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# The “Uberization” of Healthcare: The Forthcoming Legal Storm over Mobile Health Technology’s Impact on the Medical Profession

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-ARTICLES-

THE “UBERIZATION” OF  
HEALTHCARE: THE  
FORTHCOMING LEGAL STORM  
OVER MOBILE HEALTH  
TECHNOLOGY’S IMPACT ON  
THE MEDICAL PROFESSION

*Fazal Khan†*

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We don’t need and probably can’t afford doctors as the front line of defense anymore. . . That’s the problem, isn’t it? Doctors. They take a decade or more to train, and then you still have to feed them. Kind of like the Lippizaner dancing stallion. A neat trick, but terribly expensive to maintain. Okay, more like postal workers. It’s pretty neat that you can train people to sort mail, but email servers do it much quicker and cheaper. . . There aren’t 10 million nerdy-looking, khaki-wearing Ph.D.s reading search requests at Google. Instead search expertise is embedded in Google’s algorithms on servers in cool dry places. That’s scale . . . Doctors, take note. The Geeks are at the Gate.

-Andy Kessler, Silicon Valley Hedge Fund Manager<sup>1</sup>

## I. INTRODUCTION

It was not a fair fight. In 2013, Senator Ed Hernandez sponsored a bill in the California legislature that would allow nurse practitioners (NPs) to practice primary care medicine without the direct supervision of a physician.<sup>2</sup> The rationale for such a bill was clear. Like most states, California has an acute healthcare access problem, with only 16 out of 58 counties having sufficient numbers of primary care doctors.<sup>3</sup> With baby boomers entering retirement and Americans

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1. ANDY KESSLER, *THE END OF MEDICINE: HOW SILICON VALLEY (AND NAKED MICE) WILL REBOOT YOUR DOCTOR* 110-111 (2006).

2. Melanie Mason, *State Bill to Boost Use of Nurse Practitioners Goes Nowhere*, L.A. TIMES (Sept. 1, 2013), <http://articles.latimes.com/2013/sep/01/local/la-me-healthcare-20130902>.

3. *Id.*

living longer with chronic diseases, the mismatch between demand for primary care and the supply of doctors is projected to increase in magnitude. Prior to his effort, influential organizations such as the Institute of Medicine and the National Governors Association had already outlined and endorsed the enactment of state laws that would ease “scope of practice” restrictions on non-physicians in order to improve access to healthcare.<sup>4</sup> In support of his bill, Sen. Hernandez could cite several studies that empirically demonstrated that “primary care provided by NPs is of similar quality to that provided by physicians.”<sup>5</sup> Additionally, patient surveys have consistently shown high levels of satisfaction with primary care medicine delivered by NPs, with a majority of patients preferring to see a NP on the same day versus waiting an additional day to see a physician.<sup>6</sup>

Despite all of this independent validation for easing scope of practice restrictions on non-physicians, hardly anyone was surprised when Hernandez’s bill failed to even make it out of committee.<sup>7</sup> In support of Hernandez’s bill, the California Association of Nurse Practitioners paid \$55,000 to hire an outside lobbyist for half a year. On the opposing side, California Medical Association (CMA), representing the interests of the state’s doctors, deployed its army of in-house lobbyists and outside hired guns in Sacramento and gave millions in campaign contributions to key state lawmakers. Further, the CMA ran a sophisticated campaign that leveraged Facebook and Twitter to spread unsubstantiated patient safety concerns about this bill that spread to constituents casually checking social media updates on their Apple and Android devices.<sup>8</sup> This anecdote of an entrenched economic interest using restrictive licensing laws to shield itself from competition is not a new story. However, I predict that very soon a wildcard will emerge to dramatically tilt the balance of power in these legislative battles—the mobile health industry.

Mobile health constitutes the “use of mobile and wireless devices to improve health outcomes, healthcare services and health research.”<sup>9</sup>

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4. Catherine Dower et al., *Is it Time to Restructure Health Professions Scope-Of-Practice Regulations to Remove Barriers to Care*, 32 HEALTH AFF. 1971, 1971-72 (2013).
  5. Joanne Spetz et al., 32 HEALTH AFFAIRS 1977, 1982 (2013).
  6. Michael Dill et al., *Survey Shows Consumers Open To A Greater Role For Physician Assistants And Nurse Practitioners*, 32 HEALTH AFF. 1135, 1135 (2013).
  7. See Mason, *supra* note 2.
  8. *Id.*
  9. See *Definitions of Mobile Health*, mHiMSS (Jan. 5, 2012), <http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=20221>.

Even though mobile health has some ways to go before developing something akin to the mythical “Tricorder”<sup>10</sup> from Star Trek, recent developments have been impressive and the ultimate potential of this new technology is tantalizing.<sup>11</sup> Imagine the following: without requiring a costly clinic or hospital visit, a mobile device can enable a healthcare provider (e.g., the Veterans Hospital Administration (VA) or Kaiser Permanente) to remotely diagnose a patient’s condition and recommend a medically appropriate treatment plan, which might include the inexpensive and medically appropriate option of remote monitoring and follow up.<sup>12</sup> Furthermore, if a mobile health evaluation indicates that a patient’s condition is serious enough to require professional attention, a health care plan could send out a “physician extender” (e.g., physician assistant, nurse practitioner, home health aide, etc.) to your home, workplace, or long-term care facility with portable diagnostic equipment and even a mobile pharmaceutical dispensary that wirelessly interfaces with your secure electronic medical records (EMR).

The diagnostic and treatment abilities of physician extenders could be greatly amplified by mobile medical apps (MMAs) that rely on powerful artificial intelligence engines operating on cloud servers. Who needs to wait weeks or even months to see an expensive specialist when a physician extender backed up by an artificial intelligence engine like IBM’s Watson can give you an “expert” answer without the wait, and at a fraction of the cost? In other words, this technology could legitimately expand the scope of practice for physician extenders without sacrificing safety or quality. However, even assuming that mobile health can technologically

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10. See Jacopo Prisco, *Scanadu: The Medical Tricorder from Star Trek is Here*, CNN (Feb. 18, 2015), <http://www.cnn.com/2015/02/12/tech/mci-scanadu-tricorder/>. (Still, some companies claim they are not that far away. Qualcomm has sponsored the Tricorder X Prize competition to spur development of a mobile device similar to the Tricorder. Scanadu, one of ten finalists in the competition, might be the closest thing yet to the tricorder. It is a tiny puck-shaped device that can measure heart rate, temperature, blood pressure, oxygen level, and a complete EKG reading just by placing the device on your forehead.)
  11. See Nathan Cortez, *The Mobile Health Revolution?* 47 U.C. Davis L. Rev. 1173 (2014).
  12. *Testimony of Jonathan Spalter Before the Subcommittee on Health Committee on U.S. House of Representatives, Energy and Commerce Comm.*, (Mar. 20, 2013) (statement of Jonathan Spalter). See also Tracy Hampton, *Recent Advances in Mobile Technology Benefit Global Health, Research, and Care*, 307 JAMA 2013 (2012) (discussing mobile health’s potential to allow patients to monitor their health in real-time, to interact with doctors, and for developing countries’ abilities to surveil the spread of infectious disease).

deliver on its promise to deliver accessible, low cost, and high quality healthcare—which is by no means a given—restrictive medical licensing and scope of practice laws at the state level stand in the way of this digital transformation of medicine.

As business innovation scholar Clayton Christensen has observed, “Many of the most powerful innovations that disrupted other industries did so by *enabling a larger population of less-skilled people* to do in a more convenient, *less expensive setting* things that historically could be performed only by *expensive specialists* in *centralized, inconvenient locations*.”<sup>13</sup> This statement perfectly describes the potential of mobile health to dramatically transform the delivery of healthcare *if* this technology can be combined with the legislative efforts to relax restrictive state licensing and scope of practice laws so that non-physicians (i.e., “less-skilled people”) can provide care independent of physicians (i.e., “expensive specialists”) and outside of traditional clinics and hospitals (i.e., “centralized, inconvenient locations”). Thus, going forward, the CMA and other physician interest groups will likely find that nurse practitioners and other providers will have strong political and financial support to redraft licensing and scope of practice laws from information technology (IT) giants such as Apple, Google, Samsung, Facebook, and IBM. Further, from the perspective of physician organizations, this looming legislative battle might not be a fair fight.

In the near term, the mobile health industry can rhetorically frame the relaxing of overly restrictive licensing and scope of practice laws for physician extenders vis-à-vis doctors, as a long overdue rebalancing of medical authority that will empower both non-physician medical providers and consumers of healthcare. This could result in the creation of many decent paying middle class healthcare jobs.<sup>14</sup> Further, the lower level of training required for these new positions (i.e., not four years of pre-med followed by medical school and residency) could dovetail with the Obama Administration’s recently announced initiative to provide free access to community college.<sup>15</sup> More significantly, this strategy could potentially help our

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13. Clayton Christensen et al., *Will Disruptive Innovations Cure Health Care?* HARV. BUS. REV. 3 (2000) (emphasis added).
  14. See Dionne Searcy et al., *As Market Evolves, Health Care Opens Path, Often for Women*, N.Y. TIMES (Feb 23, 2015), [http://www.nytimes.com/2015/02/23/business/economy/health-care-opens-middle-class-path-taken-mainly-by-women.html?\\_r=0](http://www.nytimes.com/2015/02/23/business/economy/health-care-opens-middle-class-path-taken-mainly-by-women.html?_r=0).
  15. Adam Rubenfire, *Healthcare Could Gain from Obama’s Free Community College Bid*, MODERN HEALTHCARE (Jan. 9, 2015), <http://www.modernhealthcare.com/article/20150109/NEWS/301099948> (“A proposal floated by President Barack Obama to provide federal funds for community college students’ tuition could produce an influx of new students seeking jobs in radiologic technology, nursing and health

nation’s strained healthcare system come closer to achieving the elusive “triple aim,” a medical system that delivers high quality, accessible, and low cost healthcare.<sup>16</sup>

Perhaps foreshadowing the future of mobile health, mobile taxi service app Uber has successfully lobbied many cities that relaxing municipal licensing barriers for taxi services is an equitable measure that redistributes power from the taxi license or “medallion” owners to the actual drivers. Thus, by cutting out taxi medallion leasing and dispatch fees, Uber drivers can take home more money than they would driving for taxi companies. Plus, consumers benefit from driving services that are less costly, more convenient, and reportedly of higher quality.<sup>17</sup> The above narrative sounds like a clear “win-win” for both Uber drivers and consumers. But that is not where this story ends.

In a stunningly short amount of time, Uber has transformed from a plucky mobile app start-up with a handful of employees, to a multi-billion dollar leviathan that recently hired David Plouffe, a former chief political strategist for President Obama, to be its senior vice president for strategy and policy. The hiring of Plouffe is a “move that further signaled the grand aspirations of companies like Uber, which are challenging entrenched industries and running into resistance from some local governments.”<sup>18</sup> More significantly, Uber has quietly announced that it is testing “driverless” cars as part of its long-term strategy. Thus, empowering its drivers vis-à-vis taxi medallion owners seems to be a transitional means to an end.<sup>19</sup> The ultimate end appears to be that once Uber perfects driverless technology, it can cast aside its “empowered” drivers and make even more money. Likewise, if mobile health technology becomes advanced

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information technology, industry observers say. The funding could remove a major obstacle for those hoping to earn health-related degrees. ‘The tuition right now is preventing many people from entering the profession, so this will alleviate some of the shortages that exist,’ said Gerard Anderson, director of the Center for Hospital Finance and Management at Johns Hopkins University.”)

16. See Donald Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759 (2008).
17. Mike Isaac, *Uber Picks David Plouffe to Wage Regulatory Fight*, N.Y. TIMES (Aug. 19, 2014), [http://www.nytimes.com/2014/08/20/technology/uber-picks-a-political-insider-to-wage-its-regulatory-battles.html?\\_r=0](http://www.nytimes.com/2014/08/20/technology/uber-picks-a-political-insider-to-wage-its-regulatory-battles.html?_r=0).
18. *Id.*
19. See generally Ben Kepes, *The Battle Looms—Uber Developing Driverless Cars, Google Looking at Ridesharing*, FORBES, (Feb. 2, 2015), <http://www.forbes.com/sites/benkepes/2015/02/02/the-battle-looms-uber-developing-driverless-cars-google-looking-at-ridesharing/>.

enough, even physician extenders will be viewed as being too costly or inefficient, transforming basic healthcare into a “providerless” service.

In this article I argue that we should be cautiously ambivalent about the rise of mobile health and actively manage its integration into the practice of medicine.<sup>20</sup> Independent of mobile health, there are solid arguments to reform restrictive scope of practice and licensing laws within healthcare, as the Supreme Court recently affirmed in *North Carolina State Board of Dental Examiners v. FTC*.<sup>21</sup> Further, in order to “bend the cost curve” while our nation’s elderly populations surges, we need technological advancements in healthcare efficiency that mobile health theoretically could deliver. In addition, while the Affordable Care Act (ACA) has improved access to individual insurance, this does not necessarily translate into easier access to medical care, another challenge this technology can address. Moreover, using mobile health to eliminate preventable human errors and promote evidence-based decision-making would seem to increase the quality of healthcare. In the abstract, these are all desirable ends that mobile health *combined* with the relaxing of licensure and scope of practice laws could achieve. However, I argue that we cannot ignore the long-term implications of the mobile health industry potentially eliminating many upper and middle-income medical jobs, and that we need to negotiate a transition to digitally mediated healthcare that is safe and equitable.

In Part II of this article, I will describe in more depth the historical development of mobile health and its realistic potential to transform the future of medical delivery. Next, in Part III, I will analyze the legal barriers facing the implementation of the mobile health industry, primarily focusing on restrictive state licensing and scope of practice laws for medical providers. In Part IV, I will argue that political economy concerns will shape the starkest challenges to the rise of mobile health, drawing parallels to the legal and political battles Uber is currently fighting against regulators. Finally, in Part V, I argue that physician extender interest groups seeking to expand their scope of practice and professional influence should avoid making a Faustian bargain with the rising mobile health industry against physicians for their own long-term viability. I propose instead that doctors and physician extenders should reach a “grand bargain” to reform restrictive scope of practice reforms on a nationwide basis and stand as a united front to extract concessions from the federal government to protect against mobile health corporations and related

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20. See Nathan Cortez et al., *FDA Regulation of Mobile Health Technologies*, 371 NEW ENG. J. MED. 372, 373 (2014).

21. See *N.C. State Bd. of Dental Examiners v. FTC*, 135 S. Ct. 1101 (2015) (slip op.)



financial interests<sup>22</sup> from altering the regulatory landscape to bring about the “Uberization” of healthcare—that is, providerless medicine.

## II. THE DEVELOPMENT OF MOBILE HEALTH: FROM CONCEPT TO REALITY

### A. *The Elusive Triple Aim in Medicine*

The triple aim for any nation’s healthcare system consists of delivering medical care that is i) accessible, ii) high quality, and iii) low cost.<sup>23</sup> The historical challenge for American policymakers has always been to find a way to achieve one aim without sacrificing the other two. For instance, the advent of managed care organizations (MCO’s) in the late 1980s seemingly reined in runaway costs, but patients perceived that this was done at the expense of quality. This in turn led to a strong consumer and legal backlash against some MCO cost-control measures.<sup>24</sup> More recently, opponents of the ACA have charged that increasing the accessibility of healthcare insurance will necessarily have a negative impact on overall healthcare costs and quality.<sup>25</sup>

The growing demographic bump of elderly Americans (the “baby boomers,” ironically) poses a vexing challenge to our nation’s healthcare system. Not only will there be more elderly patients, but they will live longer with chronic diseases that require ongoing medical care. Exacerbating this problem, there is a large cohort of baby boomer physicians that have already retired or are in the process of retiring. Even if medical schools dramatically expand their class sizes, they cannot come close to closing the projected primary

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22. Here’s another quote that summarizes Silicon Valley Hedge Fund Manager Andy Kessler’s vision for medical professionals: “You can smell it from this far away. Doctors are toast. It’s the magic pill—heart attacks, stroke and cancer are cured [with scalable technology] . . . The stock market will help allocate capital to this business, rather than some socialist system of sphincter pricers at Medicare in Washington, D. C. Investors will swarm like killer bees . . . Time to start another hedge fund?” KESSLER, *supra* note 1, at 322.
23. See Berwick et al. *supra* note 16.
24. See Petrovich v. Share, 719 N.E.2d 756, 775 (Ill. 1999).
25. See Josh Kraushaar, *Obama’s Legacy: A Health Care Law the Hurts His Party*, NAT’L J. (May 2, 2013), <http://news.yahoo.com/obamas-legacy-health-care-law-hurts-party-090143251.html> (there are many other articles attacking the ACA or “Obamacare;” this one is representative of the notion that the ACA will have negative impacts on both the cost and quality of healthcare).

care shortfall of 90,000 doctors within the next five years.<sup>26</sup> This perfect storm of increased demand for healthcare occurring at the same time of low physician supply seems to signal that something has to give in terms of cost, access, or quality. Or does it? As discussed below, this seemingly intractable problem represents a huge window of opportunity for the mobile health industry.

*B. Early Attempts at Transforming Medicine With Information  
Technology*

If our nation’s supply of healthcare is dependent upon medical experts that take years to train, then seemingly there is no short-term solution to our under-supply of physicians. However, as medical informatics guru Peter Szolovits postulated over three decades ago:

If the expertise of consultants can be captured in the form of computer programs which provide advice to less-expert physicians or other health-care providers, then any practitioner could call on that expertise whenever a patient’s case suggested the need for careful thought about some aspect of the illness or therapy ... The opportunity is there to improve the health-care system by improving each physician’s ability to utilize the best ways of analyzing medical problems, as encoded in easily-duplicated and updated computer programs.<sup>27</sup>

Szolovits’ concept mirrors efforts in automation that other industries had long ago figured out—from textile manufacturing during the industrial revolution to widespread robotics use in car manufacturing beginning in the 1980s. However, the American medical profession has always been an exceptional laggard in terms of automation and the integration of information technology within its workflow. Historically, information technology only made inroads for administrative functions (patient records, billing, etc), but was hardly relied on for the core functions of medical care: diagnosis, treatment, and prevention.<sup>28</sup>

The holy grail for pioneers in medical informatics was to create computing applications that can improve medical decision-making in

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26. See Amanda Swanson & Fazal Khan, *The Legal Challenge of Incorporating Artificial Intelligence into Medical Practice*, 6 J. HEALTH & LIFE SCI. L 90, 114 (2012).

27. Peter Szolovits, *Preface*, ARTIFICIAL INTELLIGENCE IN MEDICINE, xiii-xiv (Peter Szolovits, ed., 1982), <http://groups.csail.mit.edu/medg/ftp/psz/AIM82/ch0.html#preface>.

28. See Swanson & Khan, *supra* note 26.

real world clinical settings.<sup>29</sup> Their well-founded presumption was that medical errors often resulted from a physician’s lack of medical knowledge or inadequate analytical skills, and that computers running clinical decision support programs (“CDSPs”) could bridge this gap to improve patient safety. In fact, the Institute of Medicine validated this presumption with its landmark 1999 report, “To Err is Human,” which estimated during its study period that between 44,000 and 98,000 Americans die each year from preventable medical errors.<sup>30</sup> Yet, despite decades of exploration and countless millions spent on creating computer systems that could aid in medical diagnoses and treatment, the promise of AI and CDSPs remained unfulfilled.<sup>31</sup>

The problem was that these early information technology applications did not fit well within the workflow of actual clinical practice. Currently, we might take for granted voice activated commands on our electronic devices and easy to navigate graphical interfaces on computer programs that do not even require users to read an instruction manual—your grandparents do not need to be “computer literate” in order to use an iPad. However, from the 1960s to the 1980s, computer literacy was a significant problem as one would actually have to know the proper commands to type in—mistyped or wrong instructions would lead to frustrating “syntax error” messages. In addition, early office computers were bulky and could not be brought to the patient’s bedside.<sup>32</sup> Even with the advent of more user-friendly interfaces like Microsoft Windows in the 1990s, CDSPs were still a hard sell in the clinic.<sup>33</sup> You still had to type information into a desktop computer, wait for your query to run, and then the CDSP would return a long list of medical probabilities to choose from, but no definitive diagnosis to choose from—this obviously represented a low value proposition. Early personal data assistants (PDAs) like the Palm Pilot made some headway in the late 1990s to early 2000s, but they were at most useful for storing information (e.g., a pharmaceutical reference guide) and hardly had

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29. Eta S. Berner et al., *Will the Wave Finally Break? A Brief View of the Adoption of Electronic Medical Records in the United States*, 12 J. AM. MED. INFORMATICS ASS’N 3, 3 (2005).
30. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1* (Linda T. Kohn et al. eds., 1999).
31. *See* INST. OF MED., *THE COMPUTER-BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE 45* (Richard S. Dick et al. eds., revised ed. 1997).
32. *See* John B. Dewey et al., *Acceptance of Direct Physician Access to a Computer-Based Patient Record in a Managed Care Setting*, PROC. ANN. SYMP. ON COMPUTER APPLICATION MED. CARE 79, 79 (1994).
33. Berner et al., *supra* note 29, at 4.

the processing power to run meaningful CDSPs.<sup>34</sup> Ultimately, even as other industries and professions became more digitally automated, doctors opted to rely on their own knowledge and skill, dismissing these new technologies not only as ineffectual, but as an affront to their medical authority and autonomy to boot.

*C. Laying the Foundation for Mobile Health:*

*Electronic Records, Artificial Intelligence, Evidence Based Medicine, and Case Based Reasoning*

Humans make errors. We make errors of fact and errors of judgment. We have blind spots in our field of vision and gaps in our stream of attention. Sometimes we can’t even answer the simple questions. Where was I last week at this time? How long have I had this pain in my knee? How much money do I typically spend in a day? These weaknesses put us at a disadvantage. We make decisions with partial information. We are forced to steer by guesswork. We go with our gut.<sup>35</sup>

1. Electronic Health Records

The historical physician antipathy to computer automation contributed to the American healthcare system lagging woefully behind other industrialized countries in terms of integrating information technology with the practice of medicine. In 2009, to address this deficit, President Obama signed the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) to address this technological gap.<sup>36</sup> This Act offered individual physicians and clinics generous financial incentives to encourage the adoption and use of health information technology (HIT), including specific incentives intended to accelerate the adoption of electronic health record (EHR) systems among providers.<sup>37</sup> This represents a significant milestone for the mobile health industry, because mobile

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34. See generally Daniel C. Baumgart, *Personal Digital Assistants in Health Care: Experienced Clinicians in the Palm of Your Hand?*, 366 THE LANCET 1210 (2005).

35. Gary Wolf, *The Data-Driven Life*, N.Y. TIMES (Apr. 28, 2010), [http://www.nytimes.com/2010/05/02/magazine/02self-measurement-t.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2010/05/02/magazine/02self-measurement-t.html?pagewanted=all&_r=0).

36. See Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

37. See OFFICE OF THE NAT’ COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, U.S. DEP’T OF HEALTH & HUMAN SERVS., *Health IT Adoption Programs*, <http://www.healthit.gov/policy-researchers-implementers/health-it-adoption-programs> (Feb. 24, 2014).

medical apps (MMAs) are obviously useless in a world of paper-based patient records as they could not interface with them.

## 2. Artificial Intelligence

Another unlikely milestone for mobile health occurred in 2011 on the television game show *Jeopardy!* as IBM’s Watson competed in a three-day contest against two former champions, Ken Jennings and Brad Rutter.<sup>38</sup> Watson is an AI engine designed to engage in blazing fast data analysis and to provide useful answers to questions posed in natural language.<sup>39</sup> Further, Watson can analyze data at the rate of about 200 million pages in three seconds, use voice recognition and complex algorithms to “make sense” of spoken queries, and can respond in natural language.<sup>40</sup> Watson was not perfect, but it did crush its formidable human opponents, demonstrating that it could understand human vernacular, including the clever idioms used by *Jeopardy!*, and provide “expert” answers in real time. Obviously, the primary goal for IBM was to showcase the robustness of its new technology. This strategy worked.

In late 2011, IBM announced the first commercial application of Watson’s technology. Significantly, it was in healthcare, as IBM teamed up with medical insurer Wellpoint.<sup>41</sup> The potential applications for AI technology in healthcare are numerous and diverse. Of particular interest, WellPoint stated that plans for Watson include suggesting treatment options and diagnoses for physicians, and assisting *other healthcare practitioners* to manage complex or chronic patient conditions.<sup>42</sup> In other words, this is the realization of Szolovits’ earlier vision, using AI to augment the ability

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38. John Markoff, *Computer Wins on Jeopardy!: Trivial, It’s Not*, N.Y. TIMES (Feb. 17, 2011), [www.nytimes.com/2011/02/17/science/17jeopardy-watson.html?pagewanted=all](http://www.nytimes.com/2011/02/17/science/17jeopardy-watson.html?pagewanted=all).

39. Chris Anderson, *Wellpoint to Help IBM Bring Watson Technology to Market*, HEALTHCARE IT NEWS (Sept. 12, 2011), <http://healthcareitnews.com/print/33932>.

40. *Id.*

41. Anna Wilde Mathews, *WellPoint’s New Hire. What Is Watson?*, WALL ST. J. (Sept. 12, 2011), <http://online.wsj.com/article/SB10001424053111903532804576564600781798420.html>. Additionally, early this year Watson began work for Citibank, Inc., analyzing customer needs and processing economic, financial, and client data to help personalize digital banking. Beth Jinks, *IBM’s Watson Gets Wall Street Job After ‘Jeopardy’ Win*, BLOOMBERG (Mar. 6, 2012), [www.bloomberg.com/news/2012-03-05/ibm-s-watson-computer-gets-wall-street-job-one-year-after-jeopardy-win.html](http://www.bloomberg.com/news/2012-03-05/ibm-s-watson-computer-gets-wall-street-job-one-year-after-jeopardy-win.html).

42. *See* Mathews, *supra* note 41.

of doctors and physician extenders. Consequently, Wellpoint envisions Watson, not an experienced doctor, guiding lesser-trained practitioners to the most likely diagnosis and treatment options for patients. If this strategy works according to plan, Wellpoint can increase both the efficacy and efficiency of healthcare delivered in its network.<sup>43</sup>

AI has already proven its effectiveness in medical image analysis in the context of detecting early signs of cancer in x-rays,<sup>44</sup> mammograms,<sup>45</sup> and computed tomography (CT) colonography.<sup>46</sup> Typically, a radiologist would first examine the images visually. Then, a computer-aided diagnosis (CAD) program would use algorithms to recognize and highlight areas of interest on these digital images for the radiologist, who can then determine whether the highlighted areas merit further examination.<sup>47</sup> Essentially CAD is a pattern recognition and machine-learning tool that analyzes images for patterns that correlate with cancer or precursors to cancer.

Although CAD is not good enough yet to independently diagnose lung, breast, or colon cancer,<sup>48</sup> current CAD technology is robust enough to help radiologists spot cancers they might have otherwise missed.<sup>49</sup> For instance, one FDA approved system for chest x-rays has demonstrated that it can detect up to 50 percent of the lung cancers that doctors missed in an initial x-ray reading. This enables earlier treatment of a patient’s cancer, when it is much more effective.<sup>50</sup> In dermatology, CAD has helped differentiate melanoma skin cancer from other pigmented skin lesions by analyzing digital images. In fact, studies have shown that melanoma diagnosis by a computer is as

43. Anderson, *supra* note 39.

44. Riverrain Med., *U.S. FDA Approves Improved Performance of OnGuard Chest X-Ray CAD Technology*, MEDICEXCHANGE.COM, June 24, 2010, PR NEWSWIRE (June 24, 2010), <http://www.prnewswire.com/news-releases/us-fda-approves-improved-performance-of-riverrain-medicals-onguard-chest-x-ray-computer-aided-detection-technology-96787199.html> [hereinafter *OnGuard*].

45. Jason Launders, *Computer Aided Detection*, BIOMEDICAL INSTRUMENTATION & TECH. 126, 126 (2004).

46. See Abraham H. Dachman et al., *Effect of Computer-Aided Detection for CT Colonography in a Multireader, Multicase Trial*, 256 RADIOLOGY 827 (2010).

47. Launders, *supra* note 45, at 126.

48. *Id.* at 126 (finding only about 3% of marks identified by CAD on mammograms are found by the radiologist to require further examination).

49. Dachman et al., *supra* note 46, at 828.

50. *OnGuard*, *supra* note 44.

accurate as diagnosis by expert dermatologists with a dermatoscope under experimental conditions.<sup>51</sup> When you consider how difficult it is for someone with basic insurance, let alone Medicaid, to schedule an appointment with a dermatologist or radiologist, one can see that if healthcare plans automated these expensive specialist services, they could increase access, lower costs, and yet also improve quality for cancer treatments through earlier detection.

### 3. Facilitating the Use of Evidence Based Medicine

Evidence-based medicine (EBM) is the process of basing clinical decision-making on the best available objective and unbiased medical research. This generally entails incorporating findings gained from randomized controlled clinical trials or systematic reviews of data from multiple trials.<sup>52</sup> EBM involves four steps: (i) forming the clinical question; (ii) searching for the best evidence; (iii) evaluating this evidence for validity, impact, and applicability; and (iv) implementing this evidence into clinical practice.<sup>53</sup> However, outside of academic centers, it is rare for practicing doctors to maintain their busy clinical duties while also remaining abreast of all the latest research findings. Thus, the Institute of Medicine, a part of the National Academy of Sciences, estimates that less than half of American medical practice is evidence-based.<sup>54</sup>

One strategy to incorporate EBM in patient care is for medical organizations to promulgate evidence-based guidelines (EBG) to doctors and other providers. EBGs provide specific criteria and thresholds for interventions based on published research. In theory, EBGs can standardize and improve patient care by making relevant medical evidence easily accessible in the clinical setting. In other words, doctors do not need to constantly monitor the latest scientific publications in order to practice EBM, they can simply follow the EBGs. However, in practice many doctors still do not follow EBGs because of time constraints, the lack of ready availability at all points of care, or the lack of clarity of EBGs for less-experienced

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51. *Id.* at 592.

52. Benjamin William Sissons et al., *Using Artificial Intelligence to Bring Evidence-Based Medicine a Step Closer to Making the Individual Difference*, 32 *MED. INFORMATICS & INTERNET MED.* 11, 12 (2007).

53. Joseph F. Sucher et al., *Computerized Clinical Decision Support: A Technology to Implement and Validate Evidence Based Guidelines*, 64 *J. TRAUMA INJURY, INFECTION & CRITICAL CARE* 520, 521 (2008).

54. LeighAnne Olsen et al., Workshop Summary, *Learning What Works: Infrastructure Required for Comparative Effectiveness Research*, *INST. OF MED.* 1, 97 (2011) <http://www.iom.edu/~media/Files/Activity%20Files/Quality/VSRT/ComparativeEffectivenessWhitePaperF.ashx>.

physicians.<sup>55</sup> The implication for patients is that their doctors might be delivering care that does not match up with the latest scientific evidence, which necessarily impacts quality and cost of care.

Automated clinical decisions support programs (CDSPs) can alleviate this problem. To assist with the implementation of EBGs, a CDSP can provide rule-based therapy guidance.<sup>56</sup> The process begins with an algorithm that obtains patient data measurements. These measurements are then compared with thresholds for intervention. If the threshold is met, then the CDSP makes a brightline yes/no recommendation in real-time. The information needed to generate the rules for these thresholds comes from EBGs and other medical research. The doctor can then decide if the proposed intervention is appropriate for his or her unique patient and can determine whether or not to follow the CDSP suggestions. Allscripts, a popular EHR system, has already integrated this technology into its system.<sup>57</sup>

One critique of the EBM movement is that it reflects the best treatments for the “average patient,” which is based on aggregate population data. This does not necessarily represent how an individual patient will react to a specific treatment.<sup>58</sup> However, newer CDSPs have the capability to assist in personalizing treatment guidelines for unique patients, ushering in a new era that combines the best of EBM and personalized medicine.<sup>59</sup> The CDSP can propose additional or alternative interventions based on an analysis of how a particular patient responded to previous treatments. To rely on a doctor to do this for each of her patients would obviously be cost-prohibitive. This type of rule-based therapy guidance programs for individual patients has already proven to be effective in a number of aspects of care, including blood transfusions, antibiotic therapy, trauma shock resuscitation, and glucose management using insulin.<sup>60</sup> Yet again, the important takeaway is that the advent of electronic

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55. See e.g., ATUL GAWANDE, *THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT* 196-197 (2010).

56. See *id.* at 198.

57. Allscripts incorporates the latest medical and clinical practice knowledge into its EHR systems through its Sunrise Clinical Manager module, which is embedded directly into the EHR’s screens, complementing healthcare professionals’ expertise and experience with the goal of improving the clinical decisionmaking of users. *Partner Finder*, ALLSCRIPTS (2015), <http://www.allscripts.com/company/partners/partner-finder>.

58. Sissons et al., *supra* note 52, at 12.

59. Sucher et al., *supra* note 53, at 523.

60. *Id.* at 524.



health records and the use of EBGs or rule-based guidelines enables and validates the further automation of healthcare delivery.

#### 4. Case-Based Reasoning

The analytical process of case-based reasoning (CBR) presents another option for personalizing patient care. CBR is a method of computer reasoning that entails solving new problems by analyzing solutions to similar past problems. Another way to conceptualize this process is the “nearest neighbor” algorithm, which means searching through a database of old cases and finding those most similar to the present patient, which in turn can help predict a patient’s response to different treatment options and lead to the optimal course of care.<sup>61</sup> CBR decision support programs have already been deployed to assist in diagnosis and treatment of mental health disorders, cardiovascular disease, diabetes,<sup>62</sup> and stress,<sup>63</sup> among many other ailments. CBR programs could mine the data of local patients<sup>64</sup> or even broader patient pools as national and regional health information exchanges come online. CBR programs’ machine-learning capabilities enable the CDSP to apply rules learned from prior “nearest neighbor” analyses while also taking into account the newest data provided from patient records, thereby speeding up its “learning curve.”<sup>65</sup>

#### *D. Mobile Health: The Missing Link Between Information Technology and The Triple Aim?*

##### 1. Healthcare? There’s an App for That

Already start-ups and established healthcare companies have developed numerous mobile medical applications (MMAs) that can transform smartphones or tablets into microscopes, stethoscopes, EKGs, dermatoscopes, and even mini-laboratories that can test bodily fluids.<sup>66</sup> Some of these apps have proved to be remarkably sensitive,

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61. *Id.*, at 533.

62. Alec Holt et al., *Medical Applications in Case-Based Reasoning*, 20 KNOWLEDGE ENGINEERING REV. 289, 290 (2006).

63. Shahina Begum et al., *A Case-Based Decision Support System for Individual Stress Diagnosis Using Fuzzy Similarity Matching*, 25 COMPUTATIONAL INTELLIGENCE 180,180 (2009).

64. Sissons et al., *supra* note 52, at 14.

65. *See id.* at 15.

66. *See e.g.*, David Breslauer et al., *Mobile Phone Based Clinical Microscopy for Global Health Applications*, 4 PLoS ONE 3 (2009) (discussing the use of microscope apps to diagnose malaria and tuberculosis); MOBILE STETHOSCOPE, <http://mobilestethoscope.com>; ALIVECOR’S MOBILE ECG, <http://www.alivecor.com>; MOLE DETECTIVE 2,

reporting that non-experts were able to diagnose conditions within 1.25 percent accuracy of experts.<sup>67</sup> With “microscope” apps, researchers reported that they were able to capture reliable images of infected cells by developing a microscope attachment for camera-enabled mobile phones. Where necessary, the images could then be sent wirelessly for analysis.<sup>68</sup> The researchers noted that “the fact that mobile phones are essentially embedded computer systems offers the opportunity for significant post-processing of images,” which facilitated their diagnosis of the underlying diseases of malaria, TB and sickle cell anemia.<sup>69</sup> In fact, as one expert noted, “[a] typical smartphone has more computing power than Apollo 11 did when it landed on the moon.”<sup>70</sup>

There is tremendous hope that mobile health can succeed where other efforts to alleviate cost and access problems for healthcare system have failed, by empowering patients to manage their own care and augmenting the capabilities of medical providers.<sup>71</sup> In concert with emerging clinical practices emphasizing integrated care, mobile health could facilitate monitoring of chronic diseases in real time,

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<https://itunes.apple.com/us/app/mole-detective-2/id504152136?mt=8>.

67. Tina Rosenberg, *The Benefits of Mobile Health, on Hold*, N.Y. TIMES (Mar. 13, 2013), <http://opinionator.blogs.nytimes.com/2013/03/13/the-benefits-of-mobile-health-on-hold/> (discussing a microscope attachment created by Aydogan Ozcan, out of an electrical engineering lab at UCLA, that can detect common diseases and allergens). *But see* Joel Wolf et al., *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, 149 JAMA DERMATOLOGIST 422 (2013) (reporting that findings that apps purporting to diagnose skin cancer were not up to the task. In particular, those using algorithms to analyze images were the least sensitive, whereas those that sent images to board-certified dermatologists proved the most sensitive).
68. Breslauer *et al.*, *supra* note 66, at 2.
69. *Id.*
70. *Statement of Robert Jarrin Senior Director, Government Affairs Qualcomm Incorporated: Hearing on “Health Information Technologies: Harnessing Wireless Innovation” Before the Subcomm. on Communications & Tech.* (Mar. 19, 2013), <http://docs.house.gov/meetings/IF/IF16/20130319/100525/HHRG-113-IF16-Wstate-JarrinR-20130319-U1.pdf>.
71. *See, e.g.*, Joshua Brusten, *Coming Next: Using an App as Prescribed*, N.Y. TIMES (Aug. 8, 2012) [www.nytimes.com/2012/08/20/technology/coming-next-doctors-prescribing-apps-to-patients.html?\\_r=1](http://www.nytimes.com/2012/08/20/technology/coming-next-doctors-prescribing-apps-to-patients.html?_r=1) (describing how new doctor prescribed apps might be used to reduce the amount of care patients need by providing patients with diabetes, cardiology, arthritis, and physical management systems, for example).

which in turn could provide untold benefits for understanding the causes and progressions of these diseases.<sup>72</sup>

For instance, patients or their sensors could input vital signs, which nurses or other computer programs could monitor on an ongoing basis. One example is an inexpensive mobile EKG adapter that heart patients could attach to their smartphone. In the event of chest pain, the patient or family member could place the sensor on the patient’s skin, and EKG readings could be sent to caregivers in advance of the patient’s arrival at the hospital.<sup>73</sup> Such savings in time treating coronary artery disease can have dramatic effects in patient outcome. The developers of AirStrip, a mobile health interoperability platform, reported that their technology was able to reduce time from chest pain to medical intervention (i.e., coronary catheterization) from 45 minutes to just 15-20.<sup>74</sup> For patients suffering from a heart attack, prompt treatment can increase their likelihood of survival and prevent permanent damage to heart tissue.<sup>75</sup> Widespread availability of medical apps that record patients’ health data could also prove invaluable for researchers seeking to monitor the spread of disease, understand the root causes of illness, and identify subtle effects of environmental exposures on individuals.<sup>76</sup>

Mobile health apps targeted for health professionals can also enable diagnostic and imaging support, access to patient medical

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72. See e.g., Jan van der Greef, Thomas Hankemeier & Robert McBurney, *Metabolomics-based Systems Biology and Personalized Medicine: Moving Towards n=1 Clinical Trials?* 7 PHARMACOGENOMICS 1087, 1090-1091 (2006).
73. Donna Fedor, , *Proliferation of Consumer Platforms and Devices into the Medtech Ecosystem, Part II*, MPO (2012), <http://www.mpo-mag.com/articles/2012/03/proliferation-of-consumer-platforms-and-devices-in>.
74. *Id.* See also AIRSTRIP, <http://www.airstriptechnology.com/airstrip-one>.
75. See e.g., Elizabeth Bradley et al., *Strategies for Reducing the Door-to-Balloon Time in Acute Myocardial Infarction*, 355 NEW ENG. J. MED. 2308, 2308 (2006).
76. See ERIC TOPOL, *THE CREATIVE DESTRUCTION OF MEDICINE: HOW THE DIGITAL REVOLUTION WILL CREATE BETTER HEALTH CARE* vi, at 229-31 (2012) (discussing the potential to harness sensor data from billions of patients to inform a Wikimedicine project. “Massive pooling of the granular but ‘pixelated’ data from individuals creates a positive feedback loop, such that the overabundant granular data becomes more valuable and defined - transforming the extensive data to real information and knowledge that can ultimately be used to improve the health of individuals.”)

records, monitoring programs, and even performance of diagnostic tests (e.g., EKGs and STD tests).<sup>77</sup>

The inherent portability of mobile health applications is a key attribute that cannot be stressed enough. Combined with increasingly powerful CDSPs that can be tapped into from anywhere, the portability of mobile health means that powerful medical technologies can now be untethered from expensive infrastructures like hospitals and clinics.<sup>78</sup> This same dynamic also means that eventually, medical expertise might be untethered from medical experts, posing an existential threat to the medical profession.<sup>79</sup> However, in the near term, physician groups have a powerful defense to such encroachment upon their professional domain, restrictive licensing and scope of practice laws.

### III. LEGAL BARRIERS TO MOBILE HEALTH

Medicine is remarkably conservative to the point of being properly characterized as sclerotic, even ossified. Beyond the reluctance and resistance of physicians to change, the life science industry... and government regulatory agencies are in a near paralyzed state, unable to break out of a broken model of how their products are developed or commercially approved. We need a jailbreak. We live in a time of economic crisis because of the relentless and exponentially escalating costs of health care, but we’ve done virtually nothing to embrace or leverage the phenomenal progress of the digital era. That is about to change. Medicine is about to go through its biggest shakeup in history.<sup>80</sup>

-Dr. Eric Topol

#### A. *Federal Regulations of Mobile Health and Tort Liability*

Typically, heavily regulated products like medical devices, have high performance thresholds which are intended to be barriers to entry.<sup>81</sup> Disruptive alternative technologies attempt to provide lower

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77. See Brian Edwards, *AliveCor Receives FDA 510k Approval In Just 80 Days*, MOBILE HEALTH, Dec. 11, 2012, <http://www.imedicalapps.com/2012/12/alivecor-fda-510k-approval/>.

78. See Brandon Keim, *Paging Dr. Watson: Artificial Intelligence as a Prescription for Health Care*, WIRED (Oct. 16, 2012), <http://www.wired.com/wiredscience/2012/10/watson-for-medicine/>.

79. Khan & Swanson, *supra* note 26.

80. *Supra* note 76, at vi.

81. CLAYTON CHRISTENSEN, THE INNOVATOR’S DILEMMA xviii (1997).

performance alternatives as a “response to performance oversupply.”<sup>82</sup> Thus, “[t]o the extent that the requirements established by regulation exceed the requirements of the average consumer, disruptive innovation cannot occur.”<sup>83</sup> Often, regulatory agencies may be unable or unwilling to consider whether the outcomes they produce are desirable because they are designed to deal with a “narrowly defined question” and not to consider the “net impact of the rules on efficiency and quality in the marketplace.”<sup>84</sup> In addition to statutory barriers in regulated industries, there is the potential for agency capture by the established industry, in this case the traditional medical device industry, which can result in policy decisions that make it more difficult for startup companies offering disruptive innovations.<sup>85</sup> Taken together, all of this could mean that the federal regulatory agencies such as the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) will erect high barriers to entry for mobile health devices—but in reality, nothing could be further from the truth.

The pharmaceutical and medical device industry often rail against the obstructionism of the federal government towards new medical technologies.<sup>86</sup> Further, some mobile health developers fretted about the lack of guidance from the FDA on the treatment of mobile medical apps (MMAs) and wondered whether this industry would face

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82. *Id.*

83. *Id.*

84. *Id.* at 200.

85. See John Abraham, *The Pharmaceutical Industry as a Political Player*, 360 THE LANCET 1498, 1498 (2002).

86. See Josh Makower et al., *Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, EUCOMED 1, 6-8 (2010), <http://eucomed.org/uploads/Press%20Releases/FDA%20impact%20on%20U.S.%20Medical%20Technology%20Innovation.pdf> (accessed May 9, 2013). *But see* GOV’T ACCOUNTABILITY OFFICE, FDA HAS MET MOST PERFORMANCE GOALS BUT DEVICE REVIEWS ARE TAKING LONGER, (2012), <http://www.gao.gov/assets/590/588970.pdf> (contending that according to a recent - and contested by the FDA - survey, it took an average of fifty-four months for devices to obtain market approval. Bringing “a low-to-moderate-risk 510(k) product from concept to clearance was approximately \$31 million with \$24 million spent on FDA dependent and/or related activities. For a higher-risk PMA product, the average cost from concept to approval was approximately \$94 million with \$75 million spent on stages linked to the FDA.) For the FDA’s response, see *Editors: FDA medical-device approval studies flawed*, CENTER WATCH NEWS ONLINE (JULY 22, 2011), <http://www.centerwatch.com/news-online/article/1967>

onerous regulations before it got off the ground.<sup>87</sup> However, in comparing the regulatory review process between the U.S. and E.U. for medical devices, another study refuted criticisms that the U.S. process is too “slow, risk-averse and expensive.”<sup>88</sup> Rather, the authors concluded that rather than delays to market entry, the biggest problem facing the U.S. regulation of medical devices was the inappropriate use of the lower 510(k) review for high-risk devices.<sup>89</sup> When the FDA finally released its final rule on MMAs, it essentially read like an industry wish-list. As one scholar succinctly noted, “Contrary to the prevailing wisdom, federal regulators are sympathetic, not hostile, to mobile health products.”<sup>90</sup>

For example, general wellness apps (e.g., nutrition and exercise counters), which constitute the vast majority of current MMAs, will not be regulated as medical devices but instead will be subject to marketing and privacy regulations promulgated by the FTC. Perhaps most tellingly, the FDA abstained from regulating consumer mobile device manufacturers directly (e.g., Apple, Samsung, Motorola, etc), even though the latest versions of their handsets have clearly been designed with sensors and features intended to take advantage of the growing mobile health market.

The FDA will regulate MMAs that are used for diagnostic and treatment purposes as medical devices. The level of regulation a medical device is subject to depends upon its risk classification: Class I (low risk), Class II (moderate risk), or Class III (high risk). Classification is determined by the device’s intended use and the risk it poses to the patient. Class III devices must get pre-market approval using clinical trials. Class II devices only have to submit a 501(k) notice to the FDA, which the FDA normally approves in a short time frame. For example, the mobile devices iGlucose and AliveCor, were

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87. See e.g., Alan Portela, *My wish list: FDA mobile medical app regulation*, mHiMSS, (Mar. 29, 2013), <http://www.mhimss.org/blog/my-wish-list-fda-mobile-medical-app-regulation>. CEO of mobile health care company, AirStrip, advocating for a breadth of FDA regulation which (perhaps ironically) actually underlies the problem FDA will face in delineating a well-reasoned scope for its regulation of emerging technology. For instance, Portela suggests that FDA will need to regulate the internet for content and operating systems and accessories for their reliability.

88. See e.g., Daniel Kramer, Shuai Xu & Aaron Kesselheim, *Regulation of Medical Devices in the United States and European Union*, 366 NEW ENG. MED. J. 848, 848 (2012).

89. *Id.* at 852.

90. See Cortez, *supra* note 11.

able to obtain clearance within months of first filing their 510(k).<sup>91</sup> Lastly, Class I devices typically require no pre-market notification at all.<sup>92</sup>

In other words, federal regulations that apply to the mobile health industry do not seem to be a significant barrier to this industry’s growth. Similarly, as I addressed in a previous article, unsettled medical liability issues surrounding the use of mobile health devices are not intractable, as large healthcare organizations can afford take on the enterprise risk of any technology failures, and likely will push ahead with mobile health technology in order to realize its promised benefits.<sup>93</sup> Thus, as I asserted above, the biggest legal barriers standing in the path of the putative mobile health revolution, are restrictive medical licensing and scope of practice laws at the state level.

### *B. What is Scope of Practice?*

#### 1. State-Based Medical Licensing Laws: Historical Context

One of the biggest impediments to achieving more uniform and flexible scope of practice laws is inertia. States engage in licensing and policing of scope of practice laws because that is how it has been done since colonial times. Regulation of medicine traditionally falls under the states’ police powers which permit regulation for general welfare.<sup>94</sup> This includes laws necessary to ensure effective sanitation measures, infectious disease control and regulation of professions, like law and medicine, that impact general welfare.<sup>95</sup> After a physician demonstrates sufficient medical proficiency, through meeting educational requirements and passing the medical licensing examination, a state typically permits her to practice to the full scope of medicine, subject only to requirements that she exercise good

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91. *See generally id.* The app iGlucose submits diabetic patients’ glucose readings to a portal that is accessible by health care providers. Its developer, Health ID, submitted a 510(k) in July 2011 and was cleared by November 2011. Brian Edwards, *AliveCor receives FDA 510k approval in just 80 days*, MHEALTH, (Dec. 11, 2012), <http://www.imedicalapps.com/2012/12/alivecor-fda-510k-approval/>.

92. *See Cortez, supra* note 11.

93. *See Khan & Swanson, supra* note 26.

94. *See* Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 202-03 (1999).

95. *See id.*

professional judgment and conform with industry standards.<sup>96</sup> This is an extremely generous standard for doctors, meaning that you can find psychiatrists or OB/GYNs that can legally offer botox injections for wrinkles (i.e., do not need to be a dermatologist) or radiologists that start up “men’s health” clinics (i.e., do not need to be an endocrinologist).<sup>97</sup>

Historically, regulation of medical professionals was very limited before the Civil War.<sup>98</sup> Prior to that time, physicians tended to be untrained and the medicine that they practiced tended not to work. As germ theory emerged and sanitation practices improved in the mid to late nineteenth century, treatments and diagnosis based on scientific research took hold with medical elites in charge of running hospitals and training the next generation of doctors, and less latitude granted to those who insisted upon engaging in ineffective traditional forms of medicine.<sup>99</sup> Once these new practices were discovered, the need for formal training became more imperative as demand for the new techniques increased.

Consequently, over a century ago, the American Medical Association (AMA) created the Council of Medical Education and began setting minimum standards for medical school curricula.<sup>100</sup> The movement was brought on by the sense that many doctors were continuing to use traditional procedures that were “ineffective and dangerous” and simply ignored new scientific developments. Reform was spurred on by publication in 1910 of the landmark Flexner Report, a study funded by the Carnegie Foundation that was intended to evaluate medical school performance.<sup>101</sup> The report

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96. See William P. Gunmar, *The Scope of a Physician’s Medical Practice: Is the Public Adequately Protected by State Medical Licensure, Peer Review, and the National Practitioner Data Bank?* 14 ANNALS HEALTH L. 329, 332 (2005).

97. See Donald Jablonski, *When Doctors Drift, Question of Competency and Ethics Are Key*, NORTH CAROLINA MED. BD. (Aug. 3, 2010), available at [http://www.ncmedboard.org/resources-information/professional-resources/publications/forumnewsletter/article/when\\_doctors\\_drift\\_questions\\_of\\_competency\\_and\\_ethics\\_are\\_key](http://www.ncmedboard.org/resources-information/professional-resources/publications/forumnewsletter/article/when_doctors_drift_questions_of_competency_and_ethics_are_key),

98. Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 206 (1999).

99. WILLAM BYNUM, *SCIENCE AND THE PRACTICE OF MEDICINE IN THE NINETEENTH CENTURY* 218-222 (1994).

100. Ezekiel J. Emanuel, *Changing Premed Requirements and the Medical Curriculum*, 296 JAMA 1128, 1128 (2006).

101. *Id.*



essentially “codified the need to systematically integrate [scientific advances such as new practices in bacteriology, anti-septic surgery and vaccinations] into the training of physicians.”<sup>102</sup> While recommending the integration of science into medical education and training might not seem controversial, at the time many medical doctors were highly critical of the Flexner Report and its suggested reforms—these medical practitioners that had a lot to lose with the implementation of new standards. Nevertheless, in the early 1900s, the health care system was not as well organized into factions that could effectively oppose such a massive reform. Not until the profession took the report’s recommendations seriously did dangerous practices like “purging, bleeding, cathartics and proprietary medicines” lose favor.<sup>103</sup>

There is a seeming paradox that medical licensing is state-based when every other trend in America’s healthcare system has been to establish national standards. In addition to medical school curricula, national licensing exams, residency training standards, tort liability standards, practice guidelines, and institutional accreditation standards are all nationalized. For instance, during the 1960s and 1970s courts began dismantling the “locality rule” for medical malpractice claims in favor of judicially imposing a national standard of care in delivering medicine.<sup>104</sup> Further, many doctors also opt to become “board certified” by a national medical specialty organization, such as the American College of Surgeons. These boards have existed since the early part of the twentieth century and are intended to ensure that doctors are sufficiently competent to practice within their specialty.<sup>105</sup> For institutions, the non-profit Joint Commission on Accreditation of Hospitals (now known as “The Joint Commission”) has long set national standards that hospitals have to meet in order to qualify for Medicare reimbursements.<sup>106</sup>

All of the above developments reinforce the policy argument that medical licensing standards should be uniform across state borders for clarity and to reduce fragmentation in an overly complicated

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102. *Id.*

103. *Id.*

104. David M. Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 284 (2004).

105. Troyen A. Brennan et al., *The Role of Physician Specialty Board Certification Status in the Quality Movement*, 292 JAMA 1038, 1040 (2004).

106. *The Joint Commission History*, THE JOINT COMMISSION, [http://www.jointcommission.org/assets/1/6/Joint\\_Commission\\_History\\_2012.pdf](http://www.jointcommission.org/assets/1/6/Joint_Commission_History_2012.pdf)

system.<sup>107</sup> Yet, state medical boards have jealously guarded their regulatory authority by renouncing even piecemeal efforts to achieve greater uniformity in targeted ways.<sup>108</sup> Furthermore, because medical licensing legitimately falls within the states’ police powers, states can assert a federalism defense to any encroachment upon their licensing powers.

## 2. State Scope of Practice Laws: Complex and Inconsistent

As described above, an obvious way to alleviate the effects of the shortage of primary care physicians is through expanding the roles of physician extenders, including physician assistants (PAs) and NPs, in primary care.<sup>109</sup> The amount of training needed for physician extenders is significantly less than for doctors so more of them can fill the primary care gap within a shorter time frame. For example, a Robert Wood Johnson Foundation study determined that overall NP numbers had doubled relative to primary care doctors between 1995 and 2009.<sup>110</sup> A similar trend was also seen with PAs, suggesting that these health care providers could increase in number over a relatively short period of time to help meet the growing demand in healthcare.<sup>111</sup>

Rural communities have long been disproportionately affected by this scarcity as they long have had difficulty luring sufficient numbers of doctors.<sup>112</sup> In many of these communities, nurse practitioners (NPs)

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107. See *Committee on the Robert Wood Johnson Foundation Initiative on the Future of Nursing*, INST. OF MED., NURSING: LEADING CHANGE, ADVANCING HEALTH 97 (2010), <http://www.iom.edu/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx>.

108. See *id*; *Improving Health Care: A Dose of Competition*, U.S. D.O.J. & F.T.C. 1, 112 (2004), <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

109. See Spalter, *supra* note 12, at 171.

110. Kevin M. Stange & Deborah A. Sampson, *Nurse Practitioners and Physician Assistants in the United States: Current Patterns of Distribution and Recent Trends*, <http://thefutureofnursing.org/NursingResearchNetwork7>.

111. See Joan Lynaugh, *Nursing the Great Society: The Impact of the Nurse Training Act of 1964*, 16 NURSING HIST. REV. 13, 24-25 (2008); see also LINDA H. AIKEN & ROBIN CHEUNG, *NURSE WORKFORCE CHALLENGES IN THE UNITED STATES: IMPLICATIONS FOR POLICY* (2008).

112. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, *PRIMARY CARE WORKFORCE FACTS AND STATS NO. 3: DISTRIBUTION OF THE U.S. PRIMARY CARE WORKFORCE*, <http://www.ahrq.gov/research/pcwork3.htm>. Even though primary care physicians are more likely than specialists to be in rural areas, they still tend to be concentrated in urban settings. In comparison to physicians, nurse practitioners and physicians’ assistants are more likely to work in rural areas.

are playing a more prominent role in providing primary care.<sup>113</sup> Studies of nurse-managed care clinics (NMCs) have demonstrated that they can increase quality and access to care by reducing costs and improving utilization of preventive care.<sup>114</sup> Yet, state scope of practice laws, licensing schemes, and payers’ reimbursement practices limit the potential use of these and other innovations to address the scarcity problem. For instance, in some states nurses are able to set up clinics to provide primary care services without direct physician oversight. However, in other jurisdictions, nurses with the exact same training are not able to do this without paying fees to a doctor and entering into a collaboration agreement.

In 2010, the Institute of Medicine (IOM) published a report on the future of nursing, which was spurred by the “need to assess and transform the nursing profession.”<sup>115</sup> The report started with the concept that nurses should play an expanded role in the delivery of health care.<sup>116</sup> A central finding of this report was that the existing scope of practice laws needed to be reformed to assure that nurses are able to practice to the full extent of their training. Yet, the IOM noted that efforts to achieve these expanded roles have been undermined by state medical board resistance, reimbursement limitations, professional tensions, and the fragmented nature of the health care system.<sup>117</sup> Others have also noted that the greatest obstacle to the optimal use of physician extenders is the varied scope of practice laws employed by states.<sup>118</sup> The IOM report notes that it is not even clear how different state laws are between one another.<sup>119</sup> That is because some states are very detailed about their scope of practice laws, while others contain vague provisions that leave much uncertainty as to their interpretation.<sup>120</sup> However, a different study

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113. Tina Rosenberg, *The Family Doctor, Minus the M.D.*, N.Y. TIMES (Oct. 24, 2012), <http://opinionator.blogs.nytimes.com/2012/10/24/the-family-doctor-minus-the-m-d/>.

114. Jennifer A. Coddington & Laura P. Sands, *Costs of Health Care and Quality Outcomes of Patients at Nurse-Managed Clinics*, 2 NURSING ECONOMIC\$ 75 (2008).

115. INST. OF MED., *THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH*, 2 (2010), available at <http://www.iom.edu/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx>.

116. *Id.* at 86.

117. *Id.* at 9-11.

118. See Carl F. Ameringer, *State-based Licensure of Telemedicine: The Need for Uniformity but Not a National Scheme*, 14 J. HEALTH CARE L. & POL’Y 55, 68-70 (2012).

119. See INST. OF MED., *supra* note 115, at 98.

120. *Id.*

claims that intense lobbying battles over these statutes have in fact exacerbated state-specific differences in scope of practice parameters, leading to a system of laws that vary widely by state.<sup>121</sup>

Not surprisingly, the AMA has consistently obstructed any attempts to reform scope of practice laws. To this end, in 2006 the AMA sponsored the formation of the Scope of Practice Partnership (SOPP), a committee of state medical and subspecialty associations.<sup>122</sup> The AMA designed the SOPP to serve as an organized front to challenge legislative efforts to expand the roles of “limited licensure health care providers,” or in other words non-physician health care providers.<sup>123</sup> The SOPP, with the assistance of AMA staff attorneys, has developed and disseminated templates to enable other physician interests groups to quickly and effectively oppose scope of practice expansions.<sup>124</sup> The AMA’s Litigation Center provides resources “to help defeat inappropriate scope of practice expansions,”<sup>125</sup> and has expressed an intention to continue to do so in light of the AMA’s perception that the ACA’s emphasis on collaboration will result in a greater push toward expanded roles for non-physician health care providers.<sup>126</sup> In addition, recent AMA resolutions have demonstrated an unwillingness to acknowledge the authority of boards designed to

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121. Tine Hansen-Turton et al., *Insurers’ Contracting Policies on Nurse Practitioners as Primary Care Providers: Two Years Later*, 9 POL’Y, POL. & NURSING PRACT. 241, 241 (2008).
122. Myrle Croasdale, *Physician Task Force Confronts Scope-Of-Practice Legislation: A New Coalition With Organized Medicine Cites Patient Safety As The Reason For Coming Together*, AMERICAN MEDICAL NEWS (Feb. 13, 2006), <http://www.amaassn.org/amednews/2006/02/13/prl10213.htm>; AM. MED. ASSOCIATION HOUSE OF DELEGATES, RESOLUTION 814: LIMITED LICENSURE HEALTH CARE PROVIDER TRAINING AND CERTIFICATION STANDARDS (2005), <http://www.ama-assn.org/meetings/public/interim05/refcomkannotateda05.doc>.
123. Croasdale, *supra* note 122.
124. Edward L. Langston, *Scope of Practice: Need for continuing dialogue*, AM. MED. NEWS (Jun. 2, 2008), <http://www.amaassn.org/amednews/2008/06/02/edca0602.htm>.
125. *State Legislative and Regulatory Prospectus*, AM. MED. ASS’N, 8 (2012), <http://www.amaassn.org/resources/doc/arc/state-leg-reg-prospectus-2012.pdf>; *Case Summaries*, AMERICAN MEDICAL ASSOCIATION, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/litigation-center/case-summaries-topic/scopepractice.page?;> see also AMERICAN MED. ASS’N: ABOUT US, [http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/litigation-center/about-us.page?.](http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/litigation-center/about-us.page?)
126. AM. MED. ASS’N, ADVOCACY RESOURCE CENTER, STATE HEALTH SYSTEM REFORM IMPLEMENTATION, (2012), <http://www.ama-assn.org/resources/doc/arc/x-ama/sop-workplan.pdf>.

regulate the practices of other medical professionals (e.g., boards of nursing).<sup>127</sup>

Predictably, the SOPP frames its advocacy efforts as being done for the benefit of patients. It claims that it is addressing patient safety concerns stemming from the expansion of roles for medical professionals with less training than physicians. However, empirical research consistently demonstrates equivalent outcomes for using nurses in many contexts that have traditionally been reserved for doctors.<sup>128</sup> In addition, there is a growing body of literature dedicated to studying inter-professional collaboration between the various actors in the health care system.<sup>129</sup> Some of these studies have observed better outcomes and more efficient use of resources stemming from these types of collaborative environments.<sup>130</sup> Thus, the SOPP’s stated position instead seems to be a pretext to advance the AMA’s true concern, that physicians have to increasingly compete with lower paid non-physicians.

Of course, physician groups are not the only ones lobbying for outcomes related to scope of practice laws. At the beginning of 2012, the AMA’s Advocacy Resource center predicted that non-physician advocacy groups would become even more aggressive in the coming year.<sup>131</sup> The AMA noted that over 400 scope of practice bills were introduced in state legislatures during 2011.<sup>132</sup> Most notably, the AMA reported that advanced practice nurses in nearly twenty states were seeking to eliminate collaborative practice agreements requiring physician supervision over provision of anesthesia and pain management services.<sup>133</sup>

The AMA and other associations that represent physician interests have historically had great success in defending the status

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127. AM. MED. ASS’N HOUSE OF DELEGATES, AMA RES. 902, NEED FOR ACTIVE MEDICAL BOARD OVERSIGHT OF MEDICAL SCOPE-OF-PRACTICE ACTIVITIES BY MID LEVEL PRACTITIONERS (2006), [http://www.nursingworld.org/MainMenuCategories/PolicyAdvocacy/State/IssuesResources/APRN/AMAHODResolutions904\\_1.pdf](http://www.nursingworld.org/MainMenuCategories/PolicyAdvocacy/State/IssuesResources/APRN/AMAHODResolutions904_1.pdf).

128. INST. OF MED., *supra* note 115, at 111.

129. *See, e.g.*, Anna R. Gagliardi et al., *How can we improve cancer care? A Review of Interprofessional Models and Their Use in Clinical Management*, 20 SURGICAL ONCOLOGY 146, 146 (2011).

130. *Id.* at 151.

131. *2012 State Legislative and Regulatory Prospectus*, AM. MED. ASS’N, 8 (2012), <http://www.amaassn.org/resources/doc/arc/state-leg-reg-prospectus-2012.pdf>.

132. *Id.*

133. *Id.*

quo regarding scope of practice of laws. Nevertheless, nurse practitioners (NPs) have recently gained some ground with more and more states adopting laws authorizing them to practice primary care and prescribe drugs independently.<sup>134</sup> Other states have developed new innovations such as varying collaboration-based requirements for the relationship between NPs and doctors.<sup>135</sup> Yet, even where states *de jure* require supervision or collaboration, NPs are *de facto* often effectively able to work autonomously on a day to day basis by simply following a list of standing orders, or protocols, developed in collaboration with a physician.

Many states also permit physician supervision to be done remotely, meaning direct patient care is in the hands of an NP. States also vary in what type of board regulates nurse practitioners. Many states now have joint boards composed of both doctors and nurse practitioners, whereas in other states a nursing board regulates the practice. In still other states, the Board of Nursing is given the authority to regulate NPs’ practice, but the Board of Medicine (which regulates physicians) is also permitted to enact regulations that impact the relationship between NPs and doctors. The net result is a lot of uncertainty among providers and institutions on how best to utilize and invest in providers of health care.

### 3. The Case of Telemedicine: Erecting Barriers to Out-of-State Doctors

A past effort to reform licensing laws to allow *doctors* to practice across state lines is illustrative of impediments to relaxing scope of practice regulation. As stated above, educational, residency, and specialty board standards are now effectively uniform across the states, but doctors still need to get licensed in their state before they can practice medicine in that locale. Telemedicine raised the possibility of using technology to treat certain kinds of cases without physical contact. However, under state licensing laws there was a lot of confusion as to how to regulate this type of practice.

In 1996, the Federation of State Medical Boards (FSMB), a non-profit that represents many medical boards in the United States, adopted a model act to regulate practice of medicine across state lines.<sup>136</sup> The model act came at a point when many foresaw emerging technologies, particularly the internet and higher resolution imaging, as a means of removing geographic barriers to the practice of

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134. INST. OF MED., *supra* note 115, at 108.

135. *Id.* at 98.

136. *Report of the Ad Hoc Committee on Telemedicine: A Model Act to Regulate the Practice of Medicine Across State Lines*, FED’N OF STATE MED. BDS OF THE U.S. (Apr. 1996), [http://www.fsmb.org/pdf/1996\\_grpol\\_Telemedicine.pdf](http://www.fsmb.org/pdf/1996_grpol_Telemedicine.pdf).

medicine. By facilitating the adoption of telemedicine, the industry would be able to bring experts to underserved areas or reduce costs for visits that required minimal physical contact. However, cumbersome state licensing schemes prevented adoption of the new technology because doctors seeking to practice telemedicine found it too difficult to obtain state licensure for each state.

The model act reflected the general consensus that the patient’s location should determine jurisdiction for the practice of medicine and that states should grant limited licenses to physicians wishing to engage in telemedicine to ensure that the practice could be possible. Physicians would still be subject to the state boards for their treatment of patients within the state, but they would not be required to go through full licensing procedures for each state.<sup>137</sup> Nevertheless, only a handful of states ever acted on the model act’s recommendations.<sup>138</sup> Many more states instead made explicit a continued prohibition of such unlicensed practice of telemedicine in their states, essentially condemning the viability of the practice. They defined unlicensed medicine to include practicing digitally from out-of-state with a patient in-state without a complete license to practice medicine.

These telemedicine policies by state boards, ostensibly for the protection of patients from incompetent physicians, instead reflect anti-competitive practices intended to favor in-state doctors. As one critic noted, “Barring serious differences in the quality of care provided or improper use of distance technology, these discrepancies should not exist.”<sup>139</sup> It is worth reiterating that this outcome occurred when efforts were undertaken to expand *doctors’* freedom to practice.

#### 4. Federal Antitrust Enforcement

The Federal Trade Commission (FTC) has become increasingly involved in advocating for less restrictive scope of practice laws. In the wake of the Institute of Medicine’s report on nursing and given expanded insurance coverage under the ACA’s individual mandate, many states that still require collaboration agreements are revisiting the practice. FTC comments on such proposals have recommended that “the licensure ensure that such limits [be] no stricter than patient protection requires” and that “[a]bsent a finding that there are countervailing patient care and safety concerns regarding APRN practice, suggestions to remove the collaborative agreement for prescriptive authority appear to be a procompetitive improvement in

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137. *Id.*

138. *Id.*

139. Ameringer, *supra* note 118, at 59.

the law that likely would benefit West Virginia health care consumers.”<sup>140</sup> In particular, the Commission noted that “unnecessary restrictions on APRNs are likely to exacerbate access problems and thereby harm some of the most vulnerable populations.” This effect might be compounded in areas where physician shortages result in increased costs associated with or difficulty acquiring collaboration agreements.<sup>141</sup>

Over the past decade, the FTC has targeted state dental boards for anti-competitive behavior.<sup>142</sup> The FTC’s general position is that “a state may not give private market participants unsupervised authority to suppress competition even if they act through a formally designated ‘state agency’.”<sup>143</sup> In North Carolina, the State Board of Dental Examiners (Board) regulates the practice of dentistry pursuant to North Carolina’s Dental Practice Act.<sup>144</sup> The Board is comprised of eight members, of which six are licensed dentists—in other words, seventy-five percent of the Board is made up of “private market participants.” In the 1990s, dentists started offering cosmetic teeth whitening services and earned significant professional fees for this process.<sup>145</sup> But eventually, non-dentists started offering the exact same service, often in shopping mall kiosks, and at substantially lower

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140. FTC, STAFF LETTER TO WEST VIRGINIA LEGISLATURE, PREPARED STATEMENT BEFORE SUBCOMMITTEE A OF THE JOINT COMMITTEE ON HEALTH OF THE STATE OF WEST VIRGINIA LEGISLATURE (2012), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-testimony-subcommittee-wv-legislature-laws-governing-scope-practice-advanced-practice/120907wvatestimony.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-testimony-subcommittee-wv-legislature-laws-governing-scope-practice-advanced-practice/120907wvatestimony.pdf).

141. FTC, LETTER TO LOUISIANA STATE REPRESENTATIVES WILLMOTT AND WILLIAMS (2012), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-louisiana-house-representatives-likely-competitive-impact-louisiana-house-bill-951/120425louisianastaffcomment.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-louisiana-house-representatives-likely-competitive-impact-louisiana-house-bill-951/120425louisianastaffcomment.pdf).

142. *See e.g.*, Complaint, South Carolina State Board of Dentistry, No. 9311 (F.T.C. 2003), <http://www.ftc.gov/os/2003/09/socodentistcomp.pdf>. *See also* FTC OFFICE OF POLICY PLANNING, LETTER TO NORTH CAROLINA HOUSE OF REPRESENTATIVE LAROQUE (2012), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-letter-nc-representative-stephen-laroque-concerning-nc-house-bill-698-and-regulation/1205ncdental.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-nc-representative-stephen-laroque-concerning-nc-house-bill-698-and-regulation/1205ncdental.pdf).

143. FTC, STATEMENT BY FTC CHAIRWOMAN EDITH RAMIREZ ON U.S. SUPREME COURT RULING REGARDING NORTH CAROLINA DENTAL BOARD MATTER (2015), <https://www.ftc.gov/news-events/press-releases/2015/02/statement-ftc-chairwoman-edith-ramirez-us-supreme-court-ruling>.

144. N.C. State Bd. of Dental Examiners v. FTC, 135 S. Ct. 1101 (2015) (slip op.) [*hereinafter* N.C. Board v. FTC]

145. *Id.*



prices.<sup>146</sup> Responding to complaints from dentists who saw their teeth whitening business shrinking, the Board issued official cease-and-desist letters to non-dentists offering this service and to product manufacturers that provided their supplies. The Board warned that unlicensed practice of dentistry was a crime and also sent letters to shopping malls, advising that they should expel tenants that offered these services. In 2010, the Federal Trade Commission (FTC) filed an administrative complaint against the Board, citing that its action was an unfair method of competition under the Federal Trade Commission Act and Section 1 of the Sherman Antitrust Act. Then, in 2011, the FTC issued an order requiring that the Board stop sending communications intended to prevent non-dentists from offering teeth whitening services.

Early on, the FTC’s action raised concerns at the AMA. The FTC was sending a clear signal that it was making anti-competitive behavior of all state medical boards, not just dental boards, a top priority. Tellingly, as the Board appealed the FTC’s decision to the Fourth Circuit, the AMA offered litigation support and filed an amicus brief in favor of the Board.<sup>147</sup> Whereas an earlier FTC order against South Carolina’s dental board addressed restrictions imposed despite state legislative efforts to the contrary,<sup>148</sup> the North Carolina case was more troubling to the AMA because the FTC order charged the Board with imposing anti-competitive practice restrictions in an area where the state dental statute was silent.<sup>149</sup>

The FTC order emphasized that the majority of Board members earned a living by practicing dentistry and concluded that, “given the Board’s obvious interest in the challenged restraint, the state must actively supervise the Board in order for the Board to claim state action protection from the antitrust laws.”<sup>150</sup> In its defense, the Board argued that under *Parker v. Brown*, federal antitrust laws cannot apply to their activities as they are sovereign state actions.<sup>151</sup> In *Parker*, the Court developed a two prong test for state action immunity where private actors are involved in restraining commerce:

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146. *Id.*

147. *N.C. State Bd. of Dental Examiners v. FTC*, 768 F. Supp. 2d 818 (2010).

148. Complaint, South Carolina State Board of Dentistry, No. 9311 (F.T.C. 2003), <http://www.ftc.gov/os/2003/09/socodontistcomp.pdf>.

149. Complaint at 3-4, *N.C. Bd. of Dental Examiners* (F.T.C. June 17, 2010) (No. 9343), <http://www.ftc.gov/os/adjpro/d9343/100617dentalexamcmpt.pdf>.

150. *N.C. State Bd. of Dental Examiners*, 151 F.T.C. 607, 608 (2011), <http://www.ftc.gov/os/adjpro/d9343/110208commopinon.pdf>.

151. *See Parker v. Brown*, 317 U.S. 341 (1943).

(1) the restraint is “clearly articulated” and “affirmatively expressed as state policy,” and (2) “the policy must be actively supervised by the State itself.”<sup>152</sup>

Subsequently in *Midcal*, the Court found that a California system for wine pricing did not satisfy the *Parker* test because the State merely authorized price setting generally, but did not set prices, enforce them, or review them for reasonableness.<sup>153</sup> In contrast to *Midcal*, the Court in *Town of Hallie* held that municipalities can avail themselves of the doctrine if they are able to meet the first prong because unlike private actors, there is a presumption that municipalities operate in the public interest.<sup>154</sup> Under *Town of Hallie*, the state legislature need not expressly state its intention for the authorization to have anti-competitive effects; there need only be a “clearly articulated” state policy and anti-competitive conduct that was a foreseeable consequence of that policy.<sup>155</sup>

In an amicus brief, the AMA and several state medical boards argued that boards, like municipalities, should be entitled to state action immunity “regardless of the composition of those boards” and without active state oversight.<sup>156</sup> The AMA warned that although the case appears before the court in the guise of an action targeting teeth whitening practices, “the FTC order would greatly impede state regulation of the practice of medicine, with a devastating impact on public health (nationally).”<sup>157</sup> The AMA also published a white paper condemning the FTC’s actions as a threat to the important scope delineating function these boards were intended serve.<sup>158</sup>

In the white paper, the AMA argued that dicta in the Court’s decision in *Town of Hallie*, supports the Board’s position that medical board actions should be immune to antitrust actions subject only to meeting the first prong of *Parker* test.<sup>159</sup> In that decision, the Court

152. *California Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

153. *Id.* at 105-106.

154. *Town of Hallie v. City of Eau Claire*, 471 U.S. 34, 45 (1985).

155. *Id.*

156. Brief for The American Medical Association et al. as Amici Curiae Supporting Petitioners at 8, *N.C. State Bd. of Dental Examiners v. FTC*, 717 F.3d 359 (4th Cir. 2014) (No. 12-1172)., <http://www.ama-assn.org/resources/doc/legal-issues/ncsbde-v-ftc.pdf>.

157. *Id.* at 2.

158. AM. MED. ASS’N, APPLICATION OF THE STATE ACTION ANTITRUST EXEMPTION TO ACTIONS OF STATE MEDICAL BOARDS, (2012), <http://www.ama-assn.org/resources/doc/arc/state-action-antitrust-exemption-white-paper-2012.pdf>.

159. *Id.* at 7.

noted that “it is likely that active state supervision would also not be required” for state agencies acting subordinate to the state’s legislature. The AMA asserted that like municipalities, and unlike the acts of private persons, state boards can be overturned by legislative actions and are subject to judicial review.<sup>160</sup> Further, the AMA argued that while there are fewer political checks on medical boards, compared with municipal government, enabling statutes typically require adherence to processes to assure transparency and statutes generally prohibit the types campaign contribution-type influences.<sup>161</sup>

In 2013, the Fourth Circuit upheld the FTC’s order. In 2015, the Board appealed to Supreme Court, but lost in a 6-3 decision as the majority (including Chief Justice Roberts and Justice Kennedy) affirmed the FTC’s position in *North Carolina State Board of Dental Examiners v. Federal Trade Commission*.<sup>162</sup> The Court held that the Board was acting as a private actor, and since there was no evidence of state supervision, the Board was not entitled to state action immunity.<sup>163</sup> This decision is significant for several reasons. First, it indicates that the Roberts Court does not see federal oversight of state medical licensing schemes as per se violations of state sovereignty. Second, this validates the FTC’s earlier advocacy positions that licensure requirements should be no more restrictive than required by patient safety and that overly restrictive laws harm the public interest by exacerbating preexisting healthcare access problems. But third, it does not automatically signal the death knell for physician groups like the AMA and CMA that want state boards to maintain restrictive scope of practice and licensing laws—they simply have to ensure that state boards have some measure of state “supervision” over them. The bigger picture is that in light of this legal victory, one can expect the FTC to take on a more aggressive anti-competitive stance which in turn could nudge state medical boards to adopting more liberalized licensure and scope of practice laws. In other words, pushing for the public to have access to lower cost teeth whitening technology in shopping malls or at homes, is not that different from advocating that non-physicians using mobile health technologies should be able to offer these lower cost and more accessible healthcare services free from anticompetitive state regulations.

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160. *Id.*

161. *Id.*

162. *N.C. State Bd. of Med. Examin’rs v. F.T.C.*, 717 F.3d 359 (4th Cir. 2014).

163. *Id.*

## IV. AMERICAN HEALTHCARE AND THE CASE FOR DISRUPTIVE INNOVATION

A. *The Intertwined Problems of Healthcare Costs and Access*

If nothing changes in the American healthcare system, the physician shortage is expected to increase by ten-fold between 2010 and 2025.<sup>164</sup> This problem can manifest itself in terrible ways. For instance, a whistle-blower at a VA hospital in Phoenix alleged there were “secret waiting lists” for patients that were kept off the official books in order to create “a misleading portrayal of veterans’ access to patient care.”<sup>165</sup> Bonuses for V.A. hospital administrators were tied to measures of access, including waiting times for appointments.<sup>166</sup> However, the V.A. is woefully underfunded and understaffed, especially as increased levels of veterans were coming back from Iraq and Afghanistan seeking both routine and complex care.<sup>167</sup> A subsequent federal investigation not only confirmed this practice in Phoenix, but across V.A. facilities nationwide. At the Phoenix hospital, an investigation concluded that 1,700 patients were placed on these secret lists and many may have never received medical care.<sup>168</sup> The Phoenix V.A. and many other facilities also simply lacked the physical space to see more patients.<sup>169</sup> Even more disturbing, an official from the inspector’s general office “testified that delays for care had contributed to some patient deaths.”<sup>170</sup> In the

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164. Ass’n of Am. Med. Colleges, *Physician Shortages to Worsen Without Increases in Residency Training*, [https://www.aamc.org/download/153160/data/physician\\_shortages\\_to\\_worsen\\_without\\_increases\\_in\\_residency\\_tr.pdf](https://www.aamc.org/download/153160/data/physician_shortages_to_worsen_without_increases_in_residency_tr.pdf). See also Jack M. Colwill, James M. Cultice & Robin L. Kruse, *Will Generalist Physician Supply Meet Demands of an Increasing and Aging Population?* 27 HEALTH AFF. w232 (2008).

165. Richard Oppel, *Some Top Officials Knew of V.A. Woes, Before the Scandal*, N.Y. TIMES (Dec. 25, 2014), <http://www.nytimes.com/2014/12/26/us/politics/high-level-knowledge-before-veterans-affairs-scandal.html>.

166. Richard Oppel & Michael Shear, *Severe Report Finds V.A. Hid Waiting Lists at Hospitals*, N.Y. TIMES (May 29, 2014), <http://www.nytimes.com/2014/05/29/us/va-report-confirms-improper-waiting-lists-at-phoenix-center.html>.

167. Richard Oppel, *Doctor Shortage is Cited in Delays at V.A. Hospitals*, N.Y. TIMES (May 29, 2014), <http://www.nytimes.com/2014/05/30/us/doctor-shortages-cited-in-v-a-hospital-waits.html>.

168. Oppel, *supra* note 165.

169. *Id.*

170. *Id.*

aftermath of this scandal, the V.A. disclosed that it was short over 28,000 doctors, nurses and other staff.<sup>171</sup> Further, the V.A. acknowledged that it is having a difficult time recruiting doctors to fill open positions because it pays less (\$98,000 to \$195,000 for primary care) than the private sector (\$221,000 median primary care income), but still has significant patient loads.<sup>172</sup>

Further, while the ACA has led to expansion of affordable insurance coverage and Medicaid eligibility in participating states, insurance coverage by itself does not guarantee timely access to care. A recent study found that for callers attempting to make a specialty care appointment for children on Medicaid-CHIP (Children’s Health Insurance Program), 66% were denied the ability to even make an appointment (compared to 11% denial for callers reporting Blue Cross Blue Shield insurance).<sup>173</sup> In addition, once they were able to find a specialist who accepted Medicaid-CHIP, the children had to wait on average 42 days (compared to an 20 day average wait with private insurance).<sup>174</sup> The healthcare access problems children face through Medicaid-CHIP is also scandalous, but has not made similar headlines. The problem here is the same as with the V.A.; Medicaid-CHIP pays less in reimbursements than private insurance, so many doctors refuse to see such patients, increasing patient loads on those who do accept such payments.

Throwing more money at the V.A. and the Medicaid might mitigate some of the access problems related to undersupply, but this seems like an unsustainable long-term solution given other budgetary constraints. Medicare and Social Security are the two biggest entitlement programs and both face solvency crises in the near future. A recent government forecast indicates that Medicare’s financial stability has improved under the ACA, but this only means that the fund which covers hospital costs is projected to go insolvent in 2030, as opposed to 2026.<sup>175</sup> The situation for Social Security is more dire, as the fund that pays monthly benefits for those with disabilities will

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171. *Id.*

172. Opper, *supra* note 167.

173. Joanna Bisgaier & Karin Rhodes, *Auditing Access to Specialty Care for Children with Public Insurance*, 364 NEW ENG. J. MED. 2324, 2328 (2011).

174. *Id.*

175. Amy Goldstein, *Medicare Finances Improve Partly Due to ACA, Hospital Expenses, Trustee Report Says*, WASH. POST (July 28, 2014), [http://www.washingtonpost.com/national/health-science/medicare-finances-improve-due-to-aca-lower-hospital-expenses-social-security-says-the-same-trustee-report-says/2014/07/28/5db1a2a2-165a-11e4-9e3b-7f2f110c6265\\_story.html](http://www.washingtonpost.com/national/health-science/medicare-finances-improve-due-to-aca-lower-hospital-expenses-social-security-says-the-same-trustee-report-says/2014/07/28/5db1a2a2-165a-11e4-9e3b-7f2f110c6265_story.html)

start to run short starting in 2016. With these seemingly intractable budgetary problems, it does seem as if a paradigm shift is truly needed to bend the cost curve in order to improve healthcare access.

*B. Mobile Health as Disruptive Innovation*

Disruptive innovation refers to a breakthrough that builds on a product or service in ways that are unappreciated by those established in the industry.<sup>176</sup> Typically, while disruptive innovations offer worse product performance, they provide other features that consumers value (e.g., “cheaper, simpler, smaller, and, frequently, more convenient to use”).<sup>177</sup> However, entrenched stakeholders may not adequately invest in these new breakthroughs, preferring instead to meet the demands of their existing customer base.<sup>178</sup> Entrenched stakeholders do this by producing “sustaining innovation,” or in other words products that offer higher profit margins by meeting high-end customer demands.<sup>179</sup>

In many ways, the traditional application of technology in medicine has followed this “sustaining innovation” paradigm. Think about x-rays versus MRIs and CT scans, canes and walkers versus artificial joint replacements, calorie-restricted diets versus bariatric surgery—the latter are all higher margin, higher cost procedures. In

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176. Joseph Bower & Clayton Christensen, *Disruptive Technologies: Catching the Wave*, HARV. BUS. J. 43, 47 (1995) (“A company’s revenue and cost structures play a critical role in the way it evaluates proposed technological innovations. Generally, disruptive technologies look financially unattractive to established companies. The potential revenues from the discernible markets are small, and it is often difficult to project how big the markets for the technology will be over the long term. As a result, managers typically conclude that the technology cannot make a meaningful contribution to corporate growth and therefore, that it is not worth the management effort required to develop it.”)

177. CHRISTENSEN, *supra* note 81, at xv.

178. Bower & Christensen, *supra* note 176 (“The problem is that managers keep doing what has worked in the past: serving the rapidly growing needs of their current customers. The processes that successful, well-managed companies have developed to allocate resources among proposed investments are *incapable* of funneling resources into programs that current customers explicitly don’t want and whose profit margins seem unattractive.”).

179. Lesley Curtis & Kevin Schulman, *Overregulation of Health Care: Musings on Disruptive Theory*, 69 L. & CONTEMP. PROB. 195, 197 (2006) (“Early innovators enter markets with basic products that meet the needs of a segment of the market. Over time, innovators improve the product’s capabilities (‘sustaining innovation’) to meet the demands of high-end customers, who offer potentially higher margins and more profitable markets.”).

contrast, disruptive innovation occurs when a new product “enter[s] the market at a lower level of sophistication, rapidly progresses to meet the needs of the majority of consumers in the marketplace and, as a result, captures market share from well-established firms.”<sup>180</sup> This eventually leaves established industry leaders in the lurch.<sup>181</sup>

Convergence of well-known technologies can also be disruptive—a good example of this can be seen in camera phones.<sup>182</sup> Apple claimed back in 2013 that the iPhone is now “the world’s most popular camera,” with more pictures taken on their phones than any other device.<sup>183</sup> The reason the iPhone’s camera is the most popular is not because it takes the best pictures. It is rather because it fits in your pocket, is easy to use, and is already bundled into the price of a smartphone.

Smartphones are already potent little sensors capable of capturing large quantities of data for a diversity of purposes.<sup>184</sup> Given this, mobile technology companies like Apple realize that the same dynamics (easy to use, already in your pocket, inexpensive) that enabled them to disrupt the photography industry can specifically be applied to healthcare. To this end, in 2014, Apple announced the release of its “Healthkit” software platform that according to Craig Federighi, Apple’s senior vice president of software engineering, will

180. *Id.*

181. Bower & Christensen, *supra* note 176 (“[M]anagers typically see themselves as having two choices when deciding whether to pursue disruptive technologies. One is to go *downmarket* and accept the lower profit margins of the emerging markets that the disruptive technologies will initially serve. The other is to go *upmarket* with sustaining technologies and enter market segments whose profit margins are alluringly high... Any rational resource-allocation process in companies serving established markets will choose going upmarket rather than going down.”) *See also*, Maxwell Wessel, *Stop Reinventing Disruption*, HBR BLOG NETWORK (Mar. 7, 2013), [http://blogs.hbr.org/cs/2013/03/stop\\_reinventing\\_disruption.html](http://blogs.hbr.org/cs/2013/03/stop_reinventing_disruption.html) (“Disruption is a story of rational responses to a changing environment. It’s the sensible retreat from your low margin business towards you more demanding, more profitable customers. At least, it’s a sensible retreat until you recognize that you’ve given away your business and there is nowhere left to run.”).

182. *See* Fredrik Hacklin, *How Incremental Innovation Becomes Disruptive: The Case Of Technology Convergence*, 1 INT’L ENGINEERING MGMT. CONF. 32, 34 (2004).

183. *iPhone: Features*, APPLE, <http://www.apple.com/iphone/features/> (accessed May 11, 2013).

184. *See, e.g.*, Roberta Kwok, *Phoning in Data*, 458 NATURE 959 (2009) (discussing the proliferation of projects to use mobile phones in diverse disciplines).

enable the creation of “a vast array of healthcare apps for monitoring things like heart rate, weight, blood pressure and glucose levels for people with diabetes.”<sup>185</sup> Moreover, Apple is working with Epic Systems (industry leader in EMR with over 100 million patient records) and providers like the Mayo Clinic and the Cleveland Clinic to transform smartphones into medical grade devices that can be equipped to enable self-treatment (e.g., perform diagnostic tests, monitor chronic diseases) and enhanced provider treatment (e.g., clinical decision-support software linked to patients EMR).<sup>186</sup>

For the V.A., Medicaid, and other healthcare plans generally, lack of doctors and clinical openings for outpatient care is something that mobile health theoretically could solve. Physician extenders could visit veterans at their homes to deliver care, or parents could schedule visits for children at their schools and videoconference in on their smartphones if they cannot take time off of work. Retail medical clinics, which already exist in places such as Walgreens, CVS and Walmart, could start offering more than their currently limited services and thus perform a greater role in alleviating cost and access issues.<sup>187</sup>

To fully realize the potential of disruptive technology, those investing in it must first gain entry to the market. As Curtis and Schulman have noted, “[t]he presence of regulation, however, may effectively prevent disruptive technological improvements from occurring.”<sup>188</sup> This might occur even though disruptive innovations “often can subsequently become fully performance-competitive within

185. Phil Goldstein, *Apple Moves Into Mobile Healthcare with HealthKit Software*, *Fierce Wireless*, FIERCE WIRELESS (June 2, 2014), <http://www.fiercewireless.com/story/apple-moves-mobile-healthcare-healthkit-software/2014-06-02>.

186. *Id.*

187. See Christensen et al., *supra* note 13, at 2-3 (describing how the health care industry is “overshooting the needs of average customers.” In particular hospitals have overshoot the needs of most with “impressive technological ability to deliver care [...] to address the needs of a relatively small population of very sick patients... Most types of patients that occupied hospital beds 20 years ago are not there today; they’re being treated in lower cost, more-focused setting... As a consequence, the old high-cost institutions can’t compete financially; none are there enough really sick people to sustain them.” More recently, Topol has predicted the “steady demise of hospitals and clinics,” observing that “[t]he most frequent cause of hospitalizations, such as congestive heart failure, asthma, and chronic obstructive lung disease, are all eminently amenable to digital medical strategies that forego inpatient facilities.”) See TOPOL, *supra* note 76, at 234.

188. Curtis & Schulman, *supra* note 179, at 198.



the mainstream market against established products.”<sup>189</sup> Indeed, far from erecting barriers to mobile health technology, the federal government seems to have gone out of its way to promote this industry. As other scholars have noted, the federal government has taken a relatively laissez-faire approach to the mobile health industry, with the FDA promulgating very industry-friendly regulations for mobile health app and sensor developers and almost no regulations at all for consumer handset manufacturers like Apple and Samsung.<sup>190</sup>

Further, the FTC has been probing the defenses of restrictive state-based licensing and scope of practice schemes for the last decade by going after relatively small prey, like dental boards restricting teeth whitening services. However, with the Court validating that state licensing boards cannot automatically rely on state action immunity, the future portends a more aggressive FTC going after more state boards for anti-competitive regulations in the medical licensing and scope of practice arena. Thus, what will legally stand in the way of the putative mobile health revolution is not the federal government, and maybe not even state governments (which is especially significant in light of *North Carolina State Board of Dental Examiners*), but just state medical boards. If the mobile health industry could use its influence to introduce an explicit rift between a state legislature and any perceived anti-competitive measures by the state medical board, the board loses—the FTC set that precedent when it won against South Carolina’s dental board in 2003.<sup>191</sup>

Recognizing that “tech disruption requires overcoming political and regulatory barriers,” Uber hired political strategist David Plouffe to literally take on the global taxi industry.<sup>192</sup> Plouffe was President Obama’s wunderkind campaign adviser who successfully merged electoral politics with social media technology—in other words he is a disruptive innovator. In taking on the taxi industry, Plouffe outlined his method, “To the extent that there are barriers, then we have to have a strategy to eliminate those barriers.”<sup>193</sup> He further elaborated, “We’ll be trying the change the view of established politicians, and there’s a lot of resistance coming from people who want to protect the

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189. CHRISTENSEN, *supra* note 81, at xxvii.

190. See Cortez et al., *supra* note 20.

191. See Complaint, S.C. State Bd. of Dentistry, (F.T.C. 2003) (No. 9311), <http://www.ftc.gov/os/2003/09/socodontistcomp.pdf>.

192. Emily Badger & Zachary Goldfarb, *Uber Hired David Plouffe When It Realized ‘Techies’ Can’t Do Politics*, WASH. POST (Aug. 19, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/08/19/uber-hired-david-plouffe-when-it-realized-techies-cant-do-politics/>.

193. *Id.*

status quo.”<sup>194</sup> This begs the question, if Uber can hire David Plouffe to influence legislators, just imagine who the mobile health industry could deploy to spread its message (e.g., Bill Clinton, Chris Christie, etc.) to state legislators. However, given the significant healthcare access and cost concerns that the states and their citizens face, and the actual potential of mobile health to address these problems, why should states be wary of the “Uberization” of healthcare? The answer is jobs and health care security.

## V. PROPOSAL: UNITED WE STAND, DIVIDED WE FALL

*GARY COLEMAN: Right now you are down and out and feeling really crappy.*

*NICKY: I’ll say.*

*GARY COLEMAN: And when I see how sad you are, it sort of makes me...Happy!*

*NICKY: Happy?!*

*GARY COLEMAN: Sorry, Nicky, human nature—nothing I can do!*

*It’s...Schadenfreude! Making me feel glad that I’m not you.*<sup>195</sup>  
“Schadenfreude”

*-Avenue Q the Musical*

### A. Achieving Expanded Scope of Practice Without a Faustian Bargain

Nurses, psychologists, physician assistants, pharmacists, chiropractors, physical therapists, midwives, doulas, radiology technicians, herbalists, and other non-physician medical providers have been on the losing end of many licensing and scope of practice battles with physician groups and physician-dominated state medical boards, not to mention typically being on the losing end of interpersonal interactions with physicians in the clinical setting due to

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194. Kevin Robillard, *David Plouffe’s Next Campaign: Steer Uber To Victory*, POLITICO (Aug. 19, 2014), <http://www.politico.com/story/2014/08/david-plouffe-uber-110164.html>.

195. Robert Lopez et al., “Schadenfreude,” *Avenue Q the Musical: Original Broadway Cast Recording*, RCA Victor (2003).

professional power imbalances.<sup>196</sup> It would be understandable if these non-physician groups allied themselves with the mobile health industry with the understanding that such an alliance would help them achieve long-standing goals of legally expanding their scopes of practice and breaking the political dominance physician groups have had over state legislatures and licensing boards. Further, enhancing their skill sets with mobile health technologies could conceivably increase their client base and economic prospects. However, as I describe below, in the long-term that is likely a Faustian bargain.

Paradoxically, I propose that a better strategy for non-physician groups would be to ally with physician groups (who already have a sophisticated political and legal apparatus) to protect against the possibility that they too will be squeezed out by the mobile health industry in its quest for maximal profits and “providerless” medicine. In exchange for this alliance, they could demand that physician groups support expanded scope of practice for these physician extender groups. Further, since many mobile health applications will initially leverage the significant investments in training and education by medical professionals, I propose that it is equitable to demand that the mobile health industry pay for this in the form of a federal excise tax on mobile health transactions that would help fund future medical education costs and offer debt relief for medical professionals having difficulty paying back student loans. Lastly, I argue that a sufficient “standing army” of medical professionals is necessary to maintain our healthcare security and one way to ensure this supply to enact a 15-20 year safe-harbor regulation, that requires any medical diagnoses or treatment (excepting over the counter remedies) to be mediated by a human medical professional, and not just a mobile device or app.

### *B. The Uberization of Healthcare*

#### 1. Your Current Profession? There’s an App for That

A disruptive innovation related to the iPhone camera is Instagram, the wildly successful photo-sharing mobile app. However, as Silicon Valley futurist Jaron Lanier has pointed out, there is a dark-side to overnight tech sensations that is often overlooked:

At the height of its power, the photography company Kodak employed more than 140,000 people and was worth \$28 billion. They even invented the first digital camera. But today Kodak is bankrupt, and the new face of digital photography has become Instagram. When Instagram was sold to Facebook for a billion dollars in 2012, it employed only 13 people.

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196. See SAMUEL SHEM, *THE HOUSE OF GOD* (1978) (In my opinion, even after all of these years, this novel remains the definitive narrative of the power struggles that go on behind in the scenes in a hospital.)

Where did all those jobs disappear? And what happened to the wealth that all those middle-class jobs created?<sup>197</sup>

Similarly, economist Paul Krugman remarked that in contrast to the General Motors of the 1950s and 1960s, companies like Apple today are “barely tethered to the material world.”<sup>198</sup> Even as Apple is one of the highest-valued companies in the United States, it employs a mere “less than .05 percent of our workers.”<sup>199</sup> In other words, the billions of dollars wealth associated with companies like Apple, Google, and Facebook has not led to meaningful job creation.

With concerns that the shrinking middle class and ultra-concentration of wealth might be distorting our democracy,<sup>200</sup> one bright spot for the growth of middle class jobs has been the healthcare industry. Doctors are making less than they used to in real terms, but they still earn at the top of the income spectrum. However, adjusted for inflation, registered nurses are now making 55% more than they did three decades ago and represent the third largest middle-income occupation.<sup>201</sup> To demonstrate this growth, in 1980, 1.4 million jobs in healthcare paid a middle-class wage (\$40,000-\$80,000 in inflation adjusted dollars); now that figure it up to 4.5 million.<sup>202</sup> Further, the U.S. Department of Labor projects that this trend will continue so that by 2022 more than half of the new 9.1 million consumer-related jobs will be in healthcare. In addition, unlike the multi-billion dollar tech and financial companies situated in Silicon Valley or New York, healthcare jobs are widely disseminated across the country, so they can serve as stable economic anchors even in depressed regions. But depending on how states approach licensing and scope of practice laws, more of these middle class jobs might be enabled through mobile health technology, or more of these jobs might simply go the way of Kodak. It might be hard to imagine this

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197. JARON LANIER, WHO OWNS THE FUTURE? 2 (2013).

198. Paul Krugman, *Profits Without Production*, N.Y. TIMES (Jun. 20, 2013), <http://www.nytimes.com/2013/06/21/opinion/krugman-profits-without-production.html>.

199. *Id.*

200. *See generally* THOMAS PIKETTY, CAPITAL IN THE TWENTY-FIRST CENTURY (2014). *See also* Joel Kotkin, *In the Future We’ll All Be Renters: America’s Disappearing Middle Class*, THE DAILY BEAST (Aug. 10, 2014), <http://www.thedailybeast.com/articles/2014/08/10/in-the-future-we-ll-all-be-renters-america-s-disappearing-middle-class.html>.

201. Dionne Searcy et al., *Health Care Opens Stable Career Path, Taken Mainly By Women*, N.Y. TIMES (Feb. 22, 2015), [http://www.nytimes.com/2015/02/23/business/economy/health-care-opens-middle-class-path-taken-mainly-by-women.html?\\_r=0](http://www.nytimes.com/2015/02/23/business/economy/health-care-opens-middle-class-path-taken-mainly-by-women.html?_r=0).

202. *Id.*

scenario since mobile health is still in its infancy, thus I will turn to the more “mature” example of Uber (which launched in 2010).

While taxi companies have claimed that Uber is threatening their existence and the jobs of their employees,<sup>203</sup> Uber’s cheery response has been that it is creating 50,000 new “driver jobs” per month and that its 80/20 fee splitting model allows its drivers to make more money than cab drivers.<sup>204</sup> However, the long-term stability of these “driver jobs” is not clear, there is evidence that full-time drivers cannot earn a living wage after accounting for expenses, and Uber considers its drivers to be independent contractors to avoid paying them benefits.

Some drivers have reported that Uber has lowered their fees so much in order to gain customers and drive out competitors that, “With some rides, you actually might be losing money . . . So, the money’s just, you know, not there—and you’re putting wear and tear on your car.”<sup>205</sup> Consequently, many Uber drivers have cut back to only driving peak periods when there is “surge pricing” since driving full time could mean the following: “[I]n reality Uber was making more money than I was . . . I had to pay taxes, gas, mileage and for car maintenance and repairs. I was spending time and making \$3 per hour.”<sup>206</sup> One might contend that Uber’s strategy is merely a short-term one to undermine the viability of the traditional taxi industry, which seems to be occurring as taxi medallion prices are cratering.<sup>207</sup> One also might argue that if competition from traditional taxis is largely eliminated, then Uber will logically raise the amount its drivers earn, because it cannot alienate its entire labor force if it wants to survive and make money. But here’s the dark punchline, Uber has both the desire and the technical gameplan to alienate its entire labor force and make even more money.

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203. Simone Pathe, *What it’s Really Like to be an Uber Driver*, PBS NEWSHOUR MAKING SENSE BLOG (Oct. 6, 2014 11:50 AM), <http://www.pbs.org/newshour/making-sense/what-its-really-like-to-be-an-uber-driver/>.

204. Luz Lazo, *Some Uber Drivers Say Company’s Promise of Big Pay Day Doesn’t Match Reality*, WASH. POST (Sep. 6, 2014), [http://www.washingtonpost.com/local/trafficandcommuting/some-uber-drivers-say-companys-promise-of-big-pay-day-doesnt-match-reality/2014/09/06/17f5d82c-224a-11e4-958c-268a320a60ce\\_story.html](http://www.washingtonpost.com/local/trafficandcommuting/some-uber-drivers-say-companys-promise-of-big-pay-day-doesnt-match-reality/2014/09/06/17f5d82c-224a-11e4-958c-268a320a60ce_story.html).

205. See Pathe, *supra* note 203 (interview by Diane Lincoln Estes with Bob).

206. See Lazo, *supra* note 204.

207. Josh Barro, *Drop in Taxi Medallion Prices Continues as Rivals Multiply*, N.Y. TIMES (Jan. 8, 2015), <http://www.nytimes.com/2015/01/08/upshot/new-york-city-taxi-medallion-prices-keep-falling-now-down-about-25-percent.html>.

At a tech conference in May 2014, Uber CEO Travis Kalanick expressed the following vision for his company:

[T]he reason Uber could be expensive is because you’re not just paying for the car—you’re paying for the other dude in the car. When there’s no other dude in the car, the cost of taking an Uber anywhere becomes cheaper than owning a vehicle. So the magic there is, you basically bring the cost below the cost of ownership for everybody, and then car ownership goes away.<sup>208</sup>

To get closer to this vision, the company recently launched the Uber Advanced Technologies Center in Pittsburgh to develop driverless cars in conjunction with Carnegie-Mellon University. Uber might be able to roll out this technology sooner rather than one might expect, because the proof of concept already exists—Google’s self-driving cars have already driven hundreds of thousands of miles.<sup>209</sup>

Seen from another angle, Uber is instrumentalizing its drivers in two ways. First, it is using drivers as political pawns to advance its deregulatory agenda. It is trying to accomplish this by appealing to lawmakers claim that Uber will be able to create even more “driver jobs” if regulatory barriers protecting “Big Taxi” (an actual term put into parlance by Uber)<sup>210</sup> and its monopolistic pricing are eliminated. But, since Uber actually wants driverless cars, this is a disingenuous claim. Second, Uber is leveraging its drivers’ investments in their own cars as a technology and regulatory bridging solution until it can develop driverless cars and receive regulatory approval to use them on public roads.

## 2. The Endgame: Providerless Medicine

In the mobile health context, one can imagine the exact same strategy carried out by mobile health technology companies. Initially, the rise of mobile health will be framed as an endeavor that will create more middle class jobs as nurses and physician assistants augmented by artificial intelligence apps and automated sensors can

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208. Alex Hern, *Are driverless cars the future of Uber?*, THE GUARDIAN (Feb. 3, 2015), <http://www.theguardian.com/technology/2015/feb/03/are-driverless-cars-the-future-of-uber>.

209. Matt McFarland, *Google’s Artificial Intelligence Breakthrough May Have a Huge Impact on Self-Driving Cars and Much More*, WASH. POST (Feb. 25, 2015), <http://www.washingtonpost.com/blogs/innovations/wp/2015/02/25/google-artificial-intelligence-breakthrough-may-have-a-huge-impact-on-self-driving-cars-and-much-more/>.

210. Nancy Scola, *Uber, allies kick off campaign to brand “Big Taxi.”* WASH. POST (Sep. 12, 2014), <http://www.washingtonpost.com/blogs/the-switch/wp/2014/09/12/uber-allies-kick-off-campaign-to-brand-big-taxi/>.

take on more primary care duties that are typically done by doctors. When physician groups like the AMA predictably challenge such practices as violating scope of practice and licensing laws, the mobile health industry will hit back hard against “Big Medicine” and portray physicians as exploiting government regulations to make monopolistic earnings at the expense of patients, taxpayers, and a broader pool of middle class healthcare jobs. Further, the foot soldiers in the mobile health industry’s fight in state legislatures will be nurses and other physician extenders, who after years of being outgunned by physician groups in the corridors of power, might welcome the political and economic clout an alliance with Apple, Google, and other tech companies might bring. But, the defanging of physician interest groups might be the worst thing in the world for non-physician providers.

As with Uber and its current drivers, the alliance of the mobile health industry with physician extenders might only be a temporary one, a bridging solution until mobile health technology becomes more robust. Thus, if extensive deregulation occurs at the state level to enable mobile health technology, the next biggest expense to eliminate, aside from doctors, is of course physician extenders. If mobile health devices can remotely monitor your dietary intake, physical activity, vital signs, your blood chemistry, pharmaceutical levels, and constantly upload this to an EMR platform, the mobile health industry can make the enticing pitch to the general public listed below.

Who would you want diagnosing the medical importance of all this data and recommending treatment options? One, a physician extender with perhaps a community college degree? Or two, the AI program that can not only trounce those two nerds on *Jeopardy!*,<sup>211</sup> but also can engage in “machine learning” so that its algorithms improve with every bit of patient information added to EMRs on a personal and population-wide basis? Plus, relying solely on the AI program will cost consumers and taxpayers less than including a medical provider in the transaction. The vision outlined above, that is the endgame in the Uberization of healthcare.

### 3. The Threat to Healthcare Security

Here is the problem with the above scenario: technologically we are far closer to driverless taxis than to providerless medicine, and the mobile health and medical field knows that as well. But even before

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211. No disrespect intended to Ken Jennings and Brad Rutter. I also made it onto Jeopardy!, but unlike them I could only win the second place prize, plus some Garlique and Turtle Wax as “parting gifts.” FAZAL KAHN, J ARCHIVE (Jul. 8, 1997), [http://www.j-archive.com/showplayer.php?player\\_id=1563](http://www.j-archive.com/showplayer.php?player_id=1563).

providerless medicine becomes feasible, the mere specter of it lurking in the shadows: and the fact that it might be legal in the near future would be enough to massively disrupt the healthcare industry. Imagine the current pre-med undergraduates who will be needed to replace the massive cohort of baby boomer physicians entering retirement. Will they see the writing on the wall and logically ask why they should invest the best years of their youth and take on debt equivalent to a small mortgage to enter into a dying profession with declining wages? What happens to nursing students who realize that their potential careers might be in jeopardy before they hit the age of thirty?

Even if mobile health technology eventually lives up to its heady promise some years down the line, what happens in the interim transitional period? What happens to our healthcare security when needed medical professionals are scared away from making a multi-year and expensive commitment because they might become obsolete as soon as their training period is over? This is one crucial area where the Uber analogy breaks down. If Uber drives out a significant portion of the traditional taxi supply before it (or Google) develops driverless taxi service, society will still have enough transportation options to weather this disruption. However, how long of a disruptive period can we tolerate with a severely deficient supply of medical expertise? Five years? Ten years? This is a question that lawmakers need to consider years before there is a potential exodus from the medical profession.

Professions such as lawyers and accountants have felt the sting of automation and have had to adapt as well. Further, every profession that requires a significant investment in time and money carries risk in terms of return on that investment. But as the Court recognized in *North Carolina State Board of Dental Examiners*, the states as sovereign actors are free to politically determine when it is in their best interest to legally restrain competition:

The States, however, when acting in their respective realm, need not adhere in all contexts to a model of unfettered competition. While “the States regulate their economies in many ways not inconsistent with the antitrust laws,” [ ], in some spheres they impose restrictions on occupations, confer exclusive or shared rights to dominate a market, or otherwise limit competition to achieve public objectives. If every duly enacted state law or policy were required to conform to the mandates of the Sherman Act, thus promoting competition at the expense of other values a State may deem



fundamental, federal antitrust law would impose an impermissible burden on the States’ power to regulate.<sup>212</sup>

In other words, while there may be no legally principled reason to protect highly skilled medical professionals from competition, states do have the sovereign right to erect legal barriers to competition in order to advance their own policy objectives.

Physician interest groups are sophisticated, so they will perceive the combination of physician extenders and mobile health technologies as grave threats to their professional and economic interests and dig their heels in to fight scope of practice reform at the state level.<sup>213</sup> But even if physician groups win some of these battles, the specter of diminished economic prospects could drive away new medical school candidates who consider such an investment to be too risky. This risk of low physician supply during greatly increasing demand on the system means that we would have to place a lot of faith on mobile health technologies that might be good enough to disrupt the medical field, but not good enough to deliver adequate care. In the latter case, our nation’s healthcare security will be threatened.

To solve this issue, I propose a “grand bargain” between physicians groups and other medical providers. Instead of allowing themselves to be pitted against each other to set up a deregulatory medical practice scheme that ultimately might only benefit a select few technology companies and their investors, I suggest that these warring professional factions best strategy is to work together against a greater threat to their professional livelihood. The first part of this bargain would be for physician groups like the AMA and their state counterparts (e.g., the California Medical Association) to negotiate expanded scope of practice provisions for physician extenders, including those dependent on mobile health technologies to augment their professional capabilities.<sup>214</sup> Second, to encourage an adequate supply of medical professionals, a mobile health excise tax on each transaction that use such technology would go to establish a medical education fund to help lower the risk of entering the medical profession and to defray educational debt payments that exceed a

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212. *See* N.C. State Bd. of Dental Exam’r v. FTC, 135 S. Ct. 1101 (2015) (slip op.).

213. *See* INST. OF MED., *supra* note 115, at 112-14.

214. Daniel Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. POL’Y 87, 115 (2011) (“As noted in the 1997 Telemedicine Report to Congress, there appears to be adequate legal authority for the federal government to establish uniform physician licensing and preempt state licensing regimes.”)

certain threshold of one’s income. And third, a safe-harbor period of at least 15-20 years to require that under federal law (to be administered by the FDA) medical diagnoses and treatment must be made by an actual human medical provider, not just a mobile device or software application. Obviously, both an excise tax on mobile health transactions to fund medical education and a safe-harbor period restricting providerless care (even if technologically feasible) would be aggressively challenged by the mobile health industry and perhaps others who might see this as unwarranted economic protection for medical professionals. That is a fair critique, but one that should be balanced against the loss of not only many middle and upper middle class jobs, but the attendant healthcare security of our nation as it will enter one of the most challenging periods in its history—the graying of America.

## VI. CONCLUSION

As Paul Starr recounts in his seminal work, “The Social Transformation of American Medicine,” it was not until the latter half of the 19th century to the early 20th century that we saw such developments as the rise of standardized scientific techniques, professional training for doctors and nurses, antiseptic protocols, radiology, laboratory testing, and the modern hospital as a place for curing disease rather than segregating the hopelessly ill and impoverished.<sup>215</sup> Mobile health technology fits into that narrative, not only as a scientific transformation, but also a transformation in how medical professionals will relate to one another, to patients, and to society.

We have a serious primary care shortage problem that might only be solvable by relaxing restrictive state licensing and scope of practice laws in conjunction with enabling disruptive innovations like mobile health technology. However, in making laws to address mobile health technology, we need to consider the political economy implications of “providerless” medicine and whether our healthcare security will remain intact if providers are driven out of medicine by this prospect. Thus, I propose in this article that often hostile physician and physician extender groups enter into a *détente*, to negotiate less restrictive licensing and scope of practice regimes that can better deal with healthcare cost and access problems. Connected to this measure, I also propose an excise tax on mobile health transactions in order to

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215. PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY* 79-180 (1982).

fund medical education for the next generation of healthcare providers and a 15-20 year restriction period for “providerless” medicine delivered by technology corporations. As a society, we need to assert our values in the face of transformative technologies that can dramatically alter our lives for better or for worse, and not simply accept the inevitability of being pawns in such transformations.