TECHNOLOGICAL DEVELOPMENTS IN THE HEALTH CARE INDUSTRY: SHAPING THE FUTURE OF THE PATIENT-PHYSICIAN RELATIONSHIP

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ABSTRACT

"Just as the printing press democratized information, the medicalized smartphone will democratize health care. Anywhere you can get a mobile signal, you'll have new ways to practice data-driven medicine. Patients won't just be empowered; they'll be emancipated."[1] Technology has always been at the forefront of impacting various professional industries. Today, mobile health technology is revolutionizing the medical industry. This revolution will have a direct impact on the future of the patient-physician relationship. This Comment explores the patient-physician relationship and its evolution in time with the rise of emerging technologies from electronic health records, telemedicine and the Internet to the present-day smartphone. While mobile health technology is changing the patient-physician relationship, patients and physicians along with the state legislatures and the Food and Drug Administration will play a pivotal role in shaping it.

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[1] Eric J. Topol, *The Future of Medicine Is in Your Smartphone*, WALL ST. J. (Jan. 9, 2015), http://www.wsj.com/articles/the-top-of-medicine-is-in-your-smartphone-1420828632.

INTRODUCTION

What if we lived in a world where, when we got sick, instead of consulting a doctor, we "Googled" our symptoms or sent a blood sample to a lab through our smartphone to receive a diagnosis? This world is not far off from the one we are currently living in.

The future of the patient-physician relationship is significant to the health care industry because it directly impacts the way medicine is practiced. Emerging technologies, such as electronic health records, telemedicine, and the Internet, have changed the patient-physician relationship, and this relationship continues to change through the introduction of the smartphone and mobile health applications.[2] Similar to the innovations that the banking and travel industries have experienced over the years, technological innovations in the health care industry continue to impact the way medicine is practiced.[3] The patient-physician relationship is one of the many areas in the health care industry that will be affected by the development of mobile health. Experts predict "[Mobile] health could lead to a paradigm shift in health care. Instead of a paternalistic system where doctors tell [patients] what to do, mobile health increases patients' knowledge and power, changing the relationship to a more collaborative one."[4]

Over the past fifteen years, the Internet and the usage of smartphones has led to increased connectivity between communities.[5] Amongst other things, patients now have the opportunity to "Google" treatment plans, access their medical information online, email their doctors, or download mobile applications that allow them to monitor

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[2] E. Ray Dorsey & Eric J. Topol, *State of Telehealth*, 375 N. ENGL. J. MEDICINE 154 (July 14, 2016); *see generally* Frieda Klotz, *Power to the Patient: How Mobile Technology Is Transforming Healthcare*, ECONOMIST INTELLIGENCE UNIT (Feb. 15, 2015), http://www.eiuperspectives.econ omist.com/healthcare/how-mobile-transforming-healthcare/white-paper/power-patient.

[3] Advances in mobile technology have changed the way we live and do business. For instance, banks developed online banking and are currently looking at cell phones to replace A.T.M cards. Stacy Cowley, *Banks Look to Cell Phones to Replace ATM Cards*, N.Y. TIMES, (Feb. 13, 201 7), https://www.nytimes.com/2017/02/13/business/dealbook/banks-look-to-cellphones-to-replace-atm-cards.html. Similarly, over the years, the travel industry has changed dramatically. People now use websites such as Expedia or Priceline as booking agents, rather than actual travel agencies.

[4] Klotz, *supra* note 2.

[5] *See generally id.*

their own health through their smartphones.[6] In 2014, it was estimated that Apple offered approximately 13,000 different health applications for consumers in its App Store.[7] Between 2011 to 2012 alone, the number of users who downloaded mobile health apps doubled.[8] The increased quantity of medical apps offered on the market reflects the rising demand for mobile health. By 2018, it is estimated that the value of the medical app market will generate $26 billion in revenue, an increase from the $718 million generated in 2011.[9]

In a world where more people have access to mobile devices than they do to basic sanitation,[10] it is unquestionable that the health care industry is being affected by changes in and access to technology and, consequently, the patient-physician relationship itself is changing. Medical and legal experts explored this field by looking at the Food and Drug Administration's (FDA) guidance regulation regarding mobile health apps and the various issues with regards to privacy concerns. However, little literature has been written on the effects that mobile health technologies will have on the future of the patient-physician relationship and physicians' malpractice liability before the court.

For many years, courts drew a clear line for the required standard of care between physician and patient. Will that line be re-drawn now that technology has affected the relationship between physician and patient? In addition, what will the future of medical practice look like for physicians in a world where patients have more freedom to control and make their own decisions regarding treatments? Will physicians feel comfortable recommending the use of mobile health applications if concerns about privacy and safety still exist? If the FDA is not monitoring mobile health applications, how will mobile health become safer, more reliable, and more accurate than today's health care?

This Comment seeks to explore the impact of emerging technologies in the health care industry and its effect on the patient-

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[6] *Id.* at 3–8.

[7] Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1177 (2014).

[8] *Id.* at 1191.

[9] *Id.*

[10] *Id.* at 1191–92.

physician relationship. Part II presents a background on the existing technologies changing the patient-physician relationship, the traditional establishment of the patient-physician relationship through the standard of care and explores its direct impact on medical malpractice liability suits. Part III presents the analysis and is divided into four subsections: (A) The evolution of the patient-physician relationship with the introduction of the smart phone and mobile health applications; (B) The way the medical industry has changed with the introduction of technology and the FDA's position on those changes; (C) Privacy concerns and mobile health protection; and (D) The physician's stance today, identifying solutions and predictions for the future of their practice and expectations. Part IV concludes that mobile health will change the patient-physician relationship, however, the extent of the change will only be visible once patients assume autonomy of their health and physicians feel comfortable with patients' use of technology.

I. BACKGROUND

A. Existing Technology: Electronic Health Records, Telemedicine, and the Internet

For the past several decades the introduction of technology has played a major role in shaping the health care industry and changed the practice of medicine.[11] For instance, the development of Electronic Health Records (EHRs) twenty years ago allowed patients to access their own medical records and gave hospitals the ability to update and computerize patients' health information.[12] With the use of EHRs, physicians have been able to "offer medical advice without conducting a physical examination or taking a history,"[13] because they were able to look up patients' records in the hospital's database. EHRs facilitates electronic access to clinical information by the physician and other

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[11] Sarah Costa, *Power to the People: How Medical Mobile Apps Are Increasing Patient Knowledge and Changing the Doctor-Patient Relationship*, 25 ANNALS HEALTH L. 87, at 87.

[12] Sandeep S. Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records*, 363 NEW ENG. J. MEDICINE 2060, 2060 (2010).

[13] *Id*. at 2062.

physicians in the same organization, allowing computerized entry of medication, and permitting secure communication between providers and patients.[14] The introduction of EHRs raised legal concerns because while "EHRs held considerable promise[s] for preventing harmful medical errors and associated malpractice claims, promoting complete documentation, timely access to patient information, and facilitating sound clinical decision-making,"[15] EHRs also "created vulnerability to new kinds of errors [such as] discontinuities between information systems [by causing] prescribed medications to be automatically and unexpectedly cancelled."[16] In addition, physicians found providing "fuller access to electronic patient information [could] tempt providers to rely on previously recorded patient histories, test results, and clinical findings rather than collect[ing] new information."[17]

The introduction of EHRs raised the concerns that they could increase the risk of erroneous decisions or treatment choices by physicians and patients and that they could affect liability risks for physicians depending on the physician's level of responsiveness through messaging systems.[18] In 2009 when Health Information Technology for Economic and Clinical Health Act (HITECH)[19] was introduced, experts were optimistic about the implementation and the use of EHRs; however, they remained concerned as there was still no evidence that the use of EHRs would reduce diagnostic errors.[20] Based on a thirteen year collection of data regarding the adoption of EHRs systems in physicians' offices, a Bass diffusion model predicted that by

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[14] *Id*. at 2060–61.

[15] *Id*. at 2062.

[16] *Id*.

[17] *Id.*

[18] *Id.* at 2063.

[19] HITECH is "the 2009 Health Information Technology for Economic and Clinical Health Act was signed into law with the explicit intention of accelerating the adoption and promoting the meaningful use of EHRs by US physicians." Stephen T. Mennemeyer et al., *Impact of the HITECH Act on Physician's Adoption of Electronic Health Records*, 23 J. AM. MED. INFORM. ASS'N 375, 375–79 (2016).

[20] *See* Mangalmurti et al., *supra* note 16, at 2062.

2017 the adoption rates of EHRs by physicians would be above ninety percent,[21] indicating that EHRs are working and are here to stay.[22]

Telemedicine is another type of technology that revolutionized the health care industry and, specifically, raised core questions concerning the patient-physician relationship.[23] Telemedicine is the remote diagnosis and treatment of patients by means of telecommunications technology; it is the practice of physician consultation via electronic communication, such as email or videoconference.[24] According to the American Telemedicine Association (ATA), "telemedicine is the natural evolution of health care in the digital world,"[25] and mobile health is next. The changes mobile health will bring to the health care industry can be predicated based on the evolution and adoption of telemedicine in the health industry. In addition to integrating remote consultations, mobile health takes the practice of telemedicine to another level by focusing on the autonomy and responsibility of the patient to share recorded information with the physician at a later stage.[26]

The proliferation of the Internet about twenty years ago, followed by the launch of the first iPhone a decade later, paved the way for mobile health.[27] In today's world, information is constantly accessible, and patients have more power than ever to review potential treatment

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[21] *See* Mennemeyer, *supra* note 19, at 378.

[22] Access to EHRs will be taken to the next level by Apple. On January 24, 2018, Apple made an announcement that it is working with the health community to increase access to patient's electronic medical records through a safe app portal. This would allow patients to access all of their medical records in one portal. *Apple Announces Effortless Solution Bringing Health Records to iPhone*, APPLE NEWSROOM, (Jan. 24, 2018), http://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iPhone/.

[23] *See* Ronald Weinstein et al., *Telemedicine, Telehealth, and Mobile Health Applications that Work: Opportunities and Barriers*, AM. J. MEDICINE 183, 184(2014), http://dx.doi.org/10.1016/j.amjmed.2013.09.032 ("[T]elemedicine, telehealth, and mobile health could fundamentally change the way medical services are delivered.").

[24] AM. TELEMEDICINE ASS'N, *The Ultimate Frontier for Superior Healthcare Delivery*, AMERICANTELEMED.ORG, http://www.americantelemed.org/main/about/about-telemedicine (last visited Sept. 16, 2017).

[25] *Id.*

[26] Costa, *supra* note 11, at 94.

[27] Amit Om, *E-Medicine: What it Means for Patients*, AM. J. MEDICINE 1268 (2015), http://www.amjmed.com/article/S0002-9343(15)00580-X/pdf.

plans, consult second opinions, and get in contact with other patients similarly situated, all without leaving the comfort of their home.[28]

The mobile health revolution began with WebMD, the online symptom-checker service that now serves millions of subscribers monthly[29] along with the introduction of personal digital assistants[30] and electronic medical records.[31] Subsequently, the introduction of the first iPhone revolutionized the way mobile devices were used for communication[32] and sparked the recent generational change in the patient-physician relationship.

Today, mobile health applications are the newest tool created by the natural evolution of health care technology, the building on the progress created by the Internet, EHRs, and telemedicine.[33] Mobile health applications allow users to access information through the use of a software designed to run on smartphones.[34] "A mobile medical application ("mobile medical app") can be defined as 'medical devices that are mobile apps [that] meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.'"[35]

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[28] *Id.*

[29] WebMD, founded in 1996, is an online publisher working with hundreds of practitioners nationwide to publish information pertaining to health and well-being. *The Top 10 Doctor Review Sites in 2017*, LIVECLINIC HEALTHCARE BLOG (Jan. 1, 2017), https://liveclinic.com/blog/the-top-10-doctor-review-sites/.

[30] Personal digital assistants are handheld devices that combine computing, telephone/fax, Internet, and networking features. Vangie Beal, *What Is a Personal Digital Assistant?,* WEBOPEDIA, http://www.webopedia.com/TERM/P/PDA.html (last visited, Jan. 22, 2017). Modern-day PDAs are technologies such as Siri, Alexa, Cortana, or Google. Edward C. Baig, *Personal Digital Assistants Are on the Rise (and They Want to Talk)*, USA TODAY (May 9, 2016, 6:37 PM), http://www.usatoday.com/story/tech/columnist/baig/2016/05/08/per sonal-digital-assistants-rise-and-they-want-talk/83715794/.

[31] Cortez, *supra* note 7, at 1181.

[32] *Id.*

[33] Weinstein et al., *supra* note 23, at 183 (discussing telemedicine and explaining that "mobile health is a newer concept that describes services supported by mobile communication devices").

[34] Latena Hazard, *Is Your Health Data Really Private? The Need to Update HIPAA Regulations to Incorporate Third Party and Non-Covered Entities*, 25 CATH. U.J.L. & TECH 447, 453 (2017).

[35] *Id.*

While telemedicine is "narrowly defined as the provision of medical services at a distance by a physician,"[36] mobile health is the upgraded version of telemedicine. Mobile health is defined as "services supporting mobile communication such as devices monitored wirelessly, smartphones or personal digital assistants."[37] Mobile health apps, through the use of smartphones, are the "driver for the next-generation telemedicine and telehealth."[38] From EHRs to telemedicine, state legislatures and the FDA, along with physicians and patients, played major roles in accommodating these technologies to the practice of medicine. Today, mobile health applications challenge the same players to work together to integrate this new technology into their practices. Successful implementation would result in a positive impact in the field of health care.

B. The Patient-Physician Relationship and its Establishment through the Standard of Care

The patient-physician relationship is formed when the physician owes the patient a duty of care.[39] Before a patient may bring a malpractice claim the plaintiff has to prove that the physician owed him a duty of care and show that the physician deviated from that duty, injuring the patient as a result.[40] Generally, a relationship between physician and patient is formed when there has been "direct contact and care between the physician and patient"[41] and when the "physician willingly undert[ook] the treatment of a patient before owing him or her a duty of care."[42]

Traditionally, the relationship between the patient and the physician used to involve the collection of symptoms from patients, the diagnostic evaluation, and the seeking of management or a

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[36] Weinstein et al., *supra* note 23, at 183.

[37] *Id*.

[38] *Id*. at 185.

[39] Y. Tony Yang & Ross D. Silverman, *Mobile Health Applications: The Patchwork of Legal and Liability Issues Suggests Strategies to Improve Oversight*, 33 HEALTH AFF. 222, 225 (2014).

[40] *Id.*

[41] *Id.*

[42] *Id.*

treatment plan.[43] Therefore, there are two questions raised when examining this relationship in the mobile health setting. First, when would the relationship between a patient and physician be formed if there were no face-to-face interaction? Second, what would the standard of care be when the physician provides a consultation to the patient without a face-to-face occurrence?[44]

With the decrease of face-to-face consultations between physician and patient, due to an increasing use of telemedicine, debates have sparked over when the relationship is actually established. Many states previously took the position that the use of telemedicine should only occur after the relationship had been created, meaning that telemedicine could only be used once a face-to-face encounter had occurred.[45] In contrast, Hawaii became one of the first states not to require this[46] and instead allowed a patient-physician relationship to be established without a face-to-face interaction.[47] Unlike Hawaii, Texas placed greater limitations on the use of telemedicine and provided a more detailed guide to telemedicine providers in its Administrative Code.[48] Amongst other limitations, the Texas Administrative Code provided that before providers could use telemedicine they "must give their patients notice regarding telemedicine services, including the risks and benefits of being treated *via* telemedicine, [as well as] how to receive follow-up care or

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[43] Peter Yellowlees et al., *Psychiatrist-Patient Relationship of the Future: Anytime, Anywhere?*, 18 HARV. REV. PSYCHIATRY 2, 96, 98 (2010).

[44] Bradley J. Kaspar, *Legislating for a New Age in Medicine: Defining the Telemedicine Standard of Care to Improve Healthcare in Iowa*, 99 Iowa L. Rev. 839, 851 (2014).

[45] Erin Dietsche, *Texas Law Marks Turning Point in Telemedicine,* MEDCITYNEWS (May 30, 2017), http://medcitynews.com/2017/05/texas-law-telemedicine/ ("Physicians can now utilize telemedicine services with patients they haven't met. This quashes an earlier requirement that physician-patient relationships had to be established with an in-person visit first. . . . Texas was the last state to still uphold this requirement.").

[46] Kaspar, *supra* note 44, at 856 (explaining that in 2009, Hawaii enacted a statute providing that a lower standard of care should be applied in non-face-to-face visits); Dietsche, *supra* note 45 (explaining that Hawaii enacted a statute in 2009 stating that a lower standard of care should be applied in visits not conducted in person. In 2017, Texas passed Senate Bill 1107, recognizing that a patient-physician relationship can be formed without a face-to-face encounter. *See* Dietsche, *supra* note 45.

[47] HAW. REV. STAT. § 453-1.3 (2017).

[48] 22 TEX. ADMIN. CODE § 174.2(10)(2017).

assistance in the event of adverse reaction to a treatment."[49] Compared to Hawaii's telemedicine regulations, the Texas regulation excessively limited the physician's autonomy.[50]

Until recently, the state of telemedicine in Texas was in limbo due to ongoing litigation between Teladoc and the Texas Medical Board.[51] The Texas Medical Board adopted a code provision that required "face-to-face physical examination of patients prior to prescribing any dangerous drug or controlled substance."[52] Teladoc "describes itself as providing 'Telehealth services' utilizing telecommunication technologies to provide health care services outside the traditional models."[53] Teladoc brought a claim against the Texas Medical Board asserting violations of antitrust laws and the commerce clause by adopting the new regulation.[54] As a result of the litigation, the Texas Legislature drafted Senate Bill 1107, which proposed to remove "the face-to-face or in-person requirement to establish a patient-physician relationship and lawfully provide Telehealth and telemedicine services within the state."[55] Senate Bill 1107 passed on May 27, 2017, making Texas the last state to allow a patient-physician relationship to be formed via telemedicine without the requirement of a face-to-face encounter.[56]

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[49] *Id.* at § 174.5(b).

[50] Kaspar, *supra* note 44, at 852.

[51] Teladoc, Inc. v. Tex. Med. Bd, 112 F.Supp.3d 529 (W.D. Tex. 2015).

[52] *Id.* at 534 (referring to the amendment made to 22 TEX. ADMIN. CODE §190.8(1)(L)).

[53] *Id.* at 533.

[54] *Id*. at 534.

[55] Marshall E. Jackson et al., *United States: Texas to Take a Leap Forward in Telehealth — A Proposed Bill Drops the Controversial In-Person Evaluation Requirement*, MONDAQ, http://www.mondaq.com/unitedstates/x/578306/Healthcare/Texas+To+Take+A+Leap+Forward+In+Telehealth+A+Proposed+Bill+Drops+The+Controversial+InPerson+Evaluation+Requirement (last updated Mar. 20, 2017).

[56] *Id.*; Jenny Deam, *Telemedicine Industry Expects Boost from New Law*, HOUS. CHRON., (June 21, 2017), http://www.houstonchronicle.com/business/medical/article/Telemedicine-industry-expects-boost-from-new-11223144.php; *see also* Jonah Comstock, *In-Depth: What Texas' Landmark Telemedicine Legislation Means for the Industry and the Nation*, MOBIHEALTHNEWS (May 26, 2017), http://www.mobihealthnews.com/content/depth-what-texass-landmark-tele medicine-legislation-means-industry-and-nation (discussing Arkansas and Idaho's phone-call-only restriction for telemedicine.); *Texas Senate Bill 1107*, LEGISCAN (May 27, 2017), https://legiscan.com/TX/bill/SB1107/2017.

These changes within the practice of telemedicine are significant for the future of the patient-physician relationship and the future of mobile health raising significant questions about the applicable standard of care and whether the standard will change as a result of decreased in person interactions.[57] Understanding the applicable standard of care is key as this defines whether or not a duty in the patient-physician relationship exists.[58] Traditionally, courts have adopted "the reasonable-physician standard [that] requires the fact finder to determine if a reasonable physician would have followed the defendant-physician's conduct," the exact definition of which varies by jurisdiction.[59] The issue that may arise with the use of telemedicine is that if the traditional standard of care for face-to-face consultations is applied in the telemedicine context "a patient that suffers a poor outcome might allege that the physician negligently utilized the new technology in place of customary practices."[60] For example, the physician's lack of response to a patient's email may constitute a violation of the care he owes the patient.[61] Through the use of emails, patient and physician communication is in writing as opposed to being solely verbal, creating a written record.[62] As a result, in cases of negligence, email communication could lead to a different breach of duty analysis. For instance, in some cases, one may argue that "it may even constitute negligence to e-mail advice to a patient rather than examine him or her in person."[63] On the other hand, "messaging systems may help prevent medical errors and adverse events by

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[57] *See generally* S.B. 1107, 85th Leg. Reg. Sess. (Tex. 2017).

[58] Kaspar, *supra* note 44, at 845.

[59] *Id.* at 846.

[60] *Id*. at 864 (quoting Lynn D. Fleisher & James C. Dechene, TELEMEDICINE AND E-HEALTH LAW § 1.04[3][b][i] (2010)). According to Tex. Admin. Code §174.8(b) (2013), the standard of care via telemedicine is the same as for face-to-face medicine: "treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in tradition in-person clinical settings." However, because of the recently-passed telemedicine bill, it would not be surprising if the standard were to change in the coming years.

[61] Sandeep S. Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records*, 363 NEW ENG. J. MEDICINE 2060, 2063 (2010).

[62] *Id.*

[63] *Id.*

allowing patients to easily vocalize clinically significant concerns that they do not believe warrant an office visit."[64]

With the increase use of mobile health apps and email communication between physician and patient, the question remains how can one determine whether the physician has breached the standard of care owed to the patient. In a scenario where a reasonable physician proposed a mobile health app for treatment but another physician did not, would this be considered a breach of the standard of care?[65] Similarly, in the case where one physician is more responsive than another to a patient's email, would the less responsive physician have breached the standard of care?[66] With the use of technology becoming a major component of most health consultations, it is expected that the practice of conventional medicine will decrease and move towards a more technologically-modernized practice.[67]

In response to these technological changes, medical institutions and organizations, such as the American Medical Association (AMA) and the American Medical Informatics Association (AMIA), established ethics policies and guidelines on the use of electronic communications in clinical practice.[68] For instance, "[t]he AMA policy states that physicians should not use electronic communications to establish physician–patient relationships—only to supplement 'other, more personal, encounters.'"[69] This would avoid misunderstandings and prevent liability risk on the part of the physician by shaping the patients' perceptions.[70] "The AMA guidelines [also] suggest establishing a protocol for terminating e-mail relationships with patients who repeatedly violate the rules."[71] In addition, the guidelines put forth that "before initiating an e-mail relationship, providers

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[64] *Id.*

[65] Yang & Ross, *supra* note 39; *see also* Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS HEALTH L. 62, 76–92 (2016).

[66] Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records*, *supra* note 61.

[67] *Cf.* Yellowlees, *supra* note 49, at 96–97 (discussing the increasing importance of internet usage between a doctor and a patient).

[68] Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records*, *supra* note 61.

[69] *Id.*

[70] *Id.*

[71] *Id.*

should notify patients of their guidelines and obtain informed consent for the use of electronic communications."[72]

As institutions and states focus shaping regulations,[73] the future of telemedicine and mobile health remains uncertain. The acceptance of telemedicine, creating a patient-physician relationship with a face-to-face encounter, took decades. However, as states become more accepting of telemedicine,[74] it is just a matter of time until the use of mobile health apps become the new norm in evolving the patient-physician relationship. This response to the rapid growth of telemedicine will impact the future growth and acceptance of medical mobile apps through the use of smartphones.

C. THE PATIENT-PHYSICIAN RELATIONSHIP AND ITS AFFECT ON MEDICAL MALPRACTICE LIABILITY FOR THE PHYSICIAN

Defining the standard of care is crucial to understanding the way mobile health will impact malpractice liability for the physician. For instance, with more hospitals and physicians adopting EHRs and telemedicine the question of how health care technology affects malpractice liability becomes more relevant.[75] In the context of telemedicine, it is clear that many states, including Texas, specifically state that the standard of care for telemedicine encounters is the same as face-to-face encounters.[76] This imposes the same malpractice liability on physicians as when they interacted with patients face-to-face.[77] Due to its recency, no malpractice lawsuits have been brought under the practice of telemedicine. As a result, whether the standard of care analysis will remain the same is still unknown.[78] However,

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[72] *Id.*

[73] *See* S.B. 1107, 85th Leg., Reg. Sess. (Tex. 2017).

[74] *See* Dietsche, *supra* note 45 (noting that Texas is one of the latest states to adopt a statute in support of telemedicine); *see* Weinstein, *supra* note 23, at 185 (explaining that "[p]rogress is being made to bring telemedicine and mobile health into the main stream").

[75] *See generally* Yang & Ross, *supra* note 39; *see also* Terry & Wiley, *supra* note 65.

[76] 22 TEX. ADMIN. CODE § 174.8(b)(2017).

[77] *Id.*

[78] *See generally* Neil Chesanow, *Do Virtual Patient Visits Increase Your Risk of Being Sued?*,

Hawaii accepted that the standard of care should be lowered in the telemedicine context,[79] recognizing that "physicians are at a diagnostic disadvantage when they cannot examine a patient in-person"[80] becoming one of the first states to allow a patient-physician relationship to form via telemedicine.[81] Currently, most states, like Texas impose the traditional standard of care on the practice of telemedicine; however, it remains unclear whether the practice exhibited by Hawaii will become standard of care adopted nationwide.

Generally, patients can prevail in a malpractice lawsuit if they establish that the physician breached his duty of care.[82] "Medical malpractice claims mirror traditional negligence claims; they involve: (1) a duty owed by the physician to the patient; (2) a breach of duty by the physician; (3) an injury to the patient; and (4) a causal link between the physician's breach of duty and the patient's injury."[83] As a result, under malpractice law, a physician's duty exists only if a patient-relationship exists.[84]

EHRs created new legal risks for physicians.[85] Neil Chesanow, Senior Editor of Medscape, identified that potential legal risks for physicians could come from the fact that no one had answers for whom to blame if a patient's EHRs did not work adequately.[86] However,

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MEDSCAPE (Oct. 22, 2014), https://www.americanwell.com/wp-content/uploads/2014/12/www.medscape.pdf.

[79] HAW. REV STAT § 453-1.3.

[80] Kaspar, *supra* note 44, at 862.

[81] Kaspar, *supra* note 44, at 856 (noting that as early as 2009 – before any other state – non-face-to-face encounters in Hawaii were held to a lower standard of care).

[82] Yang & Ross, *supra* note 39, at 225.

[83] Kaspar, *supra* note 44, at 845.

[84] *Id.*

[85] Neil Chesanow, *8 Malpractice Dangers In Your EHR*, MEDSCAPE (Aug. 26, 2014), http://www.medscape.com/viewarticle/828403; *see* Sue Bowman, *Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications*, PERSP. IN HEALTH INFO. MGMT. (Fall 2013), http://perspectives.ahima.org/impact-of-electronic-health-record-systems-on-information-integrity-quality-and-safety-implications/; *see also Kansas City Personal Injury Law Blog*, SHAMBERG JOHNSON & BERGMAN (June 8, 2015), http://www.sjblaw.com/electronic-health-records-helping-or-hurting-patient-safety/.

[86] Chesanow, *supra* note 85.

HIPAA clearly states that "the covered entity is responsible for maintaining the integrity of the patient's medical record."[87] Another risk identified is the physician's ability to just "copy/paste" patients' notes, which may lead to the physician introducing incorrect or outdated patient information to a patient's chart.[88] Physicians may be tempted to engage in the practice of "copy/pasting" in the belief that EHRs in practice slows them down.[89] Some lawyers also point to the fact that "EHRs may actually be altering certain aspects of medical malpractice litigation. [D]octors using EHRs can access more clinical information, [which implies] that there may be new 'duties to act' that increase a professional's liability."[90]

Exploring EHRs implications in the context of malpractice liability may predict the way malpractice litigation will be carried out as mobile health dependency increases and the patient-physician relationship changes.[91] With EHRs, there is an increase in available documentation that can be used to prove or defend a malpractice claim.[92] Indeed, EHRs create an archive for all electronic transactions "from the input of orders to time stamps of clinical activity, although they vary in their ability to produce reports of these data on demand.[93] This information, called metadata, provides a permanent electronic footprint that can be used to track physician activity."[94] This documentation may establish a provider's fault, whereas in other instances it may help build up a defense.[95]

Generally, "in a malpractice suit, each side presents expert testimony to define the applicable standard of care. Expert witnesses

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[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Kansas City Personal Injury Law Blog, supra* note 85.

[91] *See generally* Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records, supra* note 61 (discussing how medical malpractice liability issues in the context of EHRs are similar to the issues raised in the context of mobile health); *see generally* Costa, *supra* note 11; *see generally* Cortez, *supra* note 7.

[92] Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records, supra* note 61.

[93] *Id.*

[94] *Id*.

[95] *Id*. at 2064.

may rely solely on their own judgment and experience or invoke external evidence of the standard of care, such as clinical practice guidelines. Courts have permitted this use of practice guidelines and would probably also admit clinical-decision support systems as evidence of the standard of care, if an expert attests that they reflected reasonable and customary care. A physician's departure from the clinical-decision support protocols could then be used as evidence of negligence. Like practice guidelines, clinical-decision support protocols could establish a more accurate definition of the standard of care than would emerge from the clash of expert opinions alone."[96]

When EHRs were first introduced, there was a growing fear that failure to adopt an EHR system could constitute a deviation from the standard of care. The standard of care is usually defined by reference to what is customary among physicians in the same specialty in a similar setting.[97] Therefore, as physicians continue adopting EHRs, deviation of the standard of care would occur only if other physicians did not adopt EHRs.[98] The analysis seems to be similar when applied to the use of telemedicine and adoption of mobile health apps. As telemedicine and mobile health usage becomes the norm, the standard of care may evolve to the point where physicians who do not include these technologies in their practice may be culpable of deviating from this evolving standard of care.

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[96] *Id.*

[97] *Id.* at 2065.

[98] *Id.*

II. ANALYSIS

A. The Evolution of the Patient-Physician Relationship with the Introduction of the Smart Phone and Mobile Health Applications

Before the era of the Internet and smartphones, patients visited their doctor and followed the treatment plan established by their physician. The patient-physician relationship was established when the patient made an appointment with the doctor, visited the doctor's office, subjected themselves to an examination by the physician, and went home with a list of medications that needed to be bought in order to begin treatment.[99] Many medical and legal experts believe that this era of practicing medicine is changing.[100] Cardiologist Dr. Eric Topol believes in the democratization of medicine where medicine and health data would be something made available to all people.[101] While Topol's view may be regarded as optimistic, it is worthy to note that technological developments have consistently changed the norms of professions throughout history.[102]

As of the year 2000, "[fifty-five percent] of [52] million American adults with Internet access have used the Internet for health or medical information."[103] After the introduction of the Internet, even though the patient-physician relationship predominantly remained the same, patients gained the ability to "surf" the web for additional medical information.[104]

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[99] *See generally Power to the Patient: How Mobile Technology is Transforming Healthcare*, ECONOMIST INTELLIGENCE UNIT, http://www.eiuperspectives.economist.com/healthcare/how-mobile-transforming-healthcare/white-paper/power-patient.

[100] *See generally* ERIC J. TOPOL, THE PATIENT WILL SEE YOU NOW (2015).

[101] *Id*.

[102] *Id*. at 4–7 (discussing the 'Gutenberg moment': like the printing press that allowed for the dissemination of knowledge, the Internet and mobile health apps are doing the same for medicine). We can now see the same effects through technologies like Uber and Airbnb, which have revolutionized the way we travel.

[103] Diaz et. al., *Patients' Use of the Internet for Medical Information*, 17 J. GEN. & INTERNAL MED., 180, 183 (2002).

[104] *Id.* at 182–83.

In the health care industry, the Internet, among other technologies, can be used as "a tool to self-assess, increase self-efficient management, and improve treatment results."[105] When the Internet was first used as a source of medical information, it raised many concerns, as it was believed to be unreliable, inaccurate, and incomplete at times.[106] In addition, the Internet tends to simplify and generalize science; for example, WebMD would discuss coronary heart disease as a whole leaving out sub-diseases, such as hypercholesterolemia and hypolipidemia.[107] While similar, these diseases inspire different courses of treatment options. These concerns still remain today. While people in the early 2000s already had the habit of researching medical information, patients now have access to medical research and medical information at the tip of their fingers.[108]

In 2007, Steve Jobs unveiled the first iPhone,[109] giving mobile connectivity to anyone who used it. With the iPhone came the App Store, which, among other benefits, enables anyone to develop and download mobile applications.[110] Technology transported patients into a new era of medicine practice where they now have the ability to self-diagnose and assess their own health through the mobile applications they download.[111] For instance, let us consider this scenario: Mandy a twenty-five-year-old law student is having trouble reading for class because after hours of reading her eyesight is blurry, but she doesn't have the time to visit the ophthalmologist. Her smartphone gives her the possibility to diagnose her own eyesight with an app called *EyeNetra*.[112] Because the app comes with a two-

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[105] Jeongeun Kim & Sukwha Kim, *Physicians' Perception of the Effects of Internet Health Information on the Doctor-Patient Relationship*, 34 INFORMATICS FOR HEALTH & SOCIAL CARE 136, 137 (2009).

[106] *Id.* at 144–45.

[107] *See Coronary Artery Disease*, WEBMD, http://www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease#1 (last visited Nov. 18, 2017).

[108] Om, *supra* note 27, at 1268.

[109] Apple Press Info., *Apple Reinvents the Phone with the iPhone*, http://www.apple.com/pr/library/2007/01/09Apple-Reinvents-the-Phone-with-iPhone.html (Jan. 9, 2007).

[110] Costa, *supra* note 11, at 88.

[111] *See generally* Cortez, *supra* note 7.

[112] Om, *supra* note 27, at 1268.

dollar clip-on attachment, Mandy can diagnose her own eyesight at a lower cost without having to schedule an appointment.[113]

In addition to the App Store, the iPhone has built-in features, such as touch screens, cameras, wireless connectivity, and software, which allows for data collection and data processing that could develop to provide the user with individual diagnosis[114] and, in some cases, be used to gather and process users medical information.[115] For example, another app available in the App Store is *uCheck*, which can help detect twenty-five different urinary diseases by analyzing a picture of a purchasable strip soaked in urine.[116] Instead of scheduling an appointment with a physician, patients can download the app and undergo the process by themselves to derive their own diagnosis. This would give the patient a choice to save time and money.[117]

In 2014, Tim Cooks introduced the iWatch,[118] a smart watch, with a touch screen able to connect to an individual's iPhone or iPad. The Apple Watch is another technology that will be part of the digitalization of the health care industry. A year later, in 2015, Cooks, unveiled "Airstrip" a new app meant to bring "health care professionals and patients closer together."[119] Airstrip allows doctors to see their patient's vitals in real time, providing a more accurate reading than one found on a patient's phone because the Apple Watch digitalizes and registers data from a patient's wrist.[120] Even though this product is only a few years old, apps to monitor and record health data

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[113] *Id.*

[114] Cortez, *supra* note 7, at 1177; *see generally* Costa, *supra* note 11.

[115] Cortez, *supra* note 7, at 1176.

[116] Om, *supra* note 27, at 1268.

[117] See Klotz, *supra* note 2, at 12 (explaining that "with far more access to data and information . . . patients will have the ability [to] take greater charge of their own health").

[118] David Goldman, *Apple Unveils Two New iPhones, Apple Watch, and iPay*, CNN (Sept. 9, 2014), http://money.cnn.com/2014/09/09/technology/mobile/apple-iphone-iwatch-event/index.html.

[119] Steve Smith, *Apple's Tim Cook Unveils Two New Medical Apps for Apple Watch that Bring Doctors, Patients Closer Together*, MEDICAL DAILY (Sept. 9, 2015), http://www.medicaldaily.com/apples-tim-cook-unveils-two-new-medical-apps-apple-watch-bring-doctors-patients-351874.

[120] *Id.*

are increasing on the market for the iWatch.[121] Some apps available include *Apple Inc*, *Cupertino*, and *Calif*, which can all be used to record data from the wrist.[122] Through the watch, patients have the ability to monitor their heart rate, blood pressure and blood glucose levels, congestive heart failure, hypertension, and many others.[123] The data recorded from various apps on the iPhone or the iWatch can be synced to the Cloud and create an online, personal health profile, accessible on the individual's other devices.[124]

The age of health care consumerism sets a new stage for medicine where patients possess more autonomy and take individual control of their health.[125] "Educated patients are empowered patients with Google and other websites enabling the public to research their diagnosed conditions and learn about treatment options, patient are more empowered."[126]

In 2007, a qualitative study published by BMC Family Practice explored the information sought on the Internet by patients and the effect of that information on the patient-physician relationship.[127] The study suggested that the development of technology enabled patients to become more active decision-makers regarding their own health.[128] This is significant because today's literature suggests that for mobile health to be successful, patients must be more autonomous regarding their health.[129] The study also suggested that patients did not feel the need to discuss their Internet searches with physicians.[130] The authors of the study hypothesized patients did not do so as the searches patients executed did not directly relate to the care physicians provided or because patients feared that they would be overstepping

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[121] Om, *supra* note 27, at 1268.

[122] *Id.*

[123] *Id*.

[124] *Id*.

[125] *Id*.

[126] *Id*.

[127] *Id.*

[128] *Id. at* 1.

[129] Klotz, *supra* note 2, at 9–10.

[130] Stevenson, *supra* note 135, at 2.

the role of physician and would be appearing to tell the doctor how to do their job.[131]

In a 2009 study published by Informatics for Health and Social Care, the authors discussed how patients would use the Internet as a second opinion or even a first opinion on their own health concerns.[132] The Internet allows for "easy access, wide usability and acts as a secondary resource for information for traditional doctor–patient relationship by providing patients with medical knowledge specific to each condition."[133] The downside of the use of the Internet is that it can lead to patients bringing back unnecessary information in the consultation room, which in some cases could lead "doctors [to] dislike the misguided use of Internet health information because of its lack of reliability and the change it is causing on the diagnosis and treatment environment."[134]

Another study performed in 2009 was done to identify physicians' perceptions of patients' Internet use and its effect on the patient-physician relationship.[135] The study concluded that physicians believed patients generally seek Internet health information because of a lack of trust towards the physician, while only some patients seek confirmation of their diagnosis or treatment.[136] Other physicians said that patients' Internet use could be from patients having unnecessary concerns, wanting to show off their medical knowledge or simply utilizing the accessibility of the Internet's resources.[137]

In most cases, physicians' perceptions of Internet health information was both positive and negative.[138] To an extent, physicians viewed the information as having a positive effect for the patient; however, "most felt that the patients who obtained Internet health

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[131] *Id.* (quoting Henwood et al. and Broom study).

[132] Kim, *supra* note 112, at 141.

[133] *Id*. at 136 (explaining that "Internet savvy patients are obtaining information from the Internet that they failed to receive from the doctor from the previous visit."); Kim, *supra* note 112, at 137.

[134] Kim, *supra* note 112, at 137.

[135] *Id.* at 138.

[136] *Id.* at 141.

[137] *Id*.

[138] *Id*. at 143–45.

information ha[d] lower tendency to comply with the physician's instructions or advice."[139] In addition, physicians believed it was negative because patients "ha[d] unnecessary fear[s] or concern[s] about their health and that Internet health information contribute[d] to an increase in health care cost as well as causing longer and unnecessary visits."[140] Physicians were also concerned that their patient's ability to make correct choices was affected due to the inaccuracy of Internet health information.[141] These findings suggest that patients should carefully consider "the accuracy, reliability, and validity of Internet health information, and when required, make educated inquiries to their physicians," in order to improve the patient-physician relationship in the future.[142]

More recent studies echo the findings from 2007 and 2009.[143] A study conducted by Tan in 2017 concludes, similar to the previous studies, that Internet health information can improve the patient-physician relationship depending on how the patient uses the information sought and whether he discusses that information with the physician.[144] The study also suggests that "online information has the possibility of misinforming and distressing patients[,] increasing the tendencies for self-diagnosis or self-treatment and has the possibility of adding 'a new interpretive role' to physician's responsibilities during consultations."[145] Another aspect of online information is that it leads to educating and empowering the patient

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[139] *Id*. at 144–45. In 2016, this thought was still relevant. A research paper examined patient compliance with treatment recommendations and found that while "patients' compliance with their doctors' treatment recommendation has been linked with better health outcomes and patient satisfaction […] surveys of patients suggest that only 50% comply fully with the treatment regimen prescribed for them." Gayathri Sivakumar & Marie-Loiuse Mares, *The Doctor versus the Internet: Effects of Low, Medium, and High Quality Websites on Intentions to Follow the Doctor's Advice,* HEALTH COMM. (Oct. 21, 2016), http://dx.doi.org/10410236.2016.1228030.

[140] Kim, *supra* note 112, at 145.

[141] *Id*. at 145.

[142] *Id*.

[143] *See generally* Sharon Swee-Lin Tan & Nadee Goonawardene, *Internet Health Information Seeking and the Patient-Physician Relationship: A Systematic Review*, 19(1) J. MED. INTERNET RES., 12 (2017), http://www.jmir.org/2017/1/e9/.

[144] *Id*. at 12.

[145] *Id*. at 2.

by having more questions for the physician and requesting additional treatment or medication.[146] This may have the effect of pressuring the physician to prescribe antibiotics, for example, when they are not necessary.

Generally, Tan's study explained that even with seeking online information, patients' positive attitudes towards physicians did not change "unless physicians imposed restrictions on sharing online" information during the consultation.[147] The authors of the study encouraged that patients discuss their Internet searches with physicians because the Internet has the potential to misguide patients with inaccurate information—the information patients wish to use in decision-making needs to be verified to ensure that it is reliable.[148] Further, the study suggests that patients seeking health information have the "potential to improve the relationship" between physicians and patients because patients see the Internet as an additional resource to their physician; therefore, it has "the potential to change the structure of the traditional patient-physician relationship from one where patients perceive health care providers as the sole custodians of medical information"[149] to one where patients and physicians are both medically informed.

Another study conducted in 2015 focused on patient compliance and revealed that a majority of physicians generally accept the benefits of the Internet as giving patients the opportunity to be more informed.[150] Some physicians are worried that the Internet usage can cause patient confusion, unrealistic expectations, and an increase in litigation.[151] Even though the physician is the most trusted source for

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[146] *Id.*

[147] *Id.* at 11.

[148] *Id.* at 12.

[149] *Id.*

[150] Tan & Goonawardene, *supra* note 143; John Laugesen et al., *The Impact of Internet Health Information on Patient Compliance: A Research Model and an Empirical Study*, 17(6) J. MED INTERNET RES 3 (2015), http://www.ncbi.nhlm.nih.gov/articles/PMC4526934/?report=printabl l)(finding that 40% of physicians believe that the higher level of information available to patients on the internet may damage the patient-physician relationship).

[151] Tan & Goonawardene, *supra* note 143; Laugesen et al., *supra* note 150.

health information,[152] many patients utilize the Internet before making their first appointment to the doctor's office.[153]

The future of the patient-physician relationship rests in the hands of the patient and the physician. A patient's curiosity is ignited by technology use; however, it should be the patient's responsibility to recognize that not all web information is accurate. The patient needs to accept the responsibility of increased autonomy to verify the reliability and accuracy of the information he uses to make personal medical decisions. Simultaneously, as emerging technologies continue to rise in popularity and seem to be here to stay, physicians need to be more accepting of patients seeking information online. Physicians may manifest acceptance by taking the step to involve the patients on that track. It is true that physicians will be more prone to the acceptance and recommendation of patient's use of the Internet and medical mobile apps if they can be assured that they are reliable, accurate, and safe for their patients.[154]

B. The Way the Medical Industry has changed with the Introduction of Technology and the FDA's Stance on Those Changes

Before the introduction of medical mobile applications, the health care industry had already faced the use of technology in its profession with the introduction of medical device software more than twenty years ago.[155] Today, the industry faces smartphones as another

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[152] Tan & Goonawardene, *supra* 143, at 12; *see also* Daniela Haluza et. al., *Digital Natives Versus Digital Immigrants: Influence of Online Health Information Seeking on the Doctor–Patient Relationship,* HEALTH COMM., 1346-47 (Oct. 6, 2016), (http://www.tandfonline.com/doi/full/10 .1080/10410236.2016.1220044).

[153] Laugesen, *supra* note 150 ("[A]lthough physician information is the most trusted source and patients report that their preference is to go to their physician first to get information, only 10.9% of patients actually go to their physician first, whereas 48.6% go online first, most likely because of the accessibility, convenience, and immediacy of the information."); *see also* Sivakumar, *supra* note 139, at 2.

[154] Costa, *supra* note 11, at 95–96.

[155] Lisa Rannefeld, *The Doctor Will E-mail You Now: Physicians' Use of Telemedicine to Treat Patients over the Internet*, 19 J.L.& HEALTH 75, 77 (2004–2005) ("Forms of telemedicine communication began in 1960 […] telemedicine truly emerged during the information boom in the mid-1990s."); *id*.

technological interrupt that is reshaping the future of the industry. There are two parts to this analysis. The first part will address smartphones and mobile health applications as a game changer in the medical industry. The second will analyze the FDA's stance on the subject and its effect on sculpting the future of the health care industry.

1. *Smartphones and Mobile Health Applications as a Game Changer in the Medical Industry*

Using the smartphone as a tool to introduce medical mobile applications *via* the App store (or Android Apps) into conventional medicine gives individual patients more power and access to medical information.[156] Patients have the ability to access medical health information and to communicate with their physician while monitoring their own health and sending their doctors live data.[157] Let us consider the following scenario: Ken is a 40-year old investment banker; he has no children and no spouse. Due to his busy life, Ken lives an unhealthy lifestyle. He does not exercise; he does not eat a balanced diet; he sleeps minimal hours' and he incurs a significant amount of daily stress. One sunny Monday morning, on his way to work, Ken has a seizure. He is taken to the hospital and later diagnosed with diabetes.[158] This diagnosis changes everything for Ken because diabetes is a disease that requires constant monitoring and visits to the doctor. Unfortunately, Ken does not have the time to monitor his disease and visit the doctor weekly. Ken discusses several options with his physician, one of which could be to download an application on his phone that would help him identify his blood glucose, stay educated about his disease, and easily access tailored and proactive advice from a Certified Diabetes Educator.[159] This application would give Ken the ability to keep working while daily monitoring his

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[156] Costa, *supra* note 11, at 91.

[157] *Id*. at 94.

[158] According to the American Diabetes Association website, 30.3 million Americans had diabetes in 2015. *Statistics About Diabetes*, AM. DIABETES ASS'N, http://www.diabetes.org/diabetes-basics/statistics/ (last visited Nov. 18, 2017).

[159] Aditi Pai, *Roche Partners with MySugr for Accu-Chek, Logbook App Integration*, MOBIHEALTHNEWS (Oct. 22, 2017), http://www.mobihealthnews.com/content/roche-partners-mysugr-accu-chek-logbook-app-integration.

diabetes and receiving analysis on his food intake and exercise needs. Ken could even end up making yearly visits to his doctor's office or communicate with his doctor remotely *via* his phone or tablet.

Let us consider another scenario: Amy is a twenty-eight-year-old stay at home mom with two children, ages two and five. One afternoon, Amy is cooking dinner for her children, and as she takes the pot off the stove, she burns her forearm. The closest hospital to her house is an hour and a half away. She has no one to leave the kids with and has no car. Amy could call 911 and have an ambulance pick her up; however, Amy's burns could most conveniently be treated at home. What if there was an application Amy could download that would allow her to use her phone to take a picture of the burn where the app would process, analyze, and send it to an ER physician. The physician in a few moments could then tell Amy whether a physician's visit is necessary. In addition, the same app could be used to monitor the burn as it heals.

Let us consider one final scenario: Steven, a fifteen-year-old teenager, gets his appendix removed and is sent back home the next day. After an appendix surgery, it is customary for the doctor to check the incision and take a blood test to analyze the white blood cells count to make sure there is no internal or external infection. Instead of having to go to the hospital for a follow up appointment, Steven's life would be much easier if he could take his own blood test at home. *Orphidia* is a new technology that allows individuals to take a blood sample and have the data analyzed in the span of twenty minutes.[160]

The possibilities that emerging technologies give the patient are infinite; they can and will change the relationship a patient has with his doctor. From the previous scenarios, it is clear that mobile health apps would only be able to have a positive impact on the patient-physician relationship provided patient autonomy increases,[161] the technologies are safe, physicians recommend them, and patients use them more frequently. Through emerging technologies, regular patients, like Amy or Steven, will be able to "conduct tests in the privacy of their own homes using attachments or images on their cell

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160   ORPHIDIA, http://www.orphidia.com/(last visited Oct. 5, 2017).

161   Costa, *supra* note 11, at 94.

phone."[162] Similarly, patients with chronic diseases, like Ken, will also be able to have a similar luxury by being able to remotely monitor their condition and potentially make more informed health decisions with their doctors through constructive and informed conversations.[163]

In an interview on CBS, cardiologist Dr. Erik Topol described the monitor he recommends to many of his patients a mobile app used in conjunction with a sensor device attached to the smartphone.[164] He explained that this tool is not only practical for the patient, but it also saves time and reduces costs.[165] Topol explained that the patient would use the smartphone as a device to generate a cardiogram, and he also identified a situation where a patient may "feel like [their] heart is fluttering or missing beats."[166] Instead of going to the emergency room, they can pull up an app and place an additional device on the back of the phone.[167] The individual could place their thumbs on the sensors of the device, and, in seconds, the app would generate a cardiogram that could instantly be sent to the patient's doctor.[168] Topol explained that this app was a "game changer" in the way he practiced medicine, referring to a patient who sent him an email saying "I am in atrial fibrillation what should I do?"[169] He explained that prior to this use of technology, a patient in that situation would have to go to the ER and undergo several tests that would be costly and time consuming, but now in a split second—from anywhere—a patient can get an accurate reading.[170]

With mobile health applications, the patient-physician relationship will also be affected, as patients have the ability to analyze their own health in real time by performing lab tests at home. Patients

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[162] *Id.*

[163] *Id.*

[164] CBS This Morning, *The Patient Will See You Now: How Mobile Technology Empowers Change in Medicine*, YOUTUBE, https://www.youtube.com/watch?v=mj7tndUxFXM (Jan. 6, 2015).

[165] *Id.*

[166] *Id.* at 1:22, 1:39.

[167] *Id.* at 1:20.

[168] *Id.* at 1:30.

[169] *Id.* at 2:00.

[170] *Id.* at 2:10.

will have the opportunity to directly receive the results of their tests before sending them to their doctor,[171] meaning that visits to the doctor's office will decrease. In addition to changing the way medicine is practiced, mobile technology enables health care providers with the "ability to expand care to individuals in areas where hospitals and doctors are sparse,"[172] for instance, via the use of telemedicine.

Mobile health is being adopted because of the belief that it will help "reduce medical errors, improve quality care and save lives."[173] Mobile health would improve quality of care by gathering patient data in shorter timeframes, allowing patients and care providers to use this data to better tailor, coordinate, and avoid duplicative or unnecessary care.[174] Another reason for adopting mobile health is that it will decrease health care spending by preventing the progression of serious illnesses through faster and earlier diagnosis.[175] Mobile health is also believed to have the ability to decentralize medicine by shifting central care from medical facilities towards a digitally empowered patient,[176] enabling the patient to have autonomy on monitoring his or her own health and decreasing visits to the doctor.

Therefore, the face-to-face relationship between a patient and his physician will change, but not disappear, because "patients will always crave and need the human touch of a doctor."[177] The face-to-face relationship will definitely be reduced, where patients will go to the doctor yearly instead of regularly,[178] or the visits will be done through a smartphone or a tablet.[179]

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[171] Costa, *supra* note 11, at 94.

[172] *Id.*

[173] Cortez, *supra* note 7, at 1177.

[174] *Id.* at 1192–93.

[175] *Id.* at 1177.

[176] *Id.*

[177] Topol, *supra* note 107, at 100.

[178] Costa, *supra* note 11, at 95.

[179] Hugh Chapin, *A Pittsburgh Health Network Uses Telemedicine via iPads*, NYMIHA (Feb. 13, 2015), http://ems.sinaiem.org/health-information-technology/a-pittsburgh-health-network-uses-telemedicine-via-ipads/ ("Pittsburgh's Allegheny Health Network started using iPads to connect patients to doctors. This form of telemedicine allows physicians to provide direct care to patients before they go to the hospital. Most importantly, this method gives EMS the

2. *The FDA's stance has a demonstrable effect on the way the industry will be shaped with emerging technologies*

To understand the impact mobile health will have on the industry, it is important to look at the regulations that govern the technology. According to an article published in the Annals of Health Law, the development of mobile medical apps will face three challenges: "(1) regulatory issues concerning the accuracy of applications that diagnose medical conditions; (2) protection of patient information security and HIPAA and; (3) the growing need for patient involvement."[180] These three challenges will directly impact the patient-physician relationship.

Professor of Law Cortez suggests that the FDA should be actively regulating mobile health technology because in addition to facilitating the use of the technologies, the FDA has to ensure that they are safe and effective.[181] However, Cortez contends that "the FDA is adopting the same posture it did when it was first confronted with medical device software twenty years ago by adopting a nonbinding guidance document that is largely unenforceable."[182]

In 2015, the FDA released a nonbinding guidance report regarding Mobile Medical Applications, where they took a liberal stance on mobile medical applications without many restrictions.[183] Within the health care industry, the FDA regulates medical devices,[184] but does not regulate mobile applications, unless the mobile application's "functionality could pose a risk to a patient's safety if the mobile app

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opportunity to get the patients who need to go to the hospital there and bringing those that would be better suited for specialized care to the right facility.").

[180] Costa, *supra* note 11, at 91.

[181] Cortez, *supra* note 7, at 1178–79.

[182] *Id*. at 1180.

[183] *See generally* U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, (Feb. 9, 2015), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/UCM263366.pdf.

[184] *Id*. at 4. Section 201(h) of the FDCA defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory […] that is intended for use in the diagnosis of disease or conditions, or in the cure, mitigation, treatment or prevention of disease in man. *Id*. at 7.

were to not function as intended."[185] The FDA guidance gives examples of the types of mobile medical apps it considers to be subject to regulatory oversight.[186] According to Cortez, Mobile health applications can be categorized as connectors, replicators, automators, customizers, loggers and trackers.[187] This is relevant in understanding where the FDA would apply, where the guidance would apply, or if the FDA applies at all.

Connectors are applications that connect the smartphone to FDA-regulated devices, which amplifies the devices functionalities.[188] Replicators are types of applications that would turn the smartphone into a medical device by "replicating the functionality of an FDA-regulated device."[189] For example, using the phone's built in microphone to amplify body sounds, or turning the iPhone into a cardiac monitor.[190] These types of applications would be subject to FDA regulatory oversight.

Automators and customizers are the types of applications that help in making clinical decisions by using questionnaires, algorithms or other software parameters.[191] These apps are beneficial to physicians and patients alike. For example, in the context of surgery to help the anesthesiologist determine the precise dose of anesthesia, while patients may use this type of app for potential diagnosis by entering symptoms and laboratory values.[192]

Loggers and trackers are the most common apps used today. They are the apps that "allow users to log, record, and make final decisions about their general health and wellness."[193] These apps are usually

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[185] *Id.* at 4.

[186] *Id.* at 13–14 ("Mobile apps that are an extension of one or more medical devices . . . mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens or sensors . . . and mobile apps that become a regulated medical device (example a software) by performing patient-specific analysis.").

[187] *See generally* Cortez, *supra* note 7.

[188] *Id.* at 1182.

[189] *Id.* at 1184.

[190] *Id.* at 1184–85.

[191] *Id.* at 1186.

[192] *Id.* at 1187.

[193] *Id.* at 1189.

considered to be low risk[194] apps by the FDA, which means that instead of being subject to regulatory oversight, the FDA "intends to exercise enforcement discretion."[195]

Some legal and medical experts believe that for the protection of patients, the FDA needs to expand the regulation of medical mobile applications past those that are considered medical devices.[196] The reason being that if the majority of applications are not regulated, as "safe and effective" as they are, there is no enforcement mechanism to ensure that they do what they claim they are meant to do.[197]

C. Privacy Concerns

In addition to the lack of regulations with regards to mobile health applications, a major concern regarding mobile health is the privacy implications and data security. Mobile health is most commonly associated with fitness trackers.[198] Runners or people trying to lose weight commonly use it to track their miles, their routes, their calories or their food intake.[199] Some apps count steps, others can also remind you when to drink water.[200] It can be assumed that most of these apps know everything about the user.[201] In the majority of cases, the user would input their name, age, weight and contact into the app to be able to use it.[202] The data is then stored. The major problem with these apps is that the data is not subject to protection under the FDA nor HIPAA

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[194] U.S. FOOD & DRUG ADMIN., *supra* note 183, at 16.

[195] *Id*. at 15.

[196] *See* Costa, *supra* note 11, at 92; *see also* Terry & Wiley, *supra* note 65, at 65.

[197] Stephen Spotswood, *Dermatology Mobile Technology Burgeons; VA Has New App on Drawing Board*, COMPENDIUM FED. MEDICINE (2014), http://www.usmedicine.com/agencies/departme nt-of-veterans-affairs/dermatology-mobile-technology-burgeons-va-has-new-app-on-drawing-board/.

[198] Hazard, *supra* note 34, at 447.

[199] *Id*. (explaining that, in a specific scenario, a health data application could create a diary of an individual's runs and monitor their daily calories and water consumption).

[200] *Id*. at 458 ("[S]martphones have become consumers' 'life line' as they are not only for personal use but work, family, finances and now health.").

[201] *Id*. at 466.

[202] *Id*. at 447.

because the FDA regards these apps as lower risk apps[203] and HIPAA only protects data involving covered entities.[204] In most cases, users are unaware that the sensitive personal data they share to their smartphones can and may be accessible by external parties[205] since users are unaware that their data lack regulatory protection. As a result, patient privacy and data security become a significant concern as app downloads continue to increase.

At the heart of the debate is the fact that medical apps are not protected by HIPAA—the federal privacy law that controls the way doctors and health care providers store and share patients' health information.[206] To determine whether a software or an application falls under the HIPAA rules "two questions need to be answered: (1) Who will be using the application and (2) What information will be on the application?"[207] Generally, HIPAA is concerned with the Protected Health Information (PHI), which would only be protected when the information is in the possession of a "covered entity" and business associates.[208] Therefore, a mobile app that is for use by patients is not going to fall under HIPAA, as this mobile app that is used to assist the user with following a medication schedule, inputting fitness activities, or monitoring their blood glucose or blood pressure levels is not a covered entity.[209] However, when a patient starts sending information to his physician, the application itself would not be subject to HIPAA, but as soon as the information sent is received by the covered physician, the information will be subject to HIPAA.[210]

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[203] *See* U.S. FOOD & DRUG ADMIN., *supra* note 183, at 16.

[204] *Id.*

[205] Hazard, *supra* note 34, at 447.

[206] U.S. DEP'T OF HEALTH & HUMAN SERVICES, *Summary of the HIPAA Privacy Rule,* 2–3, HHS.GOV, (2015), https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.

[207] Adam H. Greene, *When HIPAA Applies to Mobile Applications*, MOBILE HEALTH NEWS (June 16, 2011), http://www.mobihealthnews.com/11261/when-hipaa-applies-to-mobile-applications.

[208] A covered entity is one of the following: (1) a health care provider; (2) a health plan; or (3) a healthcare clearinghouse. 45 CFR 164.04; Health Information Privacy, U.S. DEP'T OF HEALTH & HUMAN SERVICES, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html?language=es.

[209] *Id*.

[210] *Id*.

An additional privacy concern with regards to a patient's health information stored on one's smartphone, is the risk that the device may be stolen or lost with the patient's health data and the ease at which patients may share information with their physician by email. While the AMA guidelines suggest that doctors follow an email communication protocol[211] and while doctors must comply with HIPAA, there are still significant privacy concerns when patients and physicians share private information through emails.

Privacy concerns with regards to user friendly and accessible mobile health applications hinder the applications from being fully embraced by patients and physicians. For example, "according to a survey performed, [forty-nine percent] of individuals interviewed believed that consumer wariness and privacy concerns would be a barrier to the adoption of mobile health applications."[212] In addition to consumers, "if doctors do not believe the applications to be safe, they will not use them in their practice, which could stop the mobile health movement before it truly begins."[213] Therefore, it is critical that privacy concerns be addressed in order to facilitate a full acceptance of and to maximize the benefits of mobile health applications.[214] The FDA could address this concern by drafting "a privacy policy that will provide a consumer with a transparent view of how their information is being disclosed and collected."[215] Another way would be to provide consumers "with a choice on whether or not they would like to share personal information."[216] In addition, Congress should also step up and revise HIPAA regulations.[217] HIPAA regulations and FDA regulations need to be consistent with one another and need to address the existing gaps in order to secure and keep medical data private.[218]

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[211] Mangalmurti et al., *Medical Malpractice in the Age of Electronic Health Records*, *supra* note 12, at 2063.

[212] Costa, *supra* note 11, at 93. *See generally* Klotz, *supra* note 4.

[213] Costa, *supra* note 11, at 93.

[214] *See generally* Hazard, *supra* note 34.

[215] Hazard, *supra* note 34, at 468.

[216] *Id*.

[217] *Id*. at 472.

[218] *Id*.

As long as patient safety and privacy are a concern to physicians, the number of physicians who choose to use medical mobile applications will likely remain relatively low.[219] Until physicians can be sure that confidential patient information is safe they will be reluctant to introduce medical mobile applications into their practice.[220] As beneficial as these apps are, if patients feel that their privacy is not being respected, their benefit will be outweighed by their cost to privacy.

D. Where do Physicians Stand Today? Solutions and Predictions to the Future of their Practice and Expectations

In a world where the future of the patient-physician relationship is changing, many wonder what physician malpractice liability will look like in situations where a physician treated a patient negligently without ever meeting the patient. According to Professor of Law, Terry and Wiley, "Malpractice, product liability law, and privacy liability remain primarily case law driven, but at this stage in the development of mobile health there is a dearth of case law directly on point."[221] In an article for the Annals of Health Law, the Terry and Wiley contend that the introduction of mobile health technologies does not require the development of legal doctrines and that existing doctrines, such as, tort or privacy law, can be applied with regards to the development, use, and recommendations of the health apps.[222]

However, issues may occur with the malpractice standard of care, which could slow down the adoption of mobile health technologies by professionals.[223] Nevertheless, if over time these technologies "prove useful and reliable, they could be incorporated into the standard of care in some contexts."[224] If these technologies are incorporated, then "the customary-practice standard of care might accelerate adoption of mobile health technologies by recalcitrant physicians who would

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[219] Costa, *supra* note 11, at 93–94.

[220] Costa, *supra* note 11, at 94–95.

[221] Terry & Wiley, *supra* note 74, at 65.

[222] *Id*.

[223] *Id*. at 64–65.

[224] *Id*. at 65.

otherwise face potential liability for failing to make use of applications that have been incorporated into the prevailing practices of the profession."[225]

As different types of apps would pose different types of risks, the exposure and liability would vary depending on the role of the potential defendant.[226] The role of the defendant could vary from physician to health care facility, or from application developer to physician involved in the development of the app[227] or the defendant could also be a simple app user.

Generally, to hold a physician liable for malpractice, the plaintiff must establish four elements: duty, breach, damages, and causation.[228] The difficulty with mobile technology will be establishing duty. To establish a duty, "the plaintiff must establish that a treatment relationship was in effect at the time of breach, and such that the defendant health care professional owed a duty of care to plaintiff patient."[229] Duty will be difficult to establish because of the difficulty in proving that a patient-physician relationship was formed through the use of mobile health technology. However, case law suggests that "a physician-patient relationship can be formed with quite minimal contact between the physician and patient, or even in the absence of any direct contact between the two at all."[230] In those scenarios, the main questions are whether medical judgment has been exercised with regard to a particular patient's case and whether declining to provide medical opinion is necessary to rebut the formation of patient-physician relationship.[231]

To determine whether or not a physician-patient relationship was formed in the telemedicine context, courts have usually allowed the jury to make a determination on a case-by-case basis relating to the

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[225] *Id*.

[226] *Id*. at 69.

[227] *Id*. at 69–70.

[228] *Id*. at 70.

[229] *Id*.

[230] *Id*. at 71.

[231] *Id*. at 71–72.

specific facts of each case.[232] For example, in one case, a Vermont court found that a one-time consultation was sufficient to form a patient-physician relationship, and, as result, a duty of care was established.[233] Today, courts in all fifty states would likely conclude that a patient-physician relationship was established through a telecommunication consultation.[234]

While the use of mobile health apps is prominent and increasing, physicians' liability for malpractice will still necessitate proof of the four elements of negligence. The analysis will be reached the same way it has for the past several decades, until courts decide to adapt to this increasing usage of mobile health technologies, change their analysis, and adopt a lower the standard of care.

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[232] *Id.*

[233] *Id.* at 72–73.

[234] Senate Bill 1107 made Texas the latest state to allow a patient-physician relationship to form via telecommunication without the need for a face-to-face encounter. Comstock, *supra* note 56.

CONCLUSION

Since the introduction of the Internet, patients have used it to research medical information. Patients have also increased their involvement in monitoring their health through the use of smartphones and mobile health applications. Overall, the health care industry is accepting of the rise of mobile health technology because it gives patients the ability to make their own medical decisions with a physician by their side. However, the extent to which the patient-physician relationship will change still remains uncertain. The FDA and lawmakers will play a pivotal role in answering this question by deciding whether or not mobile health applications will be regulated, and by filling in the gaps with regards to privacy concerns.

Finally, while patients will keep downloading and using mobile health apps, physicians may not be as keen to recommend them unless they are certain of their accuracy, reliability and safety. Physician liability in a malpractice lawsuit is also contingent on the way lawmakers approach the issues surrounding mobile health technology. As of today, even though the relationship is changing, the current standard of care applied remains the same. However, as more patients rely on their smartphones for medical diagnosis, malpractice liability for physicians still remains an uncertainty.