "the enabling mechanism that shifts the locus of care . . . from solution shops to facilitated networks." *Id.* at xxxiv. Such "facilitated networks" are collaborative online communities for physicians or for patients suffering from the same disease. Second, that the transition to EMRs "will be the primary mechanism of coordination among the providers in [a] disruptive value network." *Id.* at xxxv. Here, the authors assume transparent data models between EMRs and also a shift of control of the data (again assuming the data is shareable) to patients, a prediction that explicitly references *Google Health*. *Id.* at xxxvii.

[29] At one point, Apple had the largest market cap of any company. *Apple Stock Price Touched $644, Sending Market Cap Topping $600 Bln*, BESTSTOCKWATCH (Apr. 11, 2012), http://www.beststockwatch.com/apple-stock-price-touched-644-sending-market-cap-topping-600-bln.html.

[30] *See, e.g.*, ROBERT SEAMANS & FENG ZHU, RESPONSES TO ENTRY IN MULTI-SIDED MARKETS: THE IMPACT OF CRAIGSLIST ON LOCAL NEWSPAPERS (2013), *available at* http://www.gc.cuny.edu/CUNY_GC/media/CUNY-Graduate-Center/PDF/Programs/Economics/Course%20Schedules/Seminar%20Sp.2013/seamans_zhu_craigslist%281 %29.pdf (research study reporting the effect of Craigslist on the market); Joab Jackson, *Encyclopaedia Britannica Drops Print Edition*, PC WORLD (Mar. 13, 2012, 4:20 PM), http://www.pcworld.com/businesscenter/article/251787/encyclopaedia_britannica_drops_print_edition.html.

(such as *Amazon*).[31] The financial services sector, which is somewhat comparable to health care because of its scale and domination by incumbents, reinvented itself with technology, cutting retail costs (replacing tellers with ATMs and branches with online banking) and leveraging IT expertise to extract value from mergers and acquisitions, but now faces disruptive payment services contained in smartphones.[32]

The business-school speak "disruptive innovation" model and particularly the work of Christensen and his colleagues have not escaped criticism from those who study health care. For example, Kleinke's review of *The Innovator's Prescription* memorably stated: "The book is 441 pages of postmodern business jargon, bubble charts, and marketplace anecdote, swirled into a menacing-sounding methodology and ladled across the entire U.S. health care system."[33]

Notwithstanding, there appears to be at least descriptive value in the sustaining-disruption and overshoot-undershoot models at the core of the Christensen-led literature. Christensen's work is in part based on Schumpeter's mid-twentieth century model of "creative destruction"[34] that also underlies Topol's *The Creative Destruction of Medicine*. Topol argues that the convergence of several technologies, not least the ability to digitize humans and persistent connectivity, will transform medicine: "These extraordinary accomplishments, from dissecting and defining DNA to creating such pervasive electronic technologies that immediately and intimately connect most individuals around the world, have unwittingly set up a profound digital disruption of medicine."[35] In fact, the soundness of the disruptive innovation model is not critical because much of this Article is about the prevailing *narrative* of HIT transformation or disruption. It is that narrative that is driving expectations and government policy and, at least in part, should be judged against the analytic model from which it is derived.

III. High Technology Medicine vs. HIT

U.S. health care heavily invests in high technology, which suggests a paradox given the slow rate of adoption of HIT. However, that investment primarily has been in sustaining technologies and not in nimbler and potentially disruptive information technologies. The continued adoption of high cost technology is symptomatic of the current health care system's inability or refusal to tackle

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[31] Abram Brown, *Death of Best Buy's Big Box Store? Company Will Shift To New Model, Close 50 Existing Stores*, Forbes (Mar. 29, 2012, 5:10 PM), http://www.forbes.com/sites/abrambrown/2012/03/29/death-of-best-buys-big-box-store-company-will-shift-to-new-model-close-50-existing-stores/.

[32] *See* Brett King, *The End Game in Disruption*, Finextra (Mar. 16, 2012, 3:57 PM), http://www.finextra.com/community/fullblog.aspx?blogid=6350; Brett King, *Why the iPhone 5 Means the End of the Swipe and Cards*, Finextra (Sept. 26, 2012, 2:12 AM), http://www.finextra.com/community/fullblog.aspx?blogid=6967.

[33] J.D. Kleinke, *Perfection In PowerPoint*, 28 Health Aff. 1223, 1223 (2009).

[34] *See Creative Destruction*, Wikipedia (Apr. 23, 2013, 2:59 AM), http://en.wikipedia.org/wiki/Creative_destruction.

[35] Eric Topol, The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care 5 (2012).

its escalating costs.[36] These investments are made to chase reimbursement and are emblematic of a system that provides elaborate and sophisticated care, but only on a selective basis, while focusing on sickness rather than wellness.[37] Major growth in technology utilization has been limited to secondary and tertiary care and to traditional technologies such as imaging.

A study that compared the availability of high cost medical technologies across thirteen industrialized countries concluded that the United States had above average numbers of MRI, CT, PET, and mammography and that "[u]tilization of imaging was also highest in the U.S."[38] In a similar vein, Emanuel and Pearson have been sharply critical of Medicare reimbursement for proton beam therapies because of the perverse incentive that provides to escalate the purchase of technologies that tend to support fragmented (task-centric) care and are remuneration-driven.[39] Expenditures on such technologies are more correlated to revenue and consistent with a health care culture that is largely driven by reimbursable services. As a result, investments in medical technology continue to be part of the health care "access" to services *problem* rather than its solution.[40]

Back in 2004, then Federal Reserve Chairman Alan Greenspan testified that "technological innovations can greatly improve the quality of medical care and can, in theory, reduce the costs of existing treatments. But because medical technology expands the range of treatment options, it also has the potential of adding to overall spending—in some cases, significantly."[41] Health care overspending on technology is one reason why skeptics wonder whether HIT can be even a partial solution for what ails the health care system. Bosanquet states: "Technology is often presented for healthcare as an extraneous variable, a *deus ex machina*, that can be used to explain the continuing rise in health care costs."[42] But, as he points out, this is an inaccurate and undifferentiated view of technology that fails to distinguish "big ticket" technologies from IT models.[43]

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[36] *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 384 (1982).

[37] *See* Reed Abelson, *An M.R.I. Machine for Every Doctor? Someone Has to Pay*, N.Y. TIMES, Mar. 13, 2004, at A1 (noting increasing pattern of individual doctors purchasing expensive imaging machines in large part because of the financial incentive of reimbursement).

[38] David A. Squires, *Explaining High Health Care Spending in the United States: An International Comparison of Supply, Utilization, Prices, and Quality*, 10 COMMONWEALTH FUND: ISSUES IN INT'L HEALTH POL'Y, May 2012, at 1, 7, *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/May/1595_Squires_explaining_high_hlt_care_spending_intl_brief.pdf.

[39] Ezekiel J. Emanuel & Steven D. Pearson, *It Costs More, But Is It Worth More?*, N.Y. TIMES, Jan. 3, 2012, at A25.

[40] *See generally* Rebecca Smith-Bindman, Diana L. Miglioretti & Eric B. Larson, *Rising Use of Diagnostic Medical Imaging in a Large Integrated Health System*, 27 HEALTH AFF. 1491 (2008).

[41] Alan Greenspan, Chairman of the Federal Reserve, Statement Before the House of Representatives, Committee on the Budget: Economic Outlook and Current Fiscal Issues Before the H. Comm. on the Budget 6–7 (Feb. 25, 2004), *available at* http://fraser.stlouisfed.org/docs/historical/greenspan/Greenspan_20040225.pdf.

[42] Nick Bosanquet, *Technology: Scientific Force or Power Force?*, *in* THE ECONOMICS OF NEW HEALTH TECHNOLOGIES: INCENTIVES, ORGANIZATION, AND FINANCING 43, 43 (Joan Costa-Font, Christophe Courbage & Alistair McGuire eds., 2009).

[43] *Id.* at 44–45.

Even with this distinction between traditional health care and information technologies clarified, HIT still presents as more sustaining than disruptive. A 2011 Booz Allen Hamilton report listed error reduction, improved collaboration, better patient-care coordination, improved emergency care, patient empowerment, patient convenience (e.g., with online appointment scheduling), military care, and public health responsiveness as examples of HIT's transformative potential.[44] For the most part, this is a consensus list of HIT prospects. However, it is a list of sustaining *not* disruptive technologies. Only the report's final example, enabling "discovery in new medical breakthroughs and provid[ing] a platform for innovation," could be considered potentially transformative or disruptive.[45]

A similar argument can be made about the EMR (electronic medical record). Even the most sophisticated and comprehensive EMR (comprehensive EMRs sometimes are labeled as EHRs (electronic health records)) is just a bundle of existing technologies (Computerized Physician Order Entry, Clinical Decision Support, e-Prescribing, Closed Loop Rx Delivery, Billing, Patient Portal) with inputs and outputs to an EMR-based local repository of structured data, a bundle introduced by incumbents to support existing discrete tasks.

There has been little dissent from the position that EMRs provide the answer to many of health care's quality and efficiency woes. But maybe it is time we had that conversation. Growing evidence suggests that quality improvements from basic (i.e., non-comprehensive) EMRs are marginal.[46] Furthermore, a controversial article in *Health Affairs* suggested that HIT-mediated access to prior imaging or blood test results or other physical examinations *increased* the ordering of new tests,[47] whereas conventional wisdom had suggested the reverse. Underperformance aside, there are also escalating questions about the safety of HIT, particularly relating to the real-world usability of EMRs, computerized physician order entry, and clinical decision support.[48] Nemeth and Cook likely are on point when they observe: "On the surface, healthcare work seems to flow smoothly . . . because the clinicians who provide

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[44] Booz Allen Hamilton, *Booz Allen Lists Top Nine Ways Information Technology is Transforming Health Care*, BOOZ ALLEN (Nov. 15, 2011), http://www.boozallen.com/media-center/press-releases/48399320/49523820.

[45] *Id.*

[46] Max J. Romano & Randall S. Stafford, *Electronic Health Records and Clinical Decision Support Systems: Impact on National Ambulatory Care Quality*, 171 ARCHIVES INTERNAL MED. 897, 901 (2011) ("[N]o association between EHR use and care quality for 19 indicators and a positive relationship for only 1 indicator."). *See also* Jesse C. Crosson et al., *Typical Electronic Health Record Use in Primary Care Practices and the Quality of Diabetes Care*, 10 ANNALS OF FAM. MED. 221, 224 (2012) ("Our findings show that having an EHR as opposed to a paper-based record-keeping system does not guarantee better care and suggest that many practices that have adopted EHRs have not made the necessary changes to both work processes and ways of thinking about care that would lead to improvements in chronic illness management.").

[47] *See* Danny McCormick et al., *Giving Office-Based Physicians Electronic Access to Patients' Prior Imaging and Lab Results Did Not Deter Ordering of Tests*, 31 HEALTH AFF. 488, 493 (2012), *available at* http://content.healthaffairs.org/content/31/3/488.abstract.

[48] *See generally* 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 (2013).

healthcare service make it so."[49] They argue that neither health care's "complex, poorly bounded, conflicted, highly variable, uncertain, and high-tempo work domain"[50] nor the clinicians' role in making it work smoothly are transparent. As they argue, "[t]he technical work that clinicians perform is *hiding in plain sight*. Those who know how to do research in this domain can see through the smooth surface and understand its complex and challenging reality. Occasional visitors cannot fathom this demanding work, much less create IT systems to support it."[51]

Nevertheless, it is a relatively safe bet to assume a small but consistent correlation between the introduction of EMRs (or related clinical knowledge management systems) and reduced length of stay, reduced mortality rates, and higher quality performance.[52] We may even see greater gains as the quality of analytics increases. For example, Cleveland Clinic has a project called DERT (Documentation, Extraction, Reporting and Transformation) that feeds EMR chart data into analytics software in order to flag potential complications while the patient is still in the facility.[53] It is also predicted that data outputs from EMRs could be one of the more robust sources of health care "big data," the analysis of which should give public health agencies advance warnings of disease and other threats, albeit with increased privacy costs.[54]

However, these remain examples of essentially sustaining technologies employed by a relatively thin slice of sophisticated incumbents. Even if they are shown to improve health *quality*, serious questions remain about their effect on the other two aspects of the health care triad: *access* and *cost*. Of course, some "quality" improvements will translate into lower costs. For example, a sophisticated EHR system should reduce medical and medication errors and advanced analytic packages may detect Hospital-Acquired Conditions earlier and generally reduce costly readmissions.[55] In contrast, a high probability exists that sustaining technologies will negatively affect both the access and cost legs of the health care stool. Both "big ticket" scanners and partly subsidized EMRs are expensive[56] and tend to push the incumbents' existing product

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[49] Christopher Nemeth & Richard Cook, *Hiding in Plain Sight: What Koppel et al. Tell Us About Healthcare IT*, 38 J. BIOMEDICAL INFORMATICS 262, 262 (2005).

[50] *Id.*

[51] *Id.*

[52] *See* Thomas Isaac, Jie Zheng & Ashish Jha, *Use of* UpToDate *and Outcomes in US Hospitals*, 7 J. HOSP. MED. 85, 85 (2012).

[53] Joseph Goedert, *Cleveland Clinic Puts Charts to the Test*, HEALTH DATA MGMT. (Oct. 4, 2011, 3:33 PM), http://www.healthdatamanagement.com/news/Cleveland_Clinic_using_patient_chart_analytics_daily-43338-1.html.

[54] *See generally* Nicolas P. Terry, *Protecting Patient Privacy in the Age of Big Data*, 81 UMKC L. REV. 385 (2012).

[55] *See, e.g.*, U.S. Dep't of Health and Human Servs., Agency for Healthcare Research and Quality, *Hospital-Acquired Conditions*, NAT'L GUIDELINE CLEARINGHOUSE, http://guideline.gov/resources/hospital-acquired-conditions.aspx (last visited May 6, 2013).

[56] *See, e.g.*, Francois M. Laflamme, Wayne E. Pietraszek & Nilesh V. Rajadhyax, *Reforming Hospitals With IT Investment*, MCKINSEY Q. 1, 2 (2010), http://www.mckinseyquarterly.com/Reforming_hospitals_with_IT_investment_2653 ("US hospitals will need to spend approximately $120 billion" while the American Reinvestment and Recovery Act subsidies will "offset only approximately 15 to 20 percent of total expenditures[,] . . . a spending gap of about $60,000 to $80,000 a bed.").

(here, health care) further upmarket, which increases cost and impedes access.[57]

When Steve Jobs was asked about the post-PC era,[58] he replied:

> When we were an agrarian nation, all cars were trucks, because that's what you needed on the farm. But as vehicles started to be used in the urban centers, cars got more popular. . . . PCs are going to be like trucks. They're still going to be around, they're still going to have a lot of value, but they're going to be used by one out of X people. . . . I think that we're embarked on that.[59]

The scanners and much of the current generation of HIT, such as siloed EMRs, are the sustaining "trucks" of health care incumbents. The transformation of health care is going to depend on the disruptive "cars" of entrant attackers.

IV. Health Care, HIT, and Their Market Failures

In its 2012 report *Transforming Health Care: The Role of Health IT*, the Bipartisan Policy Center listed six barriers to effective HIT adoption. "Misaligned Incentives"[60] topped the list. HIT shares a sub-optimal state with general health care markets. In the latter, this chronic form of market failure is caused by the fact that those who pay most of the costs of health care (insurers, themselves paid by employers) are distinct from those who choose or recommend treatment (doctors) and distinct again from the patients actually consuming the health care.[61] As a result, the first hurdle for any HIT-transformation argument is that the solution seems to suffer from the same disability as the problem. In the words of a KPMG report: "Healthcare lags behind other industries, where structures, systems and incentives have made it far easier to embrace creative dislocation."[62]

The Organisation for Economic Co-operation and Development's (OECD) 2011 Health Indicators study concluded: "In the United States, health expenditure has increased faster than in all other high-income OECD countries since 1970, increasing five-fold in real terms, even taking account population

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[57] For a slightly different but still negative take on EMRs, see Kauffman Task Force on Cost-Effective Health Care Innovation, Kauffman Found., Valuing Health Care: Improving Productivity and Quality 35 (2012), *available at* http://www.kauffman.org/uploadedfiles/valuing_health_care.pdf ("The principal virtues of electronic records lie in the realm of improving service, not reducing cost.").

[58] *See* Maribel Lopez, *Four Ways the Post-PC Era Differs from Today*, Forbes (May 1, 2012, 7:04 AM), http://www.forbes.com/sites/maribellopez/2012/05/01/four-ways-the-post-pc-era-differs-from-today/.

[59] John Paczkowski, *Apple CEO Steve Jobs Live at D8: All We Want to Do is Make Better Products*, All Things D (June 1, 2010, 5:45 PM), http://allthingsd.com/20100601/steve-jobs-session/.

[60] Bipartisan Policy Ctr., Transforming Health Care: The Role of Health IT 5 (2012), http://bipartisanpolicy.org/sites/default/files/Transforming%20Health%20Care.pdf.

[61] *See generally* Steven M. Teutsch & Marc L. Berger, *Misaligned Incentives in America's Health: Who's Minding the Store?*, 3 Annals Fam. Med. 485, 486 (2005).

[62] KPMG Int'l, Accelerating Innovation: The Power of the Crowd 12 (2012) [hereinafter KPMG, Accelerating Innovation], http://www.kpmg.com/Global/en/IssuesAndInsights/ArticlesPublications/accelerating-innovation/Documents/ehealth-implementation.pdf.

growth."[63] The differences are qualitative as well as quantitative. The U.S. health care system compares unfavorably to other highly developed countries on dimensions such as access, patient safety, coordination, efficiency, and equity.[64] Analyzing data from thirteen industrialized countries, a Commonwealth Fund report found that the United States spends more than seventeen percent of its GDP on health care compared to twelve percent or less in other countries.[65] Contrary to arguments frequently made, the disparity is not due to higher income, the size of the elderly population, or smoking rates in the United States.[66] The only correlations were "higher prices and perhaps more readily accessible technology and greater obesity."[67] Unfortunately, the same study confirmed prior findings that "make clear that, despite high costs, quality in the U.S. health care system is variable and not notably superior to the far less expensive systems in the other study countries."[68]

Baicker and Chandra acknowledge: "In an efficient system, more spending on health care would be a sign of prosperity and a harbinger of improved health and longevity, not a cause for concern."[69] However, they find our observed pattern of spending troubling because of increases in federal spending and because "health care resources are not being spent efficiently (and may not even be the primary driver of improved outcomes): we are neither allocating resources efficiently between health and other uses, nor getting as much health as we could for every dollar spent."[70] As to the former concern, government spending is projected to be fifty percent of national health expenditures by

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[63] OECD, HEALTH AT A GLANCE 2011: OECD INDICATORS 10 (2011), *available at* http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2011_health_glance-2011-en. OECD countries on average spent 9.6% of their GDP on health care in 2009. *Id.* at 150. The U.S. spent 17.4%. *Id.* CMS' *National Health Expenditure Projections for 2010–2020* estimate an annual growth in expenditures of over 6%, consuming 19.4% of GDP by 2019. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS FOR 2010–2020, at 1, 4 (2009), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2010.pdf. *See also* Sean P. Keehan et al., *National Health Spending Projections Through 2020: Economic Recovery and Reform Drive Faster Spending Growth*, 30 HEALTH AFF. 1594, 1594 (2011) ("National health spending is expected to grow 5.8 percent per year for the period 2010 through 2020, 1.1 percentage points faster than the expected average annual rise in gross domestic product. As a result, the health share of the gross domestic product is projected to increase from 17.6 percent in 2009 to 19.8 percent by 2020.").

[64] KAREN DAVIS, CATHY SCHOEN & KRISTOF STREMIKIS, THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY v (2010), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2010/Jun/1400_Davis_Mirror_Mirror_on_the_wall_2010.pdf.

[65] Squires, *supra* note 38, at 3.

[66] *Id.* at 2–4.

[67] *Id.* at 2. *See also* Gerard F. Anderson et al., *It's The Prices, Stupid: Why the United States Is So Different From Other Countries*, 22 HEALTH AFF. 89, 89 (2003).

[68] Squires, *supra* note 38, at 9.

[69] Katherine Baicker & Amitabh Chandra, *Aspirin, Angioplasty, and Proton Beam Therapy: The Economics of Smarter Health-Care Spending* 3 (Fed. Reserve Bank of Kansas City Econ. Policy Symposium, Achieving Growth Amid Fiscal Imbalances Paper No. 2, Aug. 25–27, 2011), *available at* http://www.kc.frb.org/publicat/sympos/2011/2011.BaickerandChandra.paper.pdf.

[70] *Id.* at 2.

2021,[71] and the Congressional Budget Office estimates that spending on federal health care programs will double to ten percent of GDP in 2037.[72]

Health economist Austin Frakt identifies several types of market failure that impact health care. These include general failures of competition,[73] public goods problems associated with entitlement programs, and information asymmetries leading to "supplier-induced demand" (part of the misaligned incentives problem).[74] As Gawande has remarked: "Health-care costs ultimately arise from the accumulation of individual decisions doctors make about which services and treatments to write an order for. The most expensive piece of medical equipment, as the saying goes, is a doctor's pen."[75] Frakt further relates how such failures are exacerbated by market failures in health *insurance* markets. Again, there is failure of competition because of concentration and non-commodified products exacerbated by information asymmetries (though here based on moral hazard-inducing patient information). In addition, health insurance markets are incomplete because insurers do not offer lower cost (and reduced profit) plans.[76] The U.S. health care system's relative lack of vertical integration and the fact that health care and health insurance markets are separate create additional and compounding-informational asymmetry-based market failures.

In general, incumbents avoid competing with their own existing products or services by themselves introducing lower cost alternatives. This is for good reason because most attempts to go against this trend fail.[77] Consistent with this model, health care incumbents have shown little ability to pivot, let alone be self-disruptive, no doubt in part because the industry has been built on ever-more byzantine layers of relationships and processes. As Starr observed thirty years ago: "The array of organizational forms in medicine is now extraordinarily complex."[78] Indeed, self-disruption (or internal transformation) is quite dif-

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[71] Sean P. Keehan et al., *National Health Expenditure Projections: Modest Annual Growth Until Coverage Expands and Economic Growth Accelerates*, 31 HEALTH AFF. 1, 10 (2012).

[72] CONG. BUDGET OFFICE, THE 2012 LONG-TERM BUDGET OUTLOOK 1 (2012), *available at* http://www.cbo.gov/sites/default/files/cbofiles/attachments/06-05-Long-Term_Budget_Outlook.pdf.

[73] Austin Frakt, *Health Insurance Market Failures (and What Can Be Done About Them)*, INCIDENTAL ECONOMIST (Feb. 16, 2011, 8:04 AM), http://theincidentaleconomist.com/wordpress/health-insurance-market-failures-and-what-can-be-done-about-them/. Essentially, Frakt identifies highly concentrated local hospital markets exacerbated by a lack of commodification in health care services that leads to "competition" between unequal products that enjoy natural monopolies.

[74] *See* JAMES W. HENDERSON, HEALTH ECONOMICS & POLICY 81–89 (4th ed. 2009).

[75] Atul Gawande, *The Cost Conundrum*, NEW YORKER (June 1, 2009), http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande.

[76] *See* Frakt, *supra* note 73.

[77] *See, e.g.*, Micheline Maynard, *Delta to Discontinue Its Low-Fare Song Airline*, N.Y. TIMES (Oct. 28, 2005), http://www.nytimes.com/2005/10/28/business/28cnd-air.html (discussing closure of "Song," a Delta Airlines low cost brand, and other failed discount secondary brands). *See also* discussion *supra* of market failure associated with health insurers failing to offer low cost products and text accompanying note 76. R

[78] STARR, *supra* note 36, at 439–40.

ficult and seen only in rare organizations that put the creation of value for their customers ahead of profit maximization.[79]

The high level of market failure exhibited by health care points to incumbent failure to innovate or provide customer satisfaction and suggests the domain is ripe for disruption. This brings us to the question of whether incumbent-proffered health care is overshooting consumer needs. Overshooting and undershooting are key aspects of the Christensen disruption model. Markets are ripe for disruption when incumbents' products overshoot the needs of consumers while early iterations of disruptive products will tend to undershoot the needs of most consumers.[80] Undershooting can be loosely translated by the popular phrase: "The next big thing is always beneath contempt."[81] A classic example is Microsoft CEO Steve Ballmer's reaction to the first iPhone: "There's no chance that the iPhone is going to get any significant market share. No chance."[82] Presumably Ballmer downplayed the threat of the new device because of its high price point in comparison to other products in the phone market marketed by experienced incumbents. In reality, the iPhone was a mobile computer that included a phone "app" which, in classic disruptive fashion, undershot the incumbent-dominated market for computers.

Christensen, Bohmer, and Kenagy assert that traditional health care exhibits overshoot, stating: "Our major health care institutions . . . have together overshot the level of care actually needed or used by the vast majority of patients."[83] That leads them to make the familiar disruption argument: "The pace of sustaining innovation nearly always outstrips the ability of customers to absorb it. That creates the potential for upstart companies to introduce *disruptive innovations*—cheaper, simpler, more convenient products or services that start by meeting the needs of less-demanding consumers."[84]

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[79] *See* James Allworth, *Steve Jobs Solved the Innovator's Dilemma*, HARV. BUS. REV. (Oct. 24, 2011, 11:38 AM), http://blogs.hbr.org/cs/2011/10/steve_jobs_solved_the_innovato.html.

[80] Bower & Christensen, *supra* note 21, at 49–50 ("A simple graph plotting product performance as it is defined in mainstream markets on the vertical axis and time on the horizontal axis can help managers identify both the right questions and the right people to ask. First, draw a line depicting the level of performance and the trajectory of performance improvement that customers have historically enjoyed and are likely to expect in the future. Then locate the estimated initial performance level of the new technology. If the technology is disruptive, the point will lie far below the performance demanded by current customers.").

[81] John Lilly, *Computers = Trucks*, JOHN'S TUMBLR (May 25, 2012), http://lilly.tumblr.com/post/23719699951/computers-trucks. Consider, for example, the criticisms directed at the "Google Glass" project. *Compare* Roberto Baldwin, *Google Glasses Face Serious Hurdles, Augmented-Reality Experts Say*, WIRED.COM (Apr. 5, 2012, 5:59 PM), http://www.wired.com/gadgetlab/2012/04/augmented-reality-experts-say-google-glasses-face-serious-hurdles/, *with* Steven Levy, *Google Glass Team: "Wearable Computing Will Be the Norm"*, WIRED.COM (June 29, 2012, 3:17 PM), http://www.wired.com/gadgetlab/2012/06/clear-glass-leaders-googles-wearable-computing-breakthrough-explain-it-all-for-you/all/.

[82] Joel Hruska, *Ballmer: iPhone Has "No Chance" of Gaining Significant Market Share*, ARS TECHNICA (Apr. 30, 2007, 2:42 PM), http://arstechnica.com/information-technology/2007/04/ballmer-says-iphone-has-no-chance-to-gain-significant-market-share/.

[83] Clayton M. Christensen, Richard Bohmer & John Kenagy, *Will Disruptive Innovations Cure Health Care?*, HARV. BUS. REV., Sept.–Oct. 2000, at 2; *see also* John W. Kenagy & Clayton M. Christensen, *Disruptive Innovation: A New Diagnosis for Health Care's "Financial Flu"*, HEALTHCARE FIN. MGMT., May 2002, at 62.

[84] Christensen, Bohmer & Kenagy, *supra* note 83, at 2.

This is a strong claim and likely wrong. A slightly different construct may be conceded: the overshoot exists but informational asymmetries or misaligned incentives (the consumer is not paying directly for the overshoot) render its consequences inoperable.[85]Another, related view also might be conceded: overshooting has occurred, but patients are culturally conditioned to expect overshooting (even unneeded) care by doctors who provide it.[86] The specifics are unimportant because the point is that the disruption tipping point requires health care consumers to *perceive* that overshoot. Through that lens, and for most health care consumers, the care offered has yet to overshoot demand.[87] That is, in the present state, consumers will take or demand as much health care as they are being supplied. Or, as admitted by Christensen and colleagues: "When cost is not a consideration, patients always choose the higher-performing technology."[88]

Given the market failure attached to so much of health care, it is not surprising that considerable attention would be given to phenomena with the potential to disrupt. A study that pre-dated the American Recovery and Reinvestment Act of 2009 ("ARRA") subsidy of EMRs[89] surveyed primary care physicians in eleven highly developed countries. It found six countries with almost universal adoption of EMRs, but U.S. physicians had one of the lowest adoption scores.[90] Here, therefore, was another data point feeding the disruption narrative and, hence, the acute contemporary interest in HIT. Statistics suggesting a low level of HIT adoption in the United States coincided with a socio-political determination that health care was ripe for change and led policymakers to the contemporary HIT-transformation hypothesis.

Unfortunately, just as market failures have been responsible for the high-cost, low-quality, limited-access spiral of health care, so misaligned incentives have impeded the development of HIT. As Christensen and Remler point out, considerable barriers inhibit potentially disruptive IT adoption *outside* of the

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[85] Christensen and his colleagues recognize that disruptive innovation by itself may be insufficient, further requiring conditions and context such that lower cost, disruptive services are possible. For example, they must be free of regulatory barriers (e.g., restricting physician extenders) and oligopolistic concentrations in health provider and insurance markets must be dismantled (e.g., absence of lower profit health insurance products). *See id.* at 9; *see also id.* at 2 ("We believe that a whole host of disruptive innovations, small and large, could end the [health care] crisis—but only if the entrenched powers get out of the way and let market forces play out.").

[86] *See, e.g.*, Elisabeth Rosenthal, *Let's (Not) Get Physicals*, N.Y. TIMES (June 2, 2012), http://www.nytimes.com/2012/06/03/sunday-review/lets-not-get-physicals.html?pagewanted=all&_r=0.

[87] Obviously the exceptional case concerns uninsured patients, who are completely overshot. However, government safety nets aside, they lack access to any affordable health or health insurance products or services.

[88] CHRISTENSEN, ANTHONY & ROTH, *supra* note 24, at 197.

[89] Specifically, ARRA included funding for the Health Information Technology for Economic and Clinical Health Act (HITECH) and that legislation's Meaningful Use (MU) subsidy program. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 3011, 4101, 13,001, 123 Stat. 115 (codified as amended in scattered sections of 19 & 26 U.S.C.), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf.

[90] Cathy Schoen et al., *A Survey of Primary Care Physicians in Eleven Countries, 2009: Perspectives on Care, Costs, and Experiences*, 28 HEALTH AFF. w1171, w1174–75 (2009).

health care domain.[91] These barriers include network externalities, low product differentiation, training costs, switching costs, and the need for interoperability between interlinked or dependent technologies.[92] Yet, they observe, "fantastic gains of [IT] have outweighed those barriers in most industries and aspects of both public and private life," leading to their question: "Why does health care ICT [information and communication technology] lag so far behind?"[93]

The answer is twofold: first, patient heterogeneity[94] and second, the oft-recognized "misaligned incentives" market failure problem that undermines U.S. health care markets.[95] As to the first, the diversity of the patient population is extraordinary. One study of trauma center records for 41,364 patients found 1,224 different ICD-9 injury diagnoses in 32,261 different combinations.[96] This heterogeneous nature of the patient population is caused by a variety of factors, including demographics, genetics, behavioral factors, and specific care contexts.[97] Barriers to IT adoption caused by differences between patients likely are exacerbated by provider heterogeneity. As noted by the Agency for Healthcare Research and Quality (AHRQ), "widespread implementation of HIT has been limited by a lack of generalizable knowledge about what types of HIT and implementation methods will improve care and manage costs for specific health organizations."[98]

The second, most salient, and most persistent barrier to HIT adoption has been market failure; the normative claim that change is too slow or "a situation in which market outcomes are not socially optimal or desirable."[99] As with health care generally, misaligned incentives are the root cause. Oversimplified, insurers want EMRs and HIT, while patients want more access to and control over their data. However, the incentives are mismatched because providers, not patients or insurers, have to pay for the non-reimbursable technology. Turning around this HIT market failure was the task set for the Office of the National Coordinator for Health (ONC) and the Center for Medicare and Medicaid Ser-

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[91] Michael C. Christensen & Dahlia Remler, *Information and Communications Technology in U.S. Health Care: Why Is Adoption So Slow and Is Slower Better?*, 34 J. HEALTH POL., POL'Y & L. 1011, 1014–16 (2009) [hereinafter Christensen & Remler, *Information and Communications Technology*].

[92] *Id.* at 1014–15.

[93] *Id.* at 1016–17.

[94] *Id.* at 1019.

[95] *See* Nicolas P. Terry, *Certification and Meaningful Use: Reframing Adoption of Electronic Health Records as a Quality Imperative*, 8 IND. HEALTH L. REV. 43, 47–48 (2011).

[96] John R. Clarke, Andrew V. Ragone & Lloyd Greenwald, *Comparisons of Survival Predictions Using Survival Risk Ratios Based on* International Classification of Diseases, Ninth Revision *and Abbreviated Injury Scale Trauma Diagnosis Codes*, 59 J. TRAUMA INJ. INFECTION & CRITICAL CARE 563, 563 (2005).

[97] *See, e.g.*, Jason Shafrin, *Patient Heterogeneity and Comparative Effectiveness Research*, MEDPEDIA (Aug. 9, 2010, 9:19 AM), http://www.medpedia.com/news_analysis/101-Healthcare-Economist/entries/41638-Patient-Heterogeneity-and-Comparative-Effectiveness-Research.

[98] AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY v–vi (2006), http://www.ahrq.gov/downloads/pub/evidence/pdf/hitsyscosts/hitsys.pdf [hereinafter AHRQ, COSTS AND BENEFITS OF HIT].

[99] HOWARD J. SHERMAN ET AL., ECONOMICS: AN INTRODUCTION TO TRADITIONAL AND PROGRESSIVE VIEWS 428 (7th ed. 2008) (emphasis omitted).

vices (CMS) by ARRA. However, as the Meaningful Use (MU) subsidy program has progressed through its initial stages consistent patterns of negative strategic stakeholder behavior have emerged.[100] Government cheerleading and cherry-picked data precede the publication of a proposed HHS rule. The draft rules are then greeted with incredulity from providers and HIT manufacturers. CMS and ONC then reduce their expectations only to see providers miss their marks. After that, the cycle starts up again with positive progress seen in quantitative benchmarks but disappointing performance in qualitative implementation (particularly in regards to patient engagement, interoperability with other data modules such as clinical decision support, and data interchange).[101]

According to the current ONC coordinator: "In 2016, it's going to be the [sic] rare to find a doctor without EHRs."[102] That level of implementation is going to be difficult to achieve. Many facilities (e.g., long-term acute care, rehabilitation, and psychiatric hospitals) are ineligible for the ARRA-MU subsidy and are adopting EMRs at a far slower rate than those receiving subsidies.[103] Among the eligible doctors and hospitals, a noticeable gap in adoption has opened up with far lower adoption rates among nonteaching and rural hospitals,[104] among physicians fifty-five and older, or in small practices.[105] Overall, a growing divide exists between HIT enabled providers and the technology-poor doctors and facilities previously identified as most in need of HIT—those "smaller clinics and practices where most Americans receive their health care."[106]

Even assuming that something close to the coordinator's predicted level of adoption is achievable the technical abilities of most installed EMRs are suspect. According to a 2012 survey, while almost 35% of acute care hospitals had adopted EMRs by 2011, only 8.8% had comprehensive systems.[107] It is only these comprehensive systems that make a real quality difference[108] because of their patient engagement potential, data exchange capabilities, or integration

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[100] *See generally* Terry, *supra* note 95; Nicolas P. Terry, *Anticipating Stage Two: Assessing the Development of Meaningful Use and EMR Deployment*, 21 ANNALS HEALTH L. 103 (2012).

[101] *See generally* Terry, *supra* note 48, 8, 18–21, 28–31.

[102] Diana Manos, *Mostashari: "Keep Our Eyes on the Prize"*, HEALTHCARE IT NEWS (Apr. 26, 2012), http://www.healthcareitnews.com/news/mostashari-keep-our-eyes-prize.

[103] Larry Wolf, Jennie Harvell & Ashish K. Jha, *Hospitals Ineligible for Federal Meaningful-Use Incentives Have Dismally Low Rates of Adoption of Electronic Health Records*, 31 HEALTH AFF. 505, 505–06 (2012).

[104] Catherine M. DesRoches et al., *Small, Nonteaching, and Rural Hospitals Continue to Be Slow in Adopting Electronic Health Record Systems*, 31 HEALTH AFF. 1092, 1095 (2012).

[105] Sandra L. Decker, Eric W. Jamoom & Jane E. Sisk, *Physicians in Nonprimary Care and Small Practices and Those Age 55 and Older Lag in Adopting Electronic Health Record Systems*, 31 HEALTH AFF. 1108, 1108 (2012).

[106] David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 501 (2010).

[107] DUSTIN CHARLES, MICHAEL FURUKAWA & MEGHAN HUFSTADER, OFFICE OF NAT'L COORDINATOR FOR HEALTH INFO. TECH., ELECTRONIC HEALTH RECORD SYSTEMS AND INTENT TO ATTEST TO MEANINGFUL USE AMONG NON-FEDERAL ACUTE CARE HOSPITALS IN THE UNITED STATES: 2008–2011, at 1, 4 (2012), *available at* http://www.healthit.gov/media/pdf/ONC_Data_Brief_AHA_2011.pdf.

[108] *See, e.g.*, Karen C. Nanji et al., *Errors Associated with Outpatient Computerized Prescribing Systems*, 18 JAMA 767, 772 (2011); Johanna I. Westbrook et al., *Effects of Two*

with other HIT modules such as clinical decision support. Yet, there is little indication that the penetration of comprehensive systems will increase dramatically. Indeed, it is the data exchange and other mandated sophisticated uses that increasingly lead providers to push back on MU initiatives.[109]

The laudable goals of the MU's architects notwithstanding, the subsidy program may well grow low-level HIT (siloed EMRs) but will do comparatively little to incentivize the sophisticated technology we really care about. Such transformative HIT primarily will be found, as it is today, in very large vertically integrated systems. Not only are those systems owned by incumbents, but incumbents already tending to do the right things, such as moving away from task-oriented to process-oriented care. In contrast, the vast majority of providers, those who are not transforming their care models, may simply slide siloed EMRs into their existing defective workflows as they too become victims of the IT productivity paradox.[110]

V. THE VALUE OF WAITING (FOR NEW HEALTH CARE CONSTRUCTS)

As the old saying goes, "no plan survives contact with the enemy."[111] And HIT's enemy may well turn out to be the health care system. This section examines a slightly different explanation for HIT's struggle to disrupt: disruptive innovation is biding its time, waiting for some broader health care issues to be resolved before it generates transformation.

The first explanation for such "waiting" is an eminently practical one: health care and HIT have reached a point where their capacity to absorb change is severely reduced. HIPAA's unfunded mandate and privacy and security costs were followed by e-prescribing,[112] then the HITECH's subsidy programs, and finally by the unparalleled complexity of ACA (Affordable Care Act) initiatives. These programs may have taxed the transformative capacity of health care institutions to the extent that pushing back against further change is inevitable. After all, it is not only MU that is finding HIT progress tough. There are also the ongoing disputes between the federal government's standard-setters and health care entities over the adoption of ICD-10[113] and the delays to

Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study, 9 PLOS MED. 1, 5 (2012).

[109] *See, e.g.*, Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass'n, to Marilyn Tavenner, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs. (Apr. 30, 2012), *available at* http://www.aha.org/advocacy-issues/letter/2012/120430-cl-cms0044p.pdf.

[110] *See infra* text accompanying notes 125–27.

[111] Attributed to Helmuth von Moltke the Elder. *Helmuth von Moltke the Elder*, WIKIQUOTE, http://en.wikiquote.org/wiki/Helmuth_von_Moltke_the_Elder (last visited May 6, 2013).

[112] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1860D-4, 117 Stat. 2066, 2087; Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 132, 122 Stat. 2494, 2527.

[113] *See* Letter from James L. Madara, Am. Med. Ass'n, to Kathleen Sebelius, Secretary, U.S. Dep't of Health & Human Servs. (Feb. 2, 2012), *available at* http://www.ama-assn.org/resources/doc/washington/icd-10-comment-letter-02feb2012.pdf; Press Release, Am. Med. Ass'n, AMA Statement in Support of HHS' Intent to Delay ICD-10 Compliance Date (Feb. 16, 2012) (statement attributed to Peter W. Carmel, AMA President), *available at* http://www.ama-assn.org/ama/pub/news/news/2012-02-16-support-delay-icd-10-compliance.page;

the enforcement of the "5010" transactional standards.[114]

Stakeholders also may be biding their time because today's HIT is relatively immature. Christensen and Remler argue: "[T]here are real advantages to approaching ICT adoption carefully and waiting for the right technology to come along before system-level adoption takes place."[115] Further, they suggest that this "value of waiting"[116] is particularly high in HIT "because the costs of adopting the wrong type of ICT are so much higher: the risks and irreversible consequences of technical errors and the consequences of lock-in into a suboptimal technology."[117] Thus, some providers may be waiting for the deprecation of barriers to HIT adoption such as high cost (even subsidized) or low quality. Large indeterminacies in the total cost of ownership of EMRs remain while vendors move in and out of the market[118] and potential HIT purchasers wait for consolidation or other changes in HIT or EMR markets.

Another obvious reason to wait is the toxic nature of the political environment. Specifically, stakeholders are worried by the indeterminacies surrounding the ACA.[119] Notwithstanding the Supreme Court upholding the legislation[120] and the subsequent re-election of President Obama, there are many regulatory indeterminacies remaining, and a bitterly divided federal legislature that will continue to make ACA an election issue in the future. ACA is important in the HIT narrative because of the tight relationship between health care reform and HIT adoption in ACA's more integrated care and reimbursement models, process-based models that better match IT. As Christensen and colleagues have argued: "Third-party reimbursement systems sap motivation for innovation—particularly disruptive innovation—out of the system."[121] Along similar lines, the Bipartisan Policy Center sees HIT as awaiting better-aligned incentives, payment based on quality outcomes and value rather than the current volume model.[122] Overall, HIT will prove a better fit for an ACA-reformed health care system.

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see also Press Release, U.S. Dep't of Health & Human Servs., HHS Announces Intent to Delay ICD-10 Compliance Date (Feb. 16, 2012), http://www.cms.gov/ICD10/Downloads/HHSPressReleaseICD10final321612.pdf. *See also* Tom Sullivan, *AMA Adds New Wrinkle to ICD-10 Delay: ICD-11*, GOV'T HEALTH IT (June 20, 2012), http://www.govhealthit.com/news/ama-adds-new-wrinkle-icd-10-delay-icd-11?topic=30,31,29,34.

[114] Press Release, U.S. Dep't of Health & Human Servs., Extension of Enforcement Discretion Period for Updated HIPAA Transaction Standards Through June 30, 2012 (Mar. 15, 2012), *available at* http://www.cms.gov/ICD10/Downloads/EnforcementDiscretionAnnouncement.pdf.

[115] Christensen & Remler, *Information and Communications Technology*, *supra* note 91, at 1024.

[116] *Id.* at 1030.

[117] *Id.*

[118] *See, e.g.*, Jim Molpus, *Meaningful Use or Useful Life? Can Both Exist?*, HEALTHLEADERS MEDIA (Jan. 10, 2012), http://www.healthleadersmedia.com/page-1/TEC-275168/Meaningful-Use-or-Useful-Life-Can-Both-Exist (discussing added costs to physician when EMR vendor acquired by another vendor that did not have product compatible with physician's network platform).

[119] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of 25, 26, 29, 42 U.S.C.).

[120] Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2608 (2012).

[121] CHRISTENSEN, ANTHONY, & ROTH, *supra* note 24, at 197.

[122] *See* TRANSFORMING HEALTH CARE, *supra* note 60, at 17.

A 2006 AHRQ literature review summarized the barriers to HIT adoption as "situational barriers (including time and financial concerns), cognitive and[/]or physical barriers (include physical disabilities and insufficient computer skills), liability barriers (including confidentiality concerns), and knowledge and attitudinal barriers."[123] The review crucially concluded: "Cutting across all these categories, however, may be the need for clinical medicine as it is now practiced in the majority of settings to undergo a major structural and ideological reorganization, so it can be integrated with and enjoy the benefits of HIT."[124]

This approach is consistent with what we have learned about the "IT productivity paradox."[125] The paradox notes the coincidence of vast increases in IT deployment and a general *slowing* of industrial productivity. Jones and colleagues have argued there are some convincing explanations for the paradox, including deficiencies in how we measure the impact of IT on complex service industries and problems relating to usability.[126] For our present purposes, their most salient observation goes to mismanagement, that is to say, health care's failure to move beyond digitizing legacy workflows because "swapping out the medical record cabinet and prescription pad for a computer is proving insufficient to realize the benefits of health IT." Rather, what is required are "IT-enabled processes that support teamwork, care coordination, and innovative approaches such as interactive patient portals."[127]

Walker and Carayon identified the current state, "[t]he focus on tasks (and payment for isolated tasks)," as a "fundamental cause of the fragmentation, low quality, and high cost of U.S. health care."[128] They contrasted process-focused care that "coordinates the work of many care team members (including patients, physicians, nurses, midlevel providers, lay caregivers, clinical educators, pharmacists, case managers, and call-center personnel) to provide each patient with high-quality, efficient care across time and across all venues of care."[129] Gawande has voiced a related criticism by decrying the over-specialization of physicians and the large number of ultra-specialized professionals required to care for a single patient: "[W]e have amazing clinicians and technologies but little consistent sense that they come together to provide an actual system of care, from start to finish, for people. We train, hire, and pay doctors

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123 AHRQ, COSTS AND BENEFITS OF HIT, *supra* note 98, at 58.

124 *Id.*

125 *See, e.g.*, Erik Brynjolfsson, *The Productivity of Information Technology: Review and Assessment* 1 (MIT Ctr. for Coordination Sci., Working Paper No. 3417-92, 1991), *available at* http://dspace.mit.edu/bitstream/handle/1721.1/2405/SWP-3417-26847896-CCSTR-130.pdf?sequence=1; *see also* Robert J. Gordon, *Does The "New Economy" Measure Up to the Great Inventions of the Past?*, 14 J. ECON. PERSP. 49, 72 (2000).

126 Spencer S. Jones et al., *Unraveling the IT Productivity Paradox—Lessons for Health Care*, NEW ENG. J. MED. 2243, 2243–44 (2012); *see also* Health IT Policy Comm., *Statement by the American Medical Association*, AM. MED. ASS'N (Apr. 21, 2011), http://www.ama-assn.org/resources/doc/hit/ama-ehr-usability-statement.pdf ("There is a direct correlation between EHR adoption and the usability of an EHR.").

127 Jones et al., *supra* note 126, at 2244.

128 James M. Walker & Pascale Carayon, *From Tasks to Processes: The Case for Changing Health Information Technology to Improve Health Care*, 28 HEALTH AFF. 467, 468 (2009).

129 *Id.*

to be cowboys. But it's pit crews people need."[130] A similar philosophy can be seen behind the *Choosing Wisely* initiative,[131] a medical specialty group-led movement aimed at persuading their colleagues "to back off on 45 diagnostic tests, procedures and treatments that often may do patients no good."[132] The challenge therefore is "to move the healthcare delivery paradigm from one where the system is the arbiter of care to one that revolves around patient-centric personal healthcare."[133]

None of this should be a surprise. The contemporary "quality" debate has focused on the "systems" reform of health care.[134] These proposed processes or systems, from reporting to peer-review to "blameless" adverse event disclosure, are intrinsically process-based. Similarly, calls for better integration transcend the clinical aspects of health care. Thus, in *The Innovator's Prescription*, Christensen and colleagues argued that tightly integrated providers (e.g., where the provider and insurer are the same entity) furnished one of the best platforms for efficiency and some disruption[135] in part because "[i]ntegrated fixed-fee provider systems can, to some extent, circumvent the inertial blocking power of guild membership because reimbursement is not an issue. They can more easily make the decisions that are best for the overall system."[136]

Supplanting fragmented or episodic care with process-based constructs is at the heart of many next generation care models. It lies at the root of reform proposals, such as Episode-Based Payment,[137] and, when extended to a defined population, ACA's Medicare Shared Savings Program available to providers who organize as Accountable Care Organizations.[138] Such ideas also underpin the patient-centered medical home (PCMH) construct. PCMH is a team-based coordinated care model supported by leading professional organizations and designed to provide comprehensive primary care for children, youth, and adults.[139] It should be no surprise that HIT is viewed as having a funda-

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[130] Atul Gawande, *Cowboys and Pit Crews*, NEW YORKER (May 26, 2011), http://www.newyorker.com/online/blogs/newsdesk/2011/05/atul-gawande-harvard-medical-school-commencement-address.html.

[131] CHOOSING WISELY, http://choosingwisely.org/ (last visited May 6, 2013).

[132] Richard Knox, *Doctors Urge Their Colleagues to Quit Doing Worthless Tests*, NPR: ALL THINGS CONSIDERED (Apr. 4, 2012, 8:45 AM), http://www.npr.org/blogs/health/2012/04/04/149978690/doctors-urge-their-colleagues-to-quit-doing-worthless-tests?ps=sh_stcathdl.

[133] KPMG, ACCELERATING INNOVATION, *supra* note 62, at 10.

[134] *See, e.g.*, COMM. ON QUALITY OF HEALTH CARE IN AM. OF THE INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 1–3 (2001), *available at* http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx.

[135] *See* CHRISTENSEN, GROSSMAN & HWANG, *supra* note 28, at 184.

[136] *Id.* at 201.

[137] CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM, TRANSITIONING TO EPISODE-BASED PAYMENT 1, http://www.chqpr.org/downloads/TransitioningtoEpisodes.pdf (last visited May 6, 2013).

[138] *See* Walker & Carayon, *supra* note 128, at 467.

[139] *See Joint Principles of the Patient-Centered Medical Home*, PATIENT-CENTERED PRIMARY CARE COLLABORATIVE, http://www.pcpcc.net/content/joint-principles-patient-centered-medical-home (last visited May 6, 2013); *see also Defining the Medical Home*, PATIENT-CENTERED PRIMARY CARE COLLABORATIVE, http://www.pcpcc.net/about/medical-home (last visited May 6, 2013).

mental role to play in both Accountable Care Organizations and PCMH models.[140]

The "waiting" model captures a further difficulty. Is HIT waiting for new care models or *vice versa*? The draft regulations for Accountable Care Organizations essentially required the participating providers to be meaningful users. When the watered-down final rule was issued, MU had been deprecated to one of many performance measures. Going in the other direction, the Bipartisan Policy Center has argued that MU may come up short. Although MU is important to promote the data properties necessary for "coordinated, accountable, patient-centered models of care," increasingly " 'data-rich' environments necessary for delivery system reforms will require health IT, eHealth and analytical tools that appropriately fall beyond the current and anticipated requirements for [MU]."[141]

A 2010 report from the National Transitions of Care Coalition suggested that several process-based initiatives were necessary to promote meaningful HIT implementation for care transitions. These included interoperability standards, best practices, optimized outcome measures, and heightened opportunities for team-based care. The report also noted the "[l]ack of real incentives for sharing information between and among all care settings, based on accountability for sending and receiving information, as well as the ultimate outcomes of transitions of care."[142] Not surprisingly, fragmented or episodic care attracts fragmented HIT "solutions," such as freestanding computerized physician order entry or basic EMRs. The focus on supporting individual tasks (e.g., prescribing or recording patient data), rather than processes, is often a function of IT seeking to support individual clinical units (often individuals) rather than cross-departmental teams that should be engaging on a continuous process.[143]

VI. Flawed Data Models: PCAST and the Parable of Google Health

This section examines a third explanation for the relative failure of HIT: flaws in our current data construct. HIT insiders argue that other types of data, such as those found in the financial services sector, are less varied and, thus, more predictable. In contrast, patient and provider heterogeneity produce data that is more dynamic, less structured, and constantly in flux because of scientific and regulatory changes.[144] The question whether our current health care data model is too proprietary or otherwise underdeveloped is examined through two lenses: the 2010 PCAST report and the demise of *Google Health*.

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[140] David Meyers et al., U.S. Dep't of Health & Human Servs., The Roles of Patient-Centered Medical Homes and Accountable Care Organizations in Coordinating Patient Care 7–8 (2010).

[141] Transforming Health Care, *supra* note 60, at 17.

[142] Nat'l Transitions of Care Coal., Improving Transitions of Care with Health Information Technology 27 (2010), *available at* http://www.ntocc.org/Portals/0/PDF/Resources/HITPaper.pdf.

[143] Walker & Carayon, *supra* note 128, at 469.

[144] Milt Freudenheim, *Digitizing Health Records, Before It Was Cool*, N.Y. Times, Jan. 15, 2012, at BU1.

In 2010, the President's Council of Advisors on Science and Technology (PCAST) challenged the model for EMR/HIT implementation that had been implicitly agreed to by the federal government, the HIT industry, and health care providers.[145] The report contained a sharply critical commentary on the HITECH subsidy program. Specifically, PCAST argued that "[t]he initial approach to meaningful use has focused on driving physicians to adopt EHR systems that perform important quality-improving functions within the practice and, to a lesser extent, on developing capabilities for broader sharing."[146] PCAST viewed ONC's data sharing plans as "very modest" in contrast to a needed "simultaneous focus on the capability for universal data exchange, able to unleash the power of the competitive market, to produce increasingly better and less expensive systems, and to create the 'network effect' that spurs further adoption."[147]

To counter this threat of merely replacing paper records siloes with electronic ones, PCAST recommended the establishment of a " 'universal exchange language' that enables health IT data to be shared across institutions; and also to create the infrastructure that allows physicians and patients to assemble a patient's data across institutional boundaries."[148] Because misaligned incentives would lead only to market failure, PCAST recommended ONC-CMS build robust data exchange into Stages Two and Three of Meaningful Use. ONC-CMS did not welcome the PCAST interference and sidestepped most of the questions posed by the report. In August of 2011, ONC published a draft set of metadata standards using a summary records model.[149] While data sharing has been increased in Stage Two and exchange models are expected to feature more prominently in Stage Three, overall the MU standards continue to prioritize clinical integration rather than exchange.

Yet PCAST raised a fundamental question: Have we failed to adopt a data model capable of supporting the transformation or disruption of health care? In fact, PCAST asked and answered *two* quite central questions about health data. First, while data interchange and necessary standards for the interchange have long been part of the lexicon of EMRs and HIT, PCAST suggested a shift away from traditional sharing models. Second, PCAST rejected the conventional model of aggregated health information (such as a patient record), preferring a far more disaggregated data model.

As to the first question, PCAST rejected a standardized records model for EMRs as "doomed to failure" because of "too much diversity and incompatibility for any kind of *a priori* standard to emerge" and the inherent limitations of systems based on "fixed records."[150] PCAST also rejected "service-oriented architecture" (bilateral agreements between end-users allowing access to their data) because of scalability issues.[151] Rather, the report recommended, "[t]he

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[145] PCAST, *supra* note 9, at 3–4.
[146] *Id.* at 3.
[147] *Id.*
[148] *Id.* at 4.
[149] Metadata Standards to Support Nationwide Electronic Health Information Exchange, 76 Fed. Reg. 48,769, 48,769–76 (Aug. 9, 2011) (to be codified at 45 C.F.R. pt. 170).
[150] PCAST, *supra* note 9, at 39.
[151] *Id.* at 39–40.

best way to achieve a national health IT ecosystem is to ensure that all electronic health systems can exchange data in a universal exchange language."[152] The proposed language was "some kind of extensible markup language (an XML variant, for example) capable of exchanging data from an unspecified number of (not necessarily harmonized) semantic realms."[153] Evans and Wurster put forward a similar model a decade earlier in *Blown to Bits*, arguing that "key information standards, if driven to critical mass, would precipitate a deconstruction of the information-bonded relations in the health care industry."[154]

The PCAST model was not simply a translational one where structured data about a patient in one EMR would be exported into a universal exchange language. Rather, in PCAST's second major proposal, the data in an individual record would be segmented (or disaggregated) into "individual data elements" (e.g., a particular diagnosis or test). These individual data elements would be annotated with metadata. This metadata would provide the patient identifying information, privacy protocols, and provenance relating to those data elements. Providers could then access, search, and process the highly scalable data with specialized and secure search engines that would crawl the metadata.[155]

Overall, PCAST gained little traction because it failed to satisfy existing stakeholders.[156] It did not provide a coherent roadmap for short-term implementation and rightly set off a number of privacy and security alarms.[157] Assume, however, that the security and confidentiality issues could be solved. The PCAST data model is radically different from anything that has come out of the MU project (indeed, it was antithetical to the technical and business models agreed on by providers, vendors, and regulators). However, the PCAST approach to data transparency would promote efficient data sharing with patients and between providers, something that stakeholder pushback on the proposed MU Stage Two requirements suggests is extremely difficult using the data models in most current EMRs. A single data standard also would substantially accelerate the collection and analysis of "big data," itself a problematic construct.[158]

Not surprisingly, because it would be built on web standards, the PCAST data model is consistent with Zittrain's concept of generativity: "a system's capacity to produce unanticipated change through unfiltered contributions from

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[152] *Id.* at 41.

[153] *Id.* (emphasis omitted). For information on XML, see generally *Extensible Markup Language (XML) 1.0 (Fifth Edition)*, W3C (Nov. 26, 2008), http://www.w3.org/TR/REC-xml/; *Introduction to XML*, W3SCHOOLS.COM, http://www.w3schools.com/xml/xml_whatis.asp (last visited May 6, 2013).

[154] PHILIP EVANS & THOMAS S. WURSTER, BLOWN TO BITS: HOW THE NEW ECONOMICS OF INFORMATION TRANSFORMS STRATEGY 187 (2000).

[155] PCAST, *supra* note 9, at 41–42.

[156] For a summary of stakeholder reactions, see Vince Kuraitis, *PCAST HIT Report Becomes a Political Piñata*, HEALTH CARE BLOG (Jan. 23, 2011), http://thehealthcareblog.com/blog/2011/01/23/pcast-hit-report-becomes-a-political-pinata/.

[157] *See, e.g.*, Mark A. Rothstein, *Debate Over Patient Privacy Controls in Electronic Health Records*, BIOETHICS F. (Feb. 17, 2011), http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5139. On privacy and security, see generally PCAST, *supra* note 9, at 45–52.

[158] *See generally* Terry, *supra* note 54.

broad and varied audiences."[159] In contrast, today too much patient data is trapped by the proprietary formats used in current-generation EMRs. With its emphasis on setting free the value in patient data, the PCAST proposals might well have enabled a platform for disruptive innovation. For example, the report itself asserted: "An important advantage of the technological approach we have described is that it would enable new markets where firms compete to provide services and tools to patients, healthcare providers, payers, public health officials, and researchers." Examples provided included "products for patients to gather information about diseases using their personal health data, to input data from home health monitors, or to compare healthcare providers."[160]

At an earlier meeting of PCAST in August 2009, Eric Schmidt, Google's then-chairman and CEO and a member of the advisory council, criticized the Obama administration over its EMR subsidy model. He argued that it would lead to an outdated system of databases rather than patient-controlled records based on the web.[161] A year before, during the last few months of the Bush administration, Schmidt's company had launched *Google Health*. Described at launch by then-Google Vice President Marissa Mayer as a "large ongoing initiative" designed to include "thousands of partners and millions of users,"[162] *Google Health* was a web-based personal health record (PHR) service that was free to consumers and designed eventually to integrate with Google's health care provider "partners."

The timing of the launch looked fortuitous. By 2008, the Bush administration realized that market failures were going to be fatal to its EHR project. In contrast, *Google Health*'s PHR model probably appeared to be a perfect substitute. PHRs would be offered directly to patients bypassing the failures in EMR markets. PHRs were also less likely to be slowed by privacy rules because at that time they operated in an essentially unregulated zone little touched by the HIPAA Code.[163]

Yet *Google Health* was destined to be the "poster child" of information technology's failure to disrupt health care. Notwithstanding an alignment of economic, political, and technical advantages, *Google Health* withered on the vine before Google's 2011 announcement that the product would be retired.[164] That announcement read in part:

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[159] JONATHAN ZITTRAIN, THE FUTURE OF THE INTERNET—AND HOW TO STOP IT 70 (2008) (emphasis omitted).

[160] PCAST, *supra* note 9, at 57.

[161] Bob Brewin, *Google, Microsoft Executives Criticize Obama's E-Health Records Plan*, NEXTGOV.COM (Aug. 6, 2009), http://www.nextgov.com/health/2009/08/google-microsoft-executives-criticize-obamas-e-health-records-plan/44481/.

[162] Steve Lohr, *Google Offers Personal Health Records on the Web*, N.Y. TIMES (May 20, 2008), http://www.nytimes.com/2008/05/20/technology/20google.html?_r=2&.

[163] PHRs run by non-covered entities would avoid most federal regulation until HITECH's breach notification provisions authorizing FTC regulation. *See* FTC Health Breach Notification Rule, 74 Fed. Reg. 42,962 (Aug. 25, 2009) (to be codified at 16 C.F.R. pt. 318) (requiring vendors of personal health records and related entities to notify consumers when the security of their individually identifiable health information has been breached).

[164] *An Update on Google Health and Google PowerMeter*, GOOGLE OFFICIAL BLOG (June 24, 2011), http://googleblog.blogspot.com/2011/06/update-on-google-health-and-google.html.

> *Google Health* is not having the broad impact that we hoped it would. There has been adoption among certain groups of users like tech-savvy patients and their caregivers, and more recently fitness and wellness enthusiasts. But we haven't found a way to translate that limited usage into widespread adoption in the daily health routines of millions of people.[165]

Various explanations for the demise of *Google Health* have been posited, primarily those suggesting that it was increasingly difficult for Google to engage patients in curating their own health records.[166] In fact, PCAST was prescient. Google's PHR *was* built on a universal exchange language, but those with which its creators wished it to exchange data *were not*. Without a common data infrastructure and with EMR data mostly locked away for the near future in proprietary formats, even one of the world's largest technology companies was unable to free the data and innovate in the health care space.

This fundamental flaw in the health care data model hindering interoperability, exchange, and data transparency remains a key barrier to HIT expansion. West and Friedman explain why health data sharing is so difficult by stating: "Medical data are more voluminous and heterogeneous than financial records. The data itself are often stored in proprietary formats, and the diversity of legacy standards and provider practices makes interoperability difficult to achieve."[167] In spite of HITECH-funded loans and grants (primarily through the State Health Information Exchange Cooperative Agreement Program[168]) and some notable established success stories in a small number of states,[169] health information exchange implementation continues to struggle.[170] There are a large number of health information exchanges based on different models, minimal incentives to share data, and difficulty in identifying a workable business model or sustainable funding.[171]

PCAST's criticisms of the current EMR/HIT data model persist. For example, in a February 2012 letter to CMS and ONC, Senator Mark Warner was critical of MU for not including "clear and robust interoperability requirements" and failing to fully support consumer access to and interaction with EHR-based data.[172] Particularly telling was the Senator's observation: "If

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[165] *Id.* (italics added).

[166] *RIP Google Health*, CHILMARK RES. (June 24, 2011), http://chilmarkresearch.com/2011/06/24/rip-google-health/.

[167] DARRELL M. WEST & ALLAN FRIEDMAN, THE BROOKINGS INST., HEALTH INFORMATION EXCHANGES AND MEGACHANGE 4 (2012), *available at* http://www.brookings.edu/~/media/research/files/papers/2012/2/08%20health%20info%20exchange%20friedman%20west/0208_health_info_exchange_west.pdf.

[168] *State Health Information Exchange Program*, HEALTHIT.GOV, http://www.healthit.gov/policy-researchers-implementers/state-health-information-exchange (last visited May 6, 2013).

[169] *See, e.g.*, Lori Stephenson & David Herr, *The Beacon Communities at One Year: The Colorado Experience*, HEALTH AFF. BLOG (May 19, 2011), http://healthaffairs.org/blog/2011/05/19/the-beacon-communities-at-one-year-the-colorado-experience/.

[170] *See, e.g.*, Phil Cauthon, *KHIE Board Turns Over Regulatory Duties to State: KDHE Now to Oversee Exchange of Electronic Health Records*, KAN. HEALTH INST. (Sept. 12, 2012), http://www.khi.org/news/2012/sep/12/khie-board-turns-over-regulatory-duties-state/.

[171] WEST & FRIEDMAN, *supra* note 167, at 7–8.

[172] Letter from Mark R. Warner, U.S. Senator, to Marilyn Tavenner, Adm'r, Dep't of Health & Human Servs., and Farzad Mostashari, Nat'l Coordinator for Health Info. Tech.,

HITECH Act funding is used to create another generation of siloed EHR systems, we will have failed in our goal to use technology to reduce the cost of providing exceptional health care."[173]

Some of health care's market failure problems (in the sense that health care is not being packaged as many customers would like it) are paralleled in other industries. Consider the following description from technology analyst Horace Dediu: "It's a value network of great breadth and complexity. It's a highly modularized industry with well-defined business model boundaries and inter-dependencies."[174] Dediu, who studied under Clayton Christensen,[175] was talking about the television industry, but his words should resonate with those who dissect health care.

Sub-optimal performance can be seen in the way video (primarily TV) content is delivered to consumers. Channels are delivered in a bundle. Whether the consumer is interested primarily in one, ten, or twenty channels, they will be delivered in a single bundle of approximately 150.[176] That bundled price is the product of a complex series of individual transactions between the delivery system (cable or satellite company) and the content providers (networks or studios) leading to an arcane cross-subsidization model. Again, paralleling health care, some delivery and content systems (e.g., NBC-Comcast[177]) are vertically integrated and thus create a market concentration. Consumers who wish to reduce costs are denied unbundling because of these and other concentrations. The forces of disruption are surrounding video distribution much as they did with music distribution.[178] However, with incumbents using concentration, ver-

Dep't of Health & Human Servs. (Feb. 21, 2012), *available at* http://thehill.com/images/stories/blogs/healthwatch/healthitwarner.pdf.

[173] *Id.*

[174] Horace Dediu, *Tele Vision*, ASYMCO (Aug. 29, 2011, 1:36 PM), http://www.asymco.com/2011/08/29/tele-vision/.

[175] *See Horace Dediu*, WIKIPEDIA (Nov. 21, 2012, 9:09 PM), http://en.wikipedia.org/wiki/Horace_Dediu.

[176] *See, e.g.*, Ryan Lawler, *How Much Would the Average Person Pay for a Standalone HBO GO Subscription? About $12 a Month*, TECHCRUNCH (June 5, 2012), http://techcrunch.com/2012/06/05/hbo-go-without-hbo/ (discussing economics of delivery of HBO without any cable provider subscription); Nick Bilton, *Disruptions: For HBO, Still Beholden to a Cable Company*, N.Y. TIMES, June 11, 2012, at B7.

[177] Kristen Hamill, *U.S. Approves Comcast-NBC Merger*, CNN MONEY (Jan. 18, 2011, 6:06 PM), http://money.cnn.com/2011/01/18/technology/fcc_comcast_nbc/index.htm.

[178] There are already technology-based disruptions/trends threatening the broadcast-cable market, but they have not yet caused major change in incumbent revenue. *See* David Carr, *A TV Schedule in the Hands of Whoever Holds the Remote*, N.Y. TIMES, May 14, 2012, at B3; Philip Elmer-DeWitt, *After Meeting with Apple Execs, Analyst Expects No Television Solution Any Time Soon*, CNN MONEY (Aug. 24, 2012, 9:52 AM), http://tech.fortune.cnn.com/2012/08/24/message-from-apple-execs-no-tv-solution-any-time-soon/; Erica Ogg, *DirecTV: Apple TV Won't "Obsolete Our Technology"*, GIGAOM (June 2, 2012, 7:55 AM), http://gigaom.com/apple/directv-apple-tv-wont-obsolete-our-technology/ (reporting comment of DirecTV Chairman Michael White: "Typically with technology, it smashes the cost structure in some new way (but) with content costs, rights fees and the cost of spectrum it's hard to see (it) obsoleting our technology."); Adam Satariano & Alex Sherman, *Apple TV No iPhone As Talks Bog Down with Media Companies*, BLOOMBERG.COM (Sept. 6, 2012, 2:14 PM), http://www.bloomberg.com/news/2012-09-06/apple-tv-no-iphone-as-talks-bog-down-with-media-companies.html; Jay Yarow, *The Apple Television Is Coming, and This Is Why It's Going to Be Revolutionary*, BUS. INSIDER (June 1, 2012, 10:09 AM), http://www.business

tical integration, and geographical exclusivity (cable franchises) to protect their markets, regulatory trust busting may be required prior to meaningful disruption.[179]

As to why television has not been disrupted by technology like the music industry has, Dediu continued: "If you look at each technological experiment to move to a new business model, they can all be reduced to the offer of an additional or substitutive module. There is no assumption made that the content being served will change."[180] His statement is the key to understanding the relative lack of disruption in health care. At the care level, the U.S. health care system is failing to offer any "additional or substitutive modules." Video distribution may well fall to the disrupters sooner than later. When it does, the manner in which the complex relationships are unraveled may well serve as an important bellwether for health care.

According to a Booz Allen Hamilton report: "As patient information becomes digitized, researchers can now analyze large sets of anonymous data, facilitating the rapid introduction of new therapies and better analysis on the effectiveness of medications and treatments."[181] This is a reference to "big data." The big data hypothesis is that sophisticated algorithms will be used to comb through increasingly vast repositories of data in order to discover patterns of conditions and behaviors that will lead to better and more focused products and services.[182] As I have discussed elsewhere there are several problems with big data, an apparently irreconcilable relationship with health privacy and its regulation being just one.[183] Notwithstanding, unless health information can be freed from the health care silos where it currently resides and put into a common data format for processing, the opportunity for big data to transform health care may be missed.[184]

Google Health was a classic example (albeit a failing one) of disruptive innovation run by an innovator new to health care, rather than by an incumbent. True to the Christensen-led disruption model, *Google Health*'s initial performance clearly was below that desired by most consumers, whether patients or physicians. This underperformance was in the features (importing and exporting data), negative externalities (uncertain level of confidentiality), and informational asymmetries (what Google would do with the data collected). Incumbents, at most, wanted to add patient portals to their EMRs primarily

insider.com/apple-television-what-to-expect-2012-6?op=1 (discussing how consumers actually want unbundled content and a cloud-based DVR).

[179] *See* Thomas Catan & Amy Schatz, *U.S. Probes Cable for Limits on Net Video*, WALL ST. J. (June 13, 2012, 12:08 PM), http://online.wsj.com/article/SB10001424052702303444204577462951166384624.html.

[180] Dediu, *supra* note 174.

[181] Allen, *supra* note 44.

[182] *See* JAMES MANYIKA ET AL., MCKINSEY GLOBAL INST., BIG DATA: THE NEXT FRONTIER FOR INNOVATION, COMPETITION, AND PRODUCTIVITY 5 (2011), *available at* http://www.mckinsey.com/~/media/McKinsey/dotcom/Insights%20and%20pubs/MGI/Research/Technology%20and%20Innovation/Big%20Data/MGI_big_data_full_report.ashx.

[183] *See, e.g.*, Terry, *supra* note 54, at 385–86.

[184] KAUFFMAN, *supra* note 57, at 20 ("Merely uploading information into a database is not very useful if the data are in a multiplicity of formats that cannot 'talk' to each other or be easily compared. Nor can information be compared widely if semantics are not standardized.").

because insurers and employers were hoping such would promote positive lifestyle changes and resultant cost savings.

Google Health was very low priced (it was free). If Google had been able to ramp-up, access more curated data (through a common language), and provide additional value to patients and data end-users, it could have been seriously disruptive. Unfortunately, Google missed an important trait of the undershooting model. Although disruptive technologies initially tend to underperform, they are "typically cheaper, simpler, smaller, and, frequently, more convenient to use" than existing mainstream products.[185] Google knew it wanted to harvest health information about its users that it could sell to advertisers. However, it failed to convince its users that the product had any, even underperforming, value to them.

VII. Disruptive Channel Innovation and Personal Health Technologies

So far this article has posited three explanations for the struggle that HIT has faced in disrupting health care. First, HIT suffers from similar market failures as health care generally, rendering widespread adoption problematic. Second, and closely linked to the first, HIT is waiting for some major structural corrections to health care such as process-based organization and remuneration. Third, although IT typically transforms industries by changing the way data is collected, shared, and processed, health care lacks an amenable data standard. This section poses a fourth explanation: a truly disruptive HIT agent or technology has not yet emerged. This pessimistic note then is itself challenged with an examination of personal health technologies, exemplified by mobile computing platforms and their downloadable mobile medical apps.

If the Christensen-led literature is correct, disruptive innovation in health care should begin with products that exhibit a different value proposition from those sold by incumbents. Such products will likely underperform initially, but may be smaller, simpler, or more convenient. They also should prosper in the pricing overhangs left by incumbents and offer "additional or substitutive modules." Personal health technologies seem to fit this model and potentially may create "Healthcare Everywhere."

One of the classic weaknesses of our current health care model is that it is resolutely location specific. Health care is available only in certain locations, whether in clinics, hospitals, medical buildings, or emergency rooms. Since the demise of the Marcus Welby MD-era culture of home visits, patients have been the only stakeholders routinely required to travel.[186] Primarily they trek to brick-and-mortar facilities. Frequently such facilities are in disjointed locations emphasizing their task-specific nature (primary, secondary, tertiary, radiography, labs, etc.) and highlighting the episodic, individually billed nature of health care services. Cost, quality, and access are all implicated. These traditional facilities are major cost centers while the friction involved in appointments and travel discourages preventive care.

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[185] Christensen, *supra* note 8, at xv.

[186] *Marcus Welby, M.D.*, Wikipedia (Mar. 24, 2013, 2:46 PM), http://en.wikipedia.org/wiki/Marcus_Welby,_M.D.

Health care delivery has high friction. For patients, it is difficult and costly (in several senses) to choose providers, get appointments, acquire convenient medical information and advice, make decisions as to procedures, etc. Beyond the clinical space, there is immense friction at the financing stage, forms, approvals, acquiring receipts, not to mention negotiating with insurers and a multitude of other agents such as flexible savings account and pharmacy benefit managers.

In *Seeing What's Next*, Christensen and colleagues discuss the potential of health care disruption with innovations as varied as home pregnancy tests and freestanding ambulatory surgical centers. They argue: "In each case, caregivers with less training became capable of providing effective care in more convenient, less expensive venues—care that historically had required expensive experts located in inconvenient, costly facilities."[187]

One of the more interesting brick-and-mortar channel innovations in health care delivery has been the retail medical clinic, sometimes referred to as a "doc-in-the-box."[188] These clinics are often housed in large, popular retail stores[189] and are typically staffed by physician extenders.[190] A RAND study found that from 2007 to 2009, the use of such clinics increased ten-fold, with geographical proximity being the strongest predictor of use.[191] This growth has occurred despite consistent opposition from professional organizations, such as the AMA.[192] If such clinics do cause disruption, it will be by offering low-cost, high-convenience care leveraging supply chain sophistication and customer analytics unknown in traditional health care.[193] The disruptive potential of

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[187] CHRISTENSEN, ANTHONY & ROTH, *supra* note 24, at 181.

[188] *See, e.g.*, Nicolas P. Terry, *Prescriptions sans Frontières (or How I Stopped Worrying About Viagra on the Web But Grew Concerned About the Future of Healthcare Delivery)*, 4 YALE J. HEALTH POL'Y L. & ETHICS 101, 172–74 (2004) [hereinafter Terry, *Prescriptions sans Frontières*]; *see also* Craig Evan Pollack & Katrina Armstrong, *The Geographic Accessibility of Retail Clinics for Underserved Populations*, 169 ARCHIVES INTERNAL MED. 945, 945 (2009), *available at* http://archinte.jamanetwork.com/article.aspx?articleid=414985.

[189] *See, e.g.*, Julie Appleby & Sarah Varney, *Wal-Mart Plans Ambitious Expansion into Medical Care*, NPR NEWS (Nov. 9, 2011, 12:01 AM), http://www.npr.org/blogs/health/2011/11/10/142156478/wal-mart-plans-ambitious-expansion-into-medical-care; Jackie Crosby, *Target Inches into Medical Clinic Business*, STAR TRIB. (Sept. 14, 2010, 7:35 PM), http://www.startribune.com/business/102656069.html.

[190] *See, e.g.*, Bruce Japsen, *More Health Clinics Pop Up Inside Retailers*, N.Y. TIMES (Jan. 9, 2012, 6:00 PM), http://prescriptions.blogs.nytimes.com/2012/01/09/more-health-clinics-pop-up-inside-retailers; *see also* CVS.COM, http://www.minuteclinic.com/ (last visited May 6, 2013).

[191] J. Scott Ashwood et al., *Trends in Retail Clinic Use Among the Commercially Insured*, 17 AM. J. MANAGED CARE e443, e444–45 (2011); *see also* Ateev Mehrotra & Judith R. Lave, *Visits to Retail Clinics Grew Fourfold from 2007 to 2009, Although Their Share of Overall Outpatient Visits Remains Low*, 31 HEALTH AFF. 2123, 2124 (2012).

[192] *See, e.g.*, Pamela Lewis Dolan, *AMA Meeting: Delegates Seek More Oversight of Retail Clinics*, AM. MED. NEWS (July 16, 2007), http://www.ama-assn.org/amednews/2007/07/16/prl20716.htm; Pamela Lewis Dolan, *AMA Toughens Stance on Retail Health Clinics*, AM. MED. NEWS (July 4, 2011), http://www.ama-assn.org/amednews/2011/07/04/prsk0704.htm.

[193] *See* Roger Foster, *Reducing Healthcare Administrative Inefficiencies with Big Data*, GOV'T HEALTH IT (May 22, 2012), http://www.govhealthit.com/news/reducing-healthcare-inefficiencies-big-data?page=0,1; *see also* Chad Terhune, *In-store Clinics Look To Be a Remedy for Healthcare Law Influx*, L.A. TIMES (July 30, 2012), http://articles.latimes.com/2012/jul/30/business/la-fi-clinic-medical-care-20120730.

these clinics has increased because of the hybrid clinic/online model, which combined in-store clinics with access to online health care advice[194] or in-store diagnostic "pods."[195]

Even with this hybrid twist, such clinics are not truly disruptive. They are at best interesting sustaining plays by incumbents (pharmacies and health insurers). The online aspects of hybrid models retain some legal risks[196] while clinics owned by health insurers seem to exhibit channel conflict. In a sense, walk-in medical clinics are really part of an emerging patchwork safety net for uninsured and underinsured patients, the very existence of which somewhat perversely supports the continued existence of low-access, high-quality health care.

In contrast, true channel innovation and a more extreme disruptive force may be seen in the growth of mobile apps. Mobile broadband and smartphone computing platforms permit omnipresent and location-neutral technologically mediated health care. Mobile platforms are highly disruptive and mobile platforms with app stores are promoting disruptive innovation across all domains, many of which have been controlled by incumbents.[197] Michael Saylor predicts that a pervasive mobile computing platform "will cause companies to replace their physical products and services with software equivalents, and it will cause companies to extend their business processes beyond the four walls of the business and out to the software resident on their consumers' mobile computers."[198]

Currently there are more than six billion devices connected to mobile networks. This number is predicted to rise to nine billion by 2017, exceeding the

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[194] The online play is from NowClinic, part of the OPTUMHealth group owned by UnitedHealth Group the parent company of health insurer UnitedHealthcare. *See* NowClinic, http://www.mynowclinic.com (last visited May 7, 2013). Its hybrid character comes from the fact that Rite Aid pharmacies and OptumHealth now offer access to NowClinic in the former's Detroit-area stores. *Rite Aid and OptumHealth Introduce NowClinic℠ Online Care Services in Detroit*, RiteAid.com (Sept. 15, 2011), http://www.riteaid.com/company/news/news_details.jsf?itemNumber=1489. *See also* Pamela Lewis Dolan, *Rite Aid Clinics Place New Twist on "Doc-in-a-Box"*, Am. Med. News (Feb. 6, 2012), http://www.ama-assn.org/amednews/2012/02/06/bil20206.htm.

[195] For example, Care4 Stations are self-contained kiosks that are fully enclosed for privacy and equipped with various diagnostic interfaces wirelessly linked back to the remote caregivers. *Press Releases*, HealthSpot, http://www.healthspot.net/about/news/mission.html (last visited May 7, 2013). Conceptualized as "medical ATMs," these kiosks are designed for installation in pharmacies, retail stores, or workplaces. Brian Dolan, *HealthSpot Adds Sprint 4G, E-Stethoscope to Kiosks*, MobiHealthNews (Feb. 20, 2012), http://mobihealthnews.com/16389/healthspot-adds-sprint-4g-e-stethoscope-to-kiosks.

[196] *See, e.g.*, Terry, *Prescriptions sans Frontières*, *supra* note 188, at 175–76 (discussing closure of MyDoc.com).

[197] *See, e.g.*, Peter Wayner, *Monitoring Your Health with Mobile Devices*, N.Y. Times (Feb. 22, 2012), http://www.nytimes.com/2012/02/23/technology/personaltech/monitoring-your-health-with-mobile-devices.html?ref=technology; *see also* Milt Freudenheim, *As Smartphones Become Health Aids, Ads May Follow*, N.Y. Times, Apr. 2, 2012, at B3.

[198] Michael Saylor, The Mobile Wave: How Mobile Intelligence Will Change Everything 6 (2012).

global population.[199] Smartphones, the mobile platforms that allow apps, now account for half of phones used in the United States and dominate sales of new devices.[200] Health care and medical app downloads will reach 44 million in 2012 and 142 million in 2016.[201] By then, three million patients will be using smartphone-enabled remote patient monitoring.[202] Overall, 2012's $150 million market for mobile medical applications will grow by twenty-five percent annually for the following five years.[203] There are signs of serious investment in mobile medical apps from incumbents, such as pharmaceutical companies[204] and venture capitalist funds.[205]

Many of the first health care apps qualify only as sustaining technologies. For example, providers of journals, books, and services that previously existed in paper or on the web now make app versions or supplements. As the resolution of smartphone screens increase, they are increasingly being used for image-based diagnostics.[206] Additionally, incumbent providers of health care or health insurance products are distributing apps that locate providers and provide coverage information.[207] App stores are full of simple personal health records, reminders, health information calendars (recording everything from food intake, menstrual cycles, and fetal growth). Many nascent web services providing information (including quality ratings) about providers are likely to

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[199] Juliette Garside, *More Mobile Devices Than People "Within Five Years"*, THEGUARDIAN (June 6, 2012, 5:00 AM), http://www.guardian.co.uk/business/2012/jun/06/more-mobile-devices-people-five-years; *see also* Fred Wilson, *Mobile Is Where the Growth Is*, AVC: MUSINGS OF A VC IN NYC (July 1, 2012), http://www.avc.com/a_vc/2012/07/mobile-is-where-the-growth-is.html.

[200] *Smartphones Account for Half of All Mobile Phones, Dominate New Phone Purchases in the US*, NIELSEN WIRE (Mar. 29, 2012), http://blog.nielsen.com/nielsenwire/online_mobile/smartphones-account-for-half-of-all-mobile-phones-dominate-new-phone-purchases-in-the-us.

[201] Brian Dolan, *Report: 44M Health App Downloads in 2012*, MOBIHEALTHNEWS (Nov. 30, 2011), http://mobihealthnews.com/15029/report-44m-health-app-downloads-in-2012/.

[202] Anthony Cox, *Press Release: mHealth Users of Remote Health Monitoring to Reach 3 Million by 2016: Smartphones Play Leading Role*, JUNIPER RES. (Feb. 2, 2012), http://www.juniperresearch.com/viewpressrelease.php?pr=285.

[203] Joseph Goedert, *Kalorama Tracks Mobile Medical App Market*, HEALTH DATA MGMT. (June 12, 2012, 5:25 PM), http://www.healthdatamanagement.com/news/mobile-medical-apps-applications-market-kalorama-44597-1.html.

[204] *See, e.g.*, Brian Dolan, *Pharma Investments in Apps, Web Rise 78 Percent*, MOBIHEALTHNEWS (Feb. 16, 2011), http://mobihealthnews.com/10249/pharma-investments-in-apps-and-web-rise-78-percent/.

[205] Anna Edney, *iPad Toting Doctors Spur Venture Funding in Medical Apps*, BLOOMBERG (June 18, 2012, 7:01 AM), http://www.bloomberg.com/news/2012-06-18/oprah-aids-doctors-as-app-investments-soar-health.html.

[206] *See, e.g.*, Cédric Lamirel et al., *Nonmydriatic Digital Ocular Fundus Photography on the iPhone 3G: The FOTO-ED Study*, 130 ARCHIVES OPHTHALMOLOGY 939, 939 (2012).

[207] *See* ROBERT OSCAR, HEALTH IT LAW & INDUSTRY REPORT, ANSWERING THE CALL: USING SMARTPHONE TECHNOLOGY TO OPTIMIZE HEALTH CARE 1–2 (2012); Justin Montgomery, *UnitedHealthcare Debuts "Health4Me" Mobile App for iOS Devices, Coming Soon for Android*, MHEALTHWATCH (Feb. 27, 2012), http://mhealthwatch.com/unitedhealthcare-debuts-health4me-mobile-app-for-ios-devices-coming-soon-for-android-18938/.

be embraced by app stores[208] as will, for example, Groupon-like promotions for health care services based on location.[209] Additionally, novel app-based products such as NFC payment will be used in the health care domain.[210] These new products and services are joined by considerable innovation in the wellness space.

Overall most of these products and services fall short of disruptive innovation. However, true disruption may be close at hand as app developers build on the smartphone reality that most Americans now have a powerful connected computer with them at all times. As Christensen and colleagues have argued: "[N]ew-market disruptive innovations . . . occur when characteristics of existing products limit the number of potential consumers or *force consumption to take place in inconvenient, centralized settings*."[211] Smartphones and their mobile apps take aim at these existing products, aiming for convenient and decentralized care.

Many disruptive direct-to-consumer products, such as diabetes monitoring kits, pregnancy tests, and at-home genetic testing kits, point the way forward, essentially replacing the medical professional with a far lower skilled, but much cheaper, caregiver and stakeholder—the patient. Mobile's great promise is in both improving the quality of care while further reducing friction. The current health care model involves having patients visit a health care facility where their data is entered into a database. The data may be objective measurements and subjective evaluations emanating from both patient and provider. This process of visitation, data acquisition, and recording is expensive, inefficient, and unpleasant. Further, as we learn from other countries and seek to cut costs by increasing our ratio of preventive to curative care, we need to drastically reduce the friction accompanying patient interactions with providers. Michael Saylor analogizes the current hospital-based system to big box stores: "Each one is designed to have at least one of every kind of specialist on hand."[212] In contrast, he argues, "co-location no longer matters so much" when "medical information can move, and patients can see specialists on video."[213] Then, "a much more efficient architecture can be created. The hospital will become much more of a network, and much less of a big box."[214]

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[208] For example, the following websites easily lend themselves to (or have already become) mobile apps: ANGIE'S LIST, www.angieslist.com (last visited May 7, 2013); *Best Health and Medical in Chicago*, YELP, http://www.yelp.com/c/chicago/health (last visited May 7, 2013); *Avvo Health Has Moved to HealthTap*, AVVO HEALTH, http://www.avvo.com/health-information?referring_url=http%3A%2F%2Fwww.avvo.com%2Ffind-a-doctor%3Fref%3Dhomepage (last visited May 7, 2013); RATEMDS, http://www.ratemds.com (last visited May 7, 2013).

[209] *See, e.g.*, Associated Press, *Uninsured Turn to Daily Deal Sites for Health Care; People Relying on Groupon for Dental, Blood Work, Lasik*, NYDAILYNEWS.COM (Dec. 30, 2011, 4:11 PM), http://www.nydailynews.com/life-style/health/uninsured-turn-daily-deal-sites-health-care-people-relying-groupon-dental-blood-work-lasik-article-1.998989.

[210] *See, e.g.*, *Near Field Payment Technology to Dominate Mobile World Congress*, COMPUTERWEEKLY.COM (Feb. 9, 2011, 2:07 PM), http://www.computerweekly.com/news/1280095104/Near-field-payment-technology-to-dominate-Mobile-World-Congress.

[211] CHRISTENSEN, ANTHONY & ROTH, *supra* note 24, at xvii (emphasis added).

[212] SAYLOR, *supra* note 198, at 156.

[213] *Id.*

[214] *Id.*

While Internet-based care promises 24/7, location-independent access, its single interface (a web browser) remains limited. Mobile apps provide more than ubiquity. First, native apps can provide more sophistication than web apps.[215] Second, the smartphones themselves are packed with sensors (such as GPS, gyroscopes, accelerometers, touch-sensitive surfaces, microphones, and cameras) that app developers can leverage through application programming interfaces.[216] Third, new generation mobile devices such as smartphones and tablets typically have physical interfaces that allow the connection of external modules (e.g., blood pressure cuffs,[217] heat sensors,[218] or blood glucose monitoring[219]) to harvest data. Arguably, it is these advances in wearable accessories that collect biometric data using non-invasive sensors that will provide the greatest impetus in the development of medical apps.[220]

Mobile apps seem consistent with the disruptive innovation model. Health care incumbents do not own the platforms and networks upon which mobile medical apps are built. Indeed, the smartphone industry's major players (Apple and Google) are infamous disrupters of industries, while app developers are start-ups or, if incumbents, tend to come from wellness, medical device, or consumer electronics backgrounds. Furthermore, just as smartphones and tablets still undershoot personal computers, mobile medical apps also undershoot the high technology devices (and interfaces) found in incumbent-owned facilities.

At the moment, mobile apps lack the range and robustness of traditional health care. This, of course, may be interpreted as pre-disruption undershooting by the potentially disruptive innovation. As McNair describes:

> Mobile apps' ability to empower consumers is naturally associated with the potential to unsafely disintermediate the services of clinically-trained professionals, from whom consumers might otherwise have sought advice and care. For people who do not have ready access to those services because of lack of insurance coverage or

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215 *See, e.g.*, Max Katz & Tiggzi, *Native Apps vs. Mobile Web: Breaking Down the Mobile Ecosystem*, WIRED (Nov. 20, 2012, 1:37 PM), http://www.wired.com/insights/2012/11/native-apps-vs-mobile-web/.

216 *See, e.g.*, *The Best Health & Fitness App on Mobile Premier Awards 2011 According to the Jury of Industry Experts and as Seen on Dr. Oz Show!*, AZUMIO, http://www.azumio.com/apps/heart-rate (last visited May 7, 2013) (describing heart rate measurement using iPhone camera); *Skin Cancer Self-Exam Mobile App: UMSkinCheck*, UOFMHEALTH.ORG, http://www.uofmhealth.org/patient%20and%20visitor%20guide/my-skin-check-app (last visited May 7, 2013) (describing skin cancer self-exam and measurement using iPhone camera).

217 *See, e.g.*, *Blood Pressure Monitor*, WITHINGS.COM, http://www.withings.com/en/bloodpressuremonitor (last visited May 7, 2013).

218 *See, e.g.*, Satish Misra, *iPhone & iPad Peripheral ThermoDock Measures Body Temperature Without Any Body Contact*, IMEDICALAPPS (Apr. 2, 2012), http://www.imedicalapps.com/2012/04/thermodock-temperature-easy-owning-smartphone.

219 *See, e.g.*, IBG STAR, http://www.ibgstar.us (last visited May 7, 2013).

220 Rip Empson, *Market for Mobile Health Apps Projected to Quadruple to $400 Million by 2016*, TECHCRUNCH (Nov. 29, 2011), http://techcrunch.com/2011/11/29/market-for-mobile-health-apps-projected-to-quadruple-to-400-million-by-2016/.

shortages of providers or other reasons, "some" medical advice is usually better than "nothing."[221]

If health-related mobile apps operating on platforms, such as smartphones and tablets, are poised to become a disruptive force, the question arises as to what could slow their growth? Clearly, the underlying platforms and app stores (e.g., Google's Android and Apple's iOS) are robust and growing at an extremely high rate.[222] Furthermore, health care incumbents looking to block disruption with their high market concentration have little influence over the medical mobile apps market.

One answer could be regulation. Generally, mobile apps have grown in an unregulated space other than, for example, rules applied by the platform owners.[223] However, regulation might operate to favor incumbents by slowing adoption. In 2011, the Food and Drug Administration (FDA) published a *Draft Guidance on Mobile Medical Applications*.[224] The guidance suggested that products such as smartphone fitness apps would generally remain unregulated, but that regulation would extend to devices that included patient sensors, alarms, diagnostics, etc. The FDA approach is to regulate only what it calls a "mobile medical app," whether executing on the mobile platform or on a server that either "is used as an accessory to a regulated medical device" or "transforms a mobile platform into a regulated medical device."[225] The agency's ultimate responsibility to create a "strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications" was confirmed by the Food and Drug Administration Safety and Innovation Act in 2012.[226] Although the FDA seems to be developing some kind of roadmap as to how to approach medical apps, the sheer numbers, variety, and the lack of clear mapping between types of apps and device classifications may make regulation a daunting task.[227] For now, the agency seems happy to keep its regulatory footprint modest as it watches the market develop.

The second regulatory model that could come into play is the state-based licensure system. Primarily controlled by incumbents, these boards can be used to stifle innovation and perceived potential competition.[228] The transmission of

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[221] Douglas S. McNair, *FDA Facing Huge Task in Regulating Mobile Medical Apps*, CERNER BLOG (Aug. 9, 2011), http://www.cerner.com/blog/fda_facing_huge_task_in_regulating_mobile_medical_apps.

[222] *See, e.g.*, Aaron Smith, *Nearly Half of American Adults are Smartphone Owners*, PEW INTERNET (Mar. 1, 2012), http://pewinternet.org/Reports/2012/Smartphone-Update-2012.aspx.

[223] *See, e.g.*, *App Review*, APPLE DEVELOPER, https://developer.apple.com/appstore/guidelines.html (last visited May 7, 2013).

[224] *Draft Guidance for Industry and Food and Drug Administration Staff—Mobile Medical Applications*, FDA (July 21, 2011), http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263280.htm.

[225] *Id.* at Part III.C.

[226] Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, § 618, 126 Stat. 1063 (codified as amended in scattered sections of 21 U.S.C.).

[227] McNair, *supra* note 221.

[228] *See, e.g.*, DIABETES-WARRIOR.NET, http://www.diabetes-warrior.net (last visited May 7, 2013) (blog about the Paleolithic diet that is under threat from the North Carolina Board of Dietetics/Nutrition for unlicensed practice); *see also* Paul Sherman, *Can State Licensing*

patient data to a physician from a patient's mobile medical app potentially could be considered a telemedical relationship requiring a special purpose license.[229] A physician's response to patient input in an app potentially could implicate diagnosis or prescribing without a physical examination.[230] Further, a biometric sensor-enabled smartphone probably will transmit an algorithm-based diagnosis across state lines leading to an incumbent arguing unauthorized practice of medicine.[231] The macro question is whether state regulators will attempt to intervene in the medical apps space or will cede regulatory authority to the FDA (and FCC).

Asch and Volpp argue that "[i]n the future, successful doctors, hospitals, and health systems will shift their activities from delivering health services within their walls toward a broader range of approaches that deliver health."[232] The challenge they identify is moving from a "product-oriented industry to a customer-oriented one[.]"[233] Leveraging the power of rapidly evolving mobile computers may well be the answer. Conceptually and technically, mobile apps are part of the rapidly expanding *Internet of Things*.[234] They also move us closer to Eric Topol's *Homo Digitus*[235] or Frank Moss's "digital nervous system" comprising "inconspicuous wireless sensors worn on your body and placed in your home [which] continuously monitor your vital signs and track the daily activities that affect your health."[236] Moving health care (even just *some* health care) out of institutions and into patients' own local body networks powered by smartphones could be truly disruptive.

VIII. CONCLUSION

HIT has failed to become a major disruptive force in health care delivery. Indeed, its missteps and uncertain adoption curve are indicative of its role as a metaphor for the problems that beset health care generally, particularly its spi-

Boards Ban Ordinary Advice on the Internet?, NAT'L L.J. (May 30, 2012), http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202556531494&Can_state_licensing_boards_ban_ordinary_advice_on_the_Internet_&slreturn=20130101200418.

[229] *See Telemedicine Overview: Board-by-Board Approach*, FED'N STATE MED. BOARDS (Aug. 2012), http://www.fsmb.org/pdf/grpol_telemedicine_licensure.pdf.

[230] *See Internet Prescribing Language: State-by-State Overview*, FED'N STATE MED. BOARDS (Jan. 26, 2012), http://www.fsmb.org/pdf/InternetPrescribing-law&policylanguage.pdf.

[231] *See, e.g.*, MO. REV. STAT. § 334.010 (2012) (State law prohibiting the unauthorized practice of medicine and the practice of medicine across state lines).

[232] David A. Asch & Kevin G. Volpp, *What Business Are We In? The Emergence of Health as the Business of Health Care*, 367 NEW ENG. J. MED. 888, 889 (2012).

[233] *Id.*

[234] *See* Kevin Ashton, *That "Internet of Things" Thing*, RFID J. (July 22, 2009), http://www.rfidjournal.com/article/view/4986; Michael Chui, Markus Loffler & Roger Roberts, *The Internet of Things*, MCKINSEY GLOBAL INST. (Mar. 2010), http://www.mckinsey.com/insights/mgi/research/technology_and_innovation/the_internet_of_things.

[235] ERIC TOPOL, THE CREATIVE DESTRUCTION OF MEDICINE: HOW THE DIGITAL REVOLUTION WILL CREATE BETTER HEALTH CARE 226–43 (2012).

[236] Frank Moss, *Our High-Tech Health-Care Future*, N.Y. TIMES, Nov. 10, 2011, at A35. According to Moss's vision, based on data collected, the patient would receive automated advice or an online consultation rather than, or as triage mechanisms ahead of, office visits. *Id.*

raling costs, reduced access, and market failures. Going forward, any positive disruptive future for HIT will depend on fundamental changes in health care, the appearance of truly novel transformative technologies, or a fundamental rethinking of the health information data model. Worst case, it may be that health care is so hopelessly fragmented and hideously complex that market failure is endemic and beyond the disruptive reach of HIT or any other market-based solution.

Primarily, this Article has challenged the conventional transformation narrative that surrounds initiatives such as the ARRA-based HIT subsidy. While some gains in quality will result from the implementation of comprehensive HIT systems, little will change regarding health care access or costs. Unfortunately, the subsidy model has failed to reverse the pattern of most providers implementing quite basic EMR systems. The decade ahead will see a struggle to reduce the delta between siloed EMRs and transformative HIT. In the meantime, any positive gains from HIT may be offset by a growing technology gap between advanced providers (those who moved early to attest to MU or who have already made radical structural changes such as by integrating vertically) and those who are ineligible, culturally unwilling, or financially unable to meet the MU conditions.[237]

Just as with existing high technology health care like MRIs, the current generation of HIT is poised to be only a sustaining rather than disruptive technology. Notwithstanding that we live in a world of disruption, health care is more akin to the stubborn television domain, where similarly complex relationships and market concentrations have slowed the forces of disruption. Those seeking the transformation of health care may have to seek a different muse.

There are three potential exceptions to this pessimistic conclusion. First, because advanced HIT is not a good fit for episodic health care delivery, we may be experiencing a holding pattern while health care rights itself. With ACA upheld by the Supreme Court and the subsequent election favoring President Obama, it is time to see whether ACA initiatives such as ACOs and PCMH will foster broader HIT implementation. Second, the 2010 PCAST report was correct, and the health care data model is broken. Partially as a result, *Google Health* failed. If Stage Three of the MU subsidy program or some other initiative can fundamentally rethink interoperability (and we can fix the privacy issues), investment and innovation could migrate to data services built on top of shareable data.

The final and potentially most interesting exception may be personal health technologies, everything from personal health records to mobile apps: products that are themselves built on hugely disruptive platforms and championed by some of our most disruptive companies. Leveraging the growing computing power of smartphones and linkable biometric sensors, these apps hold the promise for "healthcare everywhere." And, unlike other HIT, they qualify as disruptive with their initial undershooting, low price, and convenience. If HIT is to bring about a tectonic shift rather than exist as a high technology

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[237] *See* Genevra Pittman, *Poorer Hospitals May Suffer from Medicare Changes*, REUTERS (July 16, 2012, 4:40 PM), http://www.reuters.com/article/2012/07/16/us-hospitals-medicare-idUSBRE86F14K20120716 (noting likelihood of quality measures adversely affecting safety-net hospitals).

metaphor for health care's market failures, this may be where the transformation of health care will commence.