
October 2015

The Future of Health Care: We Are Our Own Worst Enemies

Nelson J. Dunlap

Follow this and additional works at: <https://via.library.depaul.edu/jhcl>

Recommended Citation

Nelson J. Dunlap, *The Future of Health Care: We Are Our Own Worst Enemies*, 16 DePaul J. Health Care L. 165 (2014)

Available at: <https://via.library.depaul.edu/jhcl/vol16/iss2/4>

This Article is brought to you for free and open access by the College of Law at Via Sapientiae. It has been accepted for inclusion in DePaul Journal of Health Care Law by an authorized editor of Via Sapientiae. For more information, please contact digitalservices@depaul.edu.

THE FUTURE OF HEALTH CARE: WE ARE OUR OWN WORST ENEMIES

*Nelson J. Dunlap**

The only thing that is constant is change. - Heraclitus

ABSTRACT

Mobile medical applications are increasingly taking center-stage in the health care industry and more importantly, in the patient-doctor relationship. Yet, as technological prevalence continues its upward trend, regulatory initiatives will also continue their march to the forefront of the discussion. This can lead to only one ultimate conclusion: an impasse between the potential for technological innovation and governmentally enforced restrictions. The first, of what will most likely prove to be many, federal regulation controlling mobile medical applications was recently enacted by the Food and Drug Administration. Overbearing governmental regulations such as these stifle innovation in the health care field and operate to the detriment of the public as a whole by restricting society's ability to advance in the health care industry. Before implementing any governmental regulation, a cost-benefit analysis should always be performed to ensure that it is truly worth it. In the situation where health care is on one side of the equation, we simply can't afford to stifle our own future. This can be, quite literally, a matter of life or death.

* J.D. Candidate, May 2015, DePaul University College of Law

I. INTRODUCTION

Technology has effectively permeated every facet of society and enhanced the quality of life exponentially. Technological advances are constantly propelling society forward, keeping individuals on the brink of discovery and innovation. Society's collective knowledge base is being continuously updated with new findings, new gadgets to disseminate these findings, and new ideas that will push the envelope even further. But, as classical science has proven, for every positive action, there is a negative and equal reaction. For all of our unbridled and untapped potential to accomplish and create great things through innovation, the ever-lurking fear of abuse reigns supreme. The fact of the matter is the only impediment that stands in the way of true innovation is human interference.

Presently, the dialogue occurring in health and legal professional circles across the United States of America is centered on health care. A different conversation needs to be had that focuses on the burgeoning field of m applications ("apps") and the role that they will play in the future. With increasing numbers of doctors and medical students using smartphones and associated applications as a source of reference material in daily clinical care, this is not a topic to be overlooked.¹ The federal government has taken notice of this marked increase in use of mobile technology in the health care industry and has responded accordingly by issuing FDA regulations on the topic.² On September 23, 2013, the U.S. Food and Drug Administration issued final guidance for developers of mobile medical applications.³ While the FDA's stated purpose is to focus its oversight only on mobile medical apps that transform a mobile platform into a regulated medical device, this is simply another occurrence in a long line of government-imposed regulations that have the impact of stifling creativity and innovation.⁴ Change is inevitable and progress is beneficial. It is with virtually little dispute that government regulation is a necessary component of a properly functioning society, but when those regulations begin to repress advancement, a cost-benefit analysis must occur. In today's day and age, the health care provider paradigm is rapidly transitioning to a model that incorporates mobile technology as the most

1 Benjamin Jelle Visser & Jonathan Bouman, *There's a Medical App for That*, MEDSCAPE (2012), http://www.medscape.com/viewarticle/763009_1.

2 *FDA Issues Final Guidance on Mobile Medical Apps*, U.S. FOOD & DRUG ADMIN. (Sept. 23, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369431.htm>.

3 *Id.*

4 *Id.*

effective way to provide the best care. So the question becomes, at what point do the theoretical benefits of government intervention no longer outweigh the actual benefits of technological advancement?

Part II of this Note reviews and discusses the regulations disseminated by the Food and Drug Administration, in regards to mobile medical applications, in its most recent guidance. Part III analyzes the implications that these regulations will have on future innovation in the health care industry by stifling creativity with overbearing and unnecessary governmental intervention and oversight. Part IV then gives a brief overview of the current state of health technology affairs by highlighting a few of the current prevalent technologies that could also fall victim to the repression of innovation as a result of future legislation. This Note concludes that overbearing regulations on innovation in the health care field operate to the detriment of the public as a whole because they restrict society's ability to advance in the field of health care by disincentivizing market entry.

II. OVERVIEW OF FDA RESTRICTIONS

The federal government has been taking precautionary steps towards regulating the mobile device segment of the health care industry for a number of years. On April 27th, 2009, the U.S. government released federal regulations that deal with the ways in which protected health information should be maintained, which steps should be taken to prevent a data breach, and how to act in such a case.⁵ These guidelines were submitted to the federal register by the Department of Health and Human Services (HHS).⁶ However, that document was simply guidance, and a request for comments under §13402 of the Health Information Technology for Economical and Clinical Health Act (HITECH).⁷ Those regulations did not deal with issues related to storage of protected health information in medical applications, so the FDA was tasked with the responsibility of filling the void.⁸

The Food and Drug Administration, in its issuance of final rules governing the development and oversight of health-related apps, reiterated that its focus of the guidance is on the apps that could be harmful if

⁵ MEDSCAPE, *supra* note 1.

⁶ 74 Fed. Reg. 19,006.

⁷ *Id.*

⁸ MEDSCAPE, *supra* note 1.

defective or misused.⁹ It is worth noting that while this guidance issued by the FDA is nothing more than a nonbinding recommendation, the FDA carries enough weight behind it that recommendations are viewed as akin to legislative action.¹⁰ The guidance issued outlines the FDA's tailored approach to mobile apps.¹¹ To be more specific, the FDA opines that it is only regulating products that turn smartphones into devices that the FDA already regulates.¹² The problem with this approach is that to the untrained eye, referring to a regulation as "tailored" would seem to imply that it is narrow in scope. However, a more detailed look at the potentially expansive nature of this guidance may reveal a different conclusion.

The FDA intends to exercise enforcement discretion for the majority of mobile apps that exist, as they pose a minimal risk to consumers.¹³ This, in turn, means that the FDA will not enforce requirements under the Federal Drug & Cosmetic Act.¹⁴ This oversight on mobile medical apps focuses on apps that fit primarily into two categories.¹⁵ The first being mobile medical apps that are intended to be used as an accessory to a regulated medical device.¹⁶ For example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system on a tablet or smartphone would qualify for oversight.¹⁷ The second category is comprised of applications that transform a mobile platform into a regulated medical device.¹⁸ An example of one such device would be an application that turns a smartphone into an electrocardiography machine (ECG) that would detect abnormal heart rhythms or determine if a patient is experiencing a heart attack.¹⁹ The one other category that FDA's guidance touches on is comprised of mobile apps that display, transfer, store, or convert patient-specific medical device data from a connected

9 Elizabeth Armstrong Moore, *FDA to Start Reining in the Wild West of Medical Apps*, CNET.com (Sept. 23, 2013), http://news.cnet.com/8301-11386_3-57604236-76/fda-to-start-reining-in-the-wild-west-of-medical-apps/.

10 *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN. (Sept. 25, 2013), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

11 FDA, *supra* note 2.

12 Moore, *supra* note 9.

13 FDA, *supra* note 2.

14 *Id.*

15 *Id.*

16 *Id.*

17 *Id.*

18 *Id.*

19 FDA, *supra* note 2.

device, and therefore are mobile medical apps.²⁰ One such example would be a mobile app that connects to a nursing central station and displays medical device data to a physician's smartphone or tablet.²¹

While the FDA will not regulate the sale of hardware, such as tablets or smartphones, or even the personal use of basic wellness apps like medical dictionaries, pedometers, or heart rate monitors, the FDA will instead regulate those apps that have the most room to grow in regards to social utility.²² Dr. Jeffrey Shuren, the director of the FDA's Center for Devices and Radiological Health, stated that in regards to the regulations, "it's not about the platform," but rather, "it's about the functionality. An ECG is an ECG."²³ Dr. Shuren also stressed that "some mobile apps carry minimal risks to consumer or patients, but others can carry significant risks if they do not operate correctly."²⁴ It is this potential for significant risk that is the motivating factor behind the FDA's final guidance.

The FDA itself has acknowledged that mobile apps have the potential to transform health care by allowing doctors to diagnose patients with potentially life-threatening conditions outside of traditional health care settings.²⁵ The FDA further concedes that these mobile apps also have the possibility of helping consumers manage their own health and wellness as well as gain access to useful information whenever and wherever consumers need it.²⁶ Although Dr. Shuren asserted that, "the FDA's tailored policy protects patients while encouraging innovation," the latter half of that statement has yet to be seen.²⁷

III. FDA REGULATIONS IMPLICATION ON FUTURE INNOVATION

The United States of America has a long and rich history of government-imposed regulations that have the effect of suppressing further innovation and growth. This is typically done for good reason, with the overall benefit to society in mind. However, as with any system, there is bound to be an instance of governmental overreach that goes beyond the

20 U.S. FOOD & DRUG ADMIN., *Medical Devices: Example of MMAs the FDA Regulates* <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368743.htm> (last updated Sept. 23, 2013).

21 *Id.*

22 Moore, *supra* note 9.

23 *Id.*

24 FDA, *supra* note 2.

25 *Id.*

26 *Id.*

27 *Id.*

purported purpose and in turn, has a deleterious and unintended consequence. The stifling of future innovation in the mobile medical app market is one such consequence. Even the President of the United States himself has expressed how imperative it is for any regulatory scheme that is put in place to take future innovation into consideration.²⁸

On their face, the regulations promulgated by the FDA could serve to constrict a market that is on the cusp of explosive growth. Mobile application developers have begun to enable the mobile health industry to successfully monetize their services.²⁹ The market for mobile health services has now entered the commercialization phase and is projected to reach \$26 billion globally by 2017.³⁰ This number is even more impressive when considering that in 2010, it was expected that 500 million smartphone users worldwide will be using a health care app by 2015.³¹ The fact of the matter is, market forces are continuing to see trends in an upward fashion relating to this industry.

With both health care providers and consumers embracing smartphones as a means to improve health care, and the substantial projected financial growth that is sure to help an ailing economy, it is counterintuitive to believe that these regulations are in the best interest of society.³² The numbers alone tell a tale of widespread public support of this shift in the industry. As of March 2013, some of the top mobile health application publishers and developers had managed to generate more than three million free app downloads and 300,000 paid downloads in the United States alone, and this only on the iOS platform.³³ The reach on other platforms and in other countries differs quite a bit, but the same study also showed an increase of business potential for mobile health applications in those markets as well.³⁴ In light of how pervasive the

28 See Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 18, 2011) (Section 1(a) states:

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.)

29 Ralf-Gordon Jahns, *The Market for mHealth App Services Will Reach \$26 Billion by 2017*, RESEARCH2GUIDANCE.COM (Mar. 7, 2013), <http://www.research2guidance.com/the-market-for-mhealth-app-services-will-reach-26-billion-by-2017/>

30 *Id.*

31 MEDSCAPE, *supra* note 1.

32 Jahns, *supra* note 28.

33 *Id.*

34 *Id.*

mobile medical app industry has become, there is finally evidence that the long-expected mobile revolution in health care is set to happen.³⁵ Medical apps have an enormous potential for improving medical practices by providing a quick, comprehensive, and up-to-date overview of current clinical guidelines, which could in turn help clinical decision making and change the way health care is delivered. It is due to the potential upside that many market analysts are not surprised by this revolution.³⁶

Mobile medical app consumers are present, support of the mobile medical app market is present, the only obstruction that could bridle the potential of mobile medical apps is governmental intervention. With every regulation that is put in place, a disincentive is placed in the market to inhibit growth. Some commentators have referred to the robust and ever evolving mobile medical apps market as the “Wild West.”³⁷ Commentators have even gone so far as to comment that the Wild West of mobile medical apps is getting a little tamer due to the recent FDA regulations.³⁸ However, “tame” is a word used to describe an animal that has been plucked from its natural habitat, and is dwelling under the thumb of an oppressive authority that intends to control its every move, not let it function as it was intended. This is no way to nurture a growing industry with such great potential.

In the mobile medical application development industry, as with many innovatively- driven fields, apps are created for one of two reasons: either to address specific purposes that the market indicates it needs or in response to a developer’s creative wants. Governmental regulations historically and continue to fly directly in the face of creativity. The main way this is accomplished is simply by the speed, or lack thereof, in which things move once governmental intervention occurs. The mobile medical app market is a fast-paced industry that is constantly changing and morphing to meet the demands of providers and consumers alike. The health care industry consistently requires flexibility and fast response time to changes, given the fact that issues could quite literally be matters of life or death. Yet, government is intentionally constructed to be a slow-moving, deliberate body. We, as a society, expect our governmental bodies to act in a cautious and calculated fashion to problems as they arise, and not necessarily reach quick decisions. It is very difficult to reconcile these two opposing approaches. In fact, out of the thousands of mobile medical

35 *Id.*

36 MEDSCAPE, *supra* note 1

37 Moore, *supra* note 9.

38 *Id.*

applications that exist, the FDA has approved about 100 apps over the past decade.³⁹ Even more telling is that 40 of those 100 apps have been approved in just the past two years.⁴⁰ This can lead the casual observer to only one logical conclusion: as problems arise in the health care industry that a mobile medical application could address, the speed with which that app can be created and implemented will be severely burdened by government regulation. If a casual observer can readily reach that logical end, the developers of mobile apps will be able to as well. Profit is realized by performance, and in a situation where your performance could be hampered by the slow-moving cogs of a government entity, it pays to simply develop mobile applications that are not subjected to such regulations. It is more prudent for top developers to be working on the next big application that will advance the state of health care, as opposed to working on the next great children's video game. If developers are not motivated to push the technological limits in the health care sphere, any mobile medical app momentum that has accumulated thus far could cease, leaving the all-important health care industry without the talent it needs to thrive.

Although the current regulations handed down by the FDA are only guidance, there is a substantiated fear of a "slippery slope" problem that comes along with such guidance. The FDA's guidance documents do not establish legally enforceable responsibilities.⁴¹ Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations.⁴² These rules begin as mere recommendations and before long they are being regarded as federal mandates. This is not to say that the power behind the Food and Drug Administration should be diminished. Rather, this is to call attention to the likelihood that the issuance of FDA guidance could very well be the basis for a future congressional act. Members of the mobile application development industry are cognizant of the fact that for a federal rule to transition from simply being an FDA guidance recommendation to being codified as a statute is not a far reach. The concerns over the impact that these regulations will have on the growth of mobile medical apps is only compounded when viewed in the light of those regulations being federal law. If developers are apprehensive about the ways in which they will be

39 FDA, *supra* note 2.

40 *Id.*

41 FDA, *supra* note 10.

42 *Id.*

constrained in the creation of their applications, they are likely to elect not to wade into those waters, leaving society as a whole to pay the price.

As always, there is an overarching responsibility and concern for protecting the health care patient. At the core of the movement to improve care, be it through conventional measures or with innovative technological advances, the focus is constantly on ways to make the patient experience better and more effective. While it is important to analyze the impact that regulations can and will have on innovation in the United States, it is equally important to understand that the concern for quality patient care as a whole, is a global concern. The General Medical Council, which sets standards of professional and ethical conduct that physicians in the United Kingdom are required to follow, releases a guidance once a year for doctors that is called the *Good Medical Practice*.⁴³ The *Good Medical Practice* states that “doctors and students must provide a good standard of practice and care” and keep their professional knowledge and skills up to date.”⁴⁴ Granted, The General Medical Council is designed to provide guidance for the United Kingdom and not the United States, but the Hippocratic Oath knows no coastal bounds. The question becomes then, will mobile medical apps provide the user with up-to-date evidence and the highest clinical standards for health care?⁴⁵

The answer to this question is not readily discernible because the conversation is truly just beginning. However, as a result of the rapid growth of the mobile market, some problem areas have already begun to arise. The growth of this industry has increased the risk of using an app that is unreliable, not evidence-based, trivial, or even dangerous.⁴⁶ For example, in 2011 the Federal Trade Commission (“FTC”) brought charges against two mobile app companies that had advertised that their smartphone applications could treat acne.⁴⁷ The FTC alleged that the mobile apps advertised being able to treat acne with colored lights emitted from smartphones or mobile devices.⁴⁸ Ultimately, the mobile app marketers settled with the FTC, agreeing to be barred from making certain health-related claims without scientific evidence.⁴⁹ Even more troubling, it

43 MEDSCAPE, *supra* note 1

44 *Id.*

45 *Id.*

46 *Id.*

47 “Acne Cure” Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements. FEDERAL TRADE COMMISSION, (Sept. 8, 2011). <http://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under> .

48 *Id.*

49 *Id.*

requires no mental gymnastics to foresee a situation where medical errors are the direct result or caused by unreliable medical apps that have emerged on the market.⁵⁰

In light of the concern for patient care, yet another question is posed, what are the remedies or consequences for when one of these risks is realized? As it stands, if there is an issue with a conventional medical device or medication, those items can be recalled, but it is yet to be seen if such can be done with a smartphone app.⁵¹ On the one hand, the problematic application can be removed from the corresponding app store, but that will only prevent new medical professionals from downloading it.⁵² The developer is not able to remove the apps from phones directly, so the users must do it themselves.⁵³ This leaves open the possibility for the risk that recalled apps would still be used by doctors, extending the risk to patients' health.⁵⁴ The FDA guidance addresses this possible problem only tangentially. The Agency's guidance details "Medical Device Reporting," or adverse event reporting.⁵⁵ The Medical Device Reporting regulation requires manufacturers and importers of medical devices to submit reports to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device they market may have caused or contributed to a death or serious injury.⁵⁶ This same reporting requirement extends to when the device has malfunctioned and the device or a similar device that is on the market would be likely to cause or contribute to a reportable death or serious injury if the malfunction were to recur.⁵⁷

After the reporting of a perceived problem has been submitted, there are further steps that must be taken to correct the problem. A mobile medical app manufacturer may voluntarily take action at any time or may be requested to take action by the FDA to correct problems.⁵⁸ Examples of the types of actions that a mobile medical app manufacturer may be requested to take include: inspecting the device for problems, repairing the device, adjusting the settings on the device, or even upgrading the software

50 MEDSCAPE, *supra* note 1

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 FDA, *supra* note 10.

56 21 C.F.R. § 803.1(a).

57 *Id.*

58 FDA, *supra* note 10.

to reduce risk from a “bug” or unintended response.⁵⁹ Given the fact that these “requests” may appear to be relatively invasive, the FDA attempts to assuage the concerns of potential app developers by detailing that when recommending corrective action, the FDA intends to take into account the essential role that certain mobile medical apps take as an integral part of a larger patient care system.⁶⁰ In the grand scheme of things, this will do little to lessen the impact of the notion that the FDA has the final say on a mobile app. Even further, in accordance with 21 CFR §806.10, mobile medical app manufacturers are required to promptly report to the FDA certain actions concerning device corrections and removals for the mobile medical app within ten working days from the time the correction is initiated.⁶¹ “Required to report” no longer sounds like compliance with a request or even an assent to a simple recommendation; it sounds much more ominous.

In the delicate ecosystem that is the mobile app industry, the health care field needs to be able to corral as many developers as possible to continue advancement. All of these regulations, and many more, are well founded, but nonetheless restrictive. Regulations such as the FDA’s Mobile Medical Application Guidance, that come across as harsh, overbearing, and stiff will only act to deter new actors from entering the field.

IV. CURRENT STATE OF HEALTH TECHNOLOGY AFFAIRS

New and innovative technological advances have the potential for vastly reshaping the look and feel of the physician-patient dichotomy. However, the potential for such is not confined solely to the operating and examining rooms or solely to the advent of mobile medical apps. Technology in the health care industry has been progressing by leaps and bounds in recent years and there is no foreseeable end to this amelioration as long as governmental interference is kept to a minimum. With new forms of cutting edge technology being made available to consumers on a daily basis, these advances are bound to become ingrained in the health care world, and do so to the great benefit of society. Alas, with every step forward we make on the technological frontier, privacy concerns are ever present and require governmental oversight.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

One of the newest technologies on the forefront of science today is Google Glass. Google Glass is essentially an Android smartphone that is void of the actual cellular transmitter, but is capable of running Android apps and is built into a pair of wearable glasses.⁶² While Google Glass is not fully open to the public yet, beta testers already have begun hypothesizing about its implications in health care. Some believe that clinicians should be able to successfully use Google Glass to improve quality, safety, and efficiency in a manner that is less bothersome to the patients than previous models of interaction.⁶³ Some individuals have gone so far as to consider health care applications that could be utilized on Google Glass to the benefit of patients and doctors alike. For example, Google Glass could be utilized to assist a clinician in making the proper decision.⁶⁴ A clinician that is responding to a cardiac arrest could use Google Glass to retrieve the appropriate decision support for the patient in question and visually see a decision tree that incorporates optimal doses of medications, the EKG of the patient, and vital signs.⁶⁵ Another envisioned use for Google Glass has been aiding nurses in their daily routines. A nurse could put on a pair of Google Glasses, walk into a patient room and a Wi-Fi enabled locating function could show the nurse a picture of the patient in the room who should be receiving specific medications and then pictures of the actual medications.⁶⁶ Neither of these two examples have come to fruition as of yet, but both highlight not only the potential of Google Glass but also the willingness of individuals to begin the process of assimilating the technology into the health care realm.

Notwithstanding this potential, it is just as easy to envision the potential privacy concerns that could be raised by the inclusion of Google Glass to a medical practice. Given the strong and justified importance that is placed on patient privacy, governmental oversight is bound to occur. Furthermore, the oversight would not be as lax as to be administered by the Food and Drug Administration, but will more than likely be the byproduct of congressional action. This is, yet again, a predictable impediment to technological growth as it will act as a barrier to entry into the field.

62 John Halamka, *Five Potential Healthcare Applications for Google Glass*, THE HEALTH CARE BLOG (July 17, 2013), <http://thehealthcareblog.com/blog/2013/07/17/five-potential-healthcare-applications-for-google-glass/>.

63 *Id.*

64 *Id.*

65 *Id.*

66 *Id.*

Impediments to technological growth not only prevent furtherance of societal advancement, but also act as a disservice to subsections of the population that could benefit greatly from an increased prevalence of technology. It has been noted that when mobile medical applications are appropriately utilized, they possess tremendous potential for improving the quality and affordability of health care, especially in rural areas of the country.⁶⁷ All health care is not created equal and there is a substantial difference between health care access in urban areas as compared to more rural areas.⁶⁸ There are, on average, 57 general physicians per 100,000 residents in rural areas, compared to 78 per 100,000 in urban areas.⁶⁹ With this inequality gap becoming widely known, mobile medical apps have the potential to help close the gap and subsequently increase quality of care. When viewed in light of the fact that rural areas tend to have a higher prevalence of chronic diseases, the potential of mobile medical apps even more important.⁷⁰ Mobile devices and their accompanying apps are becoming such an indispensable part of everyday life, regardless of rural or urban setting, that it is incumbent upon society to truly embrace the substantive good that can come about as a result of mobile app development. A relatively recent survey by the Pew Internet & American Life Project found that 31% of cell phone owners use their phone to look for health or medical information online, which was an increase of 17% from 2010.⁷¹ The combination of large scale public adoption of mobile devices, paired with the social benefit that mobile medical apps possess should be justification enough to avoid any tactics that may inhibit innovation. Even with all of the potential widespread good that mobile

67 James G. Kahn et al., *Mobile' Health Needs and Opportunities in Developing Countries*, 29 HEALTH AFF. 254, 254 (2010) (finding that there is some evidence that mHealth technology may improve health care in the developing world, but calling for the structured evaluation of this potential); Warren A. Kaplan, *Can the Ubiquitous Power of Mobile Phones Be Used to Improve Health Outcomes in Developing Countries?*, GLOBALIZATION & HEALTH (May 23, 2006), <http://www.globalizationandhealth.com/content/2/1/9> (finding that current evidence both supports and refutes the idea that mHealth technology will improve healthcare outcomes in the developing world).

68 Eric H. Larson & Thomas E. Norris, *Rural Demography and the Health Workforce: Interstate Comparisons*, State of the Health Workforce in Rural America: Profiles and Comparisons 23, 26 (2003), available at <http://depts.washington.edu/uwrhrc/uploads/RuralCh4Comparisons.pdf>.

69 *Id.* at 27

70 Larry Gamm et al., *Rural Healthy People 2010: A Companion Document to Healthy People 2010*, 91 (2003) (“The disproportionate prevalence of chronic disease is reflected in the higher crude all-causes mortality rates reported for rural areas”).

71 Susannah Fox & Maeve Duggan, *Mobile Health 2012*, PEW INTERNET & AM. LIFE PROJECT 2 (2012), <http://www.pewinternet.org/Reports/2012/Mobile-Health/Key-Findings.aspx> (“One in three cell phone owners (31%) have used their phone to look for health information. In a comparable, national survey conducted two years ago, 17% of cell phone users had used their phones to look for health advice”).

medical apps may bring, there is an ever-present fear of inadequate security or insufficient privacy.

Privacy is a justifiable concern in our society today, especially as it implicates the medical field. Some commentators view privacy and security concerns as active barriers to successfully utilizing the power of mobile health applications due to the regulatory oversight that will have to be enacted.⁷² Most notably, the concerns center on the storage of personal health information (“PHI”) on mobile phones and then the transferring of that data over unsecured networks.⁷³ As it stands, the Health Insurance Portability and Accountability Act, or HIPAA, governs the regulation of security and privacy standards for electronically transmitted PHI.⁷⁴ Without delving too deeply into HIPAA and its many facets, it is worth noting that HIPAA established rules for viewing electronic PHI as well as standardized data transmission requirements.⁷⁵ Yet, the argument has been made that these standards are inadequate within the changing landscape of the health IT environment.⁷⁶ For instance, HIPAA does not cover third party developers whose applications may not have stringent data protection standards for transmission or storage in compliance with HIPAA.⁷⁷ While HIPAA might not have the requisite scope to cover third party developers, the FDA and any future legislation most certainly will attempt to pick up where HIPAA left off.

To date, the FDA has narrowed its focus solely to mobile medical apps that have the potential to transform mobile devices into medical devices.⁷⁸ However, the slippery slope that a privacy-centered rationale will set this country down is readily foreseeable. While the privacy and

72 Daniel F. Schulke, *The Regulatory Arms Race: Mobile-Health Applications and Agency Posturing*, 93 B.U.L. REV. 1699, 1710 (2013).

73 *Id.*

74 HIPAA delegates authority to HHS to issue regulations on privacy and security standards. See 42 U.S.C. § 1320d-9 (2006) (defining the Secretary’s power to issue rules concerning the establishment of standards and requirements for transmitting electronic health information); HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.102-.106, 164.500-.534 (2012); HIPAA Security Rule, 45 C.F.R. §§ 160, 164.102-.106, 164.302-.318 (2012) (establishing national standards to protect electronic personal health information).

75 See 45 C.F.R. §§ 164.302-.318 (establishing security requirements for PHI for electronic and physical access).

76 Schulke, *supra* at 1711.

77 HIPAA only applies to covered entities and their business associates. Covered entities are health plans, healthcare clearinghouses, and healthcare providers who electronically transmit health information. 45 C.F.R. § 160.103; MHealth application developers will need to determine whether their applications will be used by a covered entity and involve the transmission or storage of PHI. Adam H. Greene, *When HIPAA Applies to Mobile Applications*, MOBIHEALTHNEWS (June 16, 2011), <http://mobihealthnews.com/11261/when-hipaa-applies-to-mobile-applications/> (Applications used by patients, however, are not covered by HIPAA unless a covered entity is involved).

78 Moore, *supra* note 9.

security concerns related to PHI on mobile devices are unique to mobile applications that contain Electronic Health Records (EHRs), and fall within the purview of HIPAA, those same concerns can be applied to the new wave of mobile medical applications that the FDA intends to regulate. Virtually any mobile medical applications that you can think of, will obtain and store personal information regarding the end-user. That is simply the nature of mobile applications. Given the fact that these mobile applications will be used as medical devices, it is clear to see how these apps could also obtain and store some personal health information. The fear with EHRs is that if the information is not encrypted, it may be easily accessible if a provider's device is lost or stolen, hacked, or simply displayed in an inappropriate location.⁷⁹ Even more compelling of a worry is the notion that if a mobile device has malware or spyware, then the storage of the unencrypted information on the mobile device poses a substantial security risk.⁸⁰ Neither one of these two concerns are exclusive to health records. These are legitimate concerns that mobile medical application developers have to grapple with. The security and privacy of the applications being developed to address needs in the medical community are pressing issues as well.

Even in light of ever-rising privacy concerns, overbearing governmental regulations are not the answer. In order for the app developers to stay on the forefront of innovation, and ahead of potential security breaches, it is essential that their creativity to address these problems is not hampered by unnecessary regulatory oversight. Privacy is important, but the individuals who can help maintain privacy and security are the same ones that government intervention tends to stifle.

IV. CONCLUSION

Mobile medical applications have huge potential for expansion throughout the industry and society as a whole. As long as we, as a country, continue to push the proverbial envelope and advance the state of the art of both technology and health care, there will continue to be a cutting edge intersection between health and technology. It is at this intersection that a decision must be made. What is the cost of innovation and are we willing to pay it?

⁷⁹ Schulke, *supra* note 68 at 1711.

⁸⁰ *Mobile Device Security: The Insider's Guide. Opinions and Tips from the World-Leading Experts*, MOBITHINKING, <http://mobithinking.com/mobile-device-security> (last visited Dec. 28, 2013) (interviewing three experts on the security risks posed by the storage of PHI on mobile phones).

History has, time and time again, shown that when governmental intervention occurs, and legislation or agency regulations are implemented, innovation suffers. This is due in large part to the system of governance that is in place. The United States governmental structure is not intended to be a fast-moving body, but rather slow and deliberate. This inherently results in decisions reached and promulgated a significant amount of time after the initial issue came to be. With an industry as fast-paced as technology, governmental oversight is bound to be a step behind. The Food and Drug Administration's most recent guidance on mobile medical apps is just one, in a long line of examples, of regulations that have been set forth after an industry or practice is well-established. Mobile application development has been the newest creative outlet in our society and has generated massive amounts of product because of this. For the FDA to wade into these uncharted waters now, and attempt to control the industry or set seemingly arbitrary standards will be met with opposition by market forces. The problem being, that the market forces are the app developers and their opposition will simply be to divert their resources to the creation of non-medical applications. In today's day and age, we cannot afford to miss out on the next wave of health-related technological improvements simply because the government delayed its decision to exert control. For some portions of the population, this is quite literally a matter of life or death.

In our society, we have a propensity to capitalize on any burgeoning field and to then regulate said field. Arguably, it's the American way. However, the search for how to make an idea profitable and how the government can then exert dominion and control over such, typically stifles creativity, which in turn prohibits innovation, and subsequently slows progress. The argument is not that this model does not work, but rather to elucidate the cost-benefit analysis that must occur. The health care industry is not going anywhere. Its importance is directly correlated to survival. The tech industry is here to stay as well. Most every faction of daily life is slowing being infiltrated by new forms of technology. The intermingling of these two industries will continue, in perpetuity. This is simply a fact of life in the twenty first century. But, what should not be a fact of life is the continued governmental intervention at the expense of ingenuity. Change may be constant, but interference with progress does not have to be.

The Frank H. Netter, MD School of Medicine at Quinnipiac University in North Haven, Connecticut welcomed its first class of

medical students in the fall of 2013.⁸¹ In an interview, one professor of the medical school pointed out that as students began their medical education at Quinnipiac, they found that the curriculum included learning how to use medically-related mobile applications in practice.⁸² While Quinnipiac may currently be in the minority of institutions providing this type of education, the inclusion of mobile medical apps in provider care is only going to grow. As we face the next set of challenges and begin creating inspired and inventive responses to tomorrow's health problems, we will face no bigger hurdle than ourselves. Once we decide to stop being our own worst enemy, then, and only then, will we be able to become our own greatest asset.

81 See generally Quinnipiac University Frank H. Netter MD School of Medicine, <http://www.quinnipiac.edu/academics/colleges-schools-and-departments/school-of-medicine/> (last visited Feb. 26, 2014).

82 Diane Cooper, *Understanding the Impact of the FDA Guidance for Mobile Medical Applications: Is There an App For That?*, 32 QUINNIPIAC L. REV 95, 95 (2013).

