

**Seton Hall University**  
**eRepository @ Seton Hall**

---

Law School Student Scholarship

Seton Hall Law

---

5-1-2013

# Apps As Medical Devices: Utilizing One of Computer Technology's Newest Inventions for the Advancement of Medicine and the Healthcare System

Lauren Schmale Estacio

Follow this and additional works at: [https://scholarship.shu.edu/student\\_scholarship](https://scholarship.shu.edu/student_scholarship)

---

## Recommended Citation

Estacio, Lauren Schmale, "Apps As Medical Devices: Utilizing One of Computer Technology's Newest Inventions for the Advancement of Medicine and the Healthcare System" (2013). *Law School Student Scholarship*. 216.  
[https://scholarship.shu.edu/student\\_scholarship/216](https://scholarship.shu.edu/student_scholarship/216)

APPS AS MEDICAL DEVICES: UTILIZING ONE OF COMPUTER TECHNOLOGY'S NEWEST INVENTIONS  
FOR THE ADVANCEMENT OF MEDICINE AND THE HEALTHCARE SYSTEM

by Lauren Estacio

**INTRODUCTION**

Mounting stress on America's healthcare system calls for reform that can handle the country's growing population and increasing medical needs. Such reformation must take advantage of rapid innovation and improving technology that can be applied in the healthcare field, which subsequently will improve overall physician efficiency and patient care. In fact, it is estimated that, between 2010 and 2020, the bulk of U.S. federal debt will be from Medicare and Medicaid.<sup>1</sup> The answer to avoiding, or at least limiting, a negative impact of healthcare governance is not as simple as increasing the number of healthcare facilities and professionals to match increases in population and need. For example, in Denmark two decades ago, there were over 150 hospitals for its population of five million.<sup>2</sup> Since then, the country has improved the quality and availability of outpatient primary care services, and decreased the number of hospitals by over fifty percent to seventy-one.<sup>3</sup>

Exploiting the ever-expanding world of technology can help alleviate the burden on and of the healthcare system, and help American healthcare evolve into a more efficient system like that in Denmark. This will both improve patient care and patient health, and increase the efficiency of healthcare providers. One such solution is to use technology to gather and analyze large amounts of data in order to locate and better serve those sectors of society – whether

---

<sup>1</sup> Jeffrey Brenner, Executive Director, Camden Coal. of Healthcare Providers, Address at the 2011 Seton Hall University School of Law Law Review Symposium: Implementing the Affordable Care Act: What Role for Accountable Care Organization? (Oct. 28, 2011).

<sup>2</sup> Atul Gawande, *The Hot Spotters: Can We Lower Medical Costs by Giving the Neediest Patients Better Care?*, New Yorker, Jan. 24, 2011, available at [http://www.newyorker.com/reporting/2011/01/24/110124fa\\_fact\\_gawande](http://www.newyorker.com/reporting/2011/01/24/110124fa_fact_gawande).

<sup>3</sup> *Id.*

delineated by age, geographic location, or medical condition – that put substantial economic and treatment strain on the system. A second way is by providing physicians and other healthcare providers with programs that help them more accurately and quickly diagnose patients in order to dispense the proper treatment. Although both of these solutions elicit various privacy concerns, with the proper regulation and administration, the healthcare field can in this way harness the power of the internet and technology to help achieve and advance America’s healthcare goals for the future.

Part I of this paper presents a background of the history of the use of technology in the healthcare field. Part II explores the current use of computer programs and applications by healthcare professionals, as well as the potential impact of this technology on patient care and the U.S. healthcare system. Finally, Part III will examine the regulation of medical apps, including the role of the U.S. Food and Drug Administration, and the implications of this regulation on the future use of medical mobile apps in the healthcare field.

## **I. THE HISTORICAL DEVELOPMENT OF TECHNOLOGY IN THE HEALTHCARE FIELD**

### **A. The Historical Role of Science in Medicine**

Technology as a general term can take on many meanings and be applied in a variety of ways. According to Merriam Webster’s dictionary, technology is “the practical application of knowledge especially in a particular area” and “a capability given by the practical application of knowledge.”<sup>4</sup> Technology can be applied to knowledge, systems, objects, and activities.<sup>5</sup> In the healthcare field, it can impact the way the system is run on a micro and macro level, the knowledge bank of the human species and the diseases and conditions that affect it, and the

---

<sup>4</sup> *Technology Definition*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/technology> (last visited March 27, 2013).

<sup>5</sup> Joel D. Howell, *Diagnostic Technologies: X-Rays, Electrocardiograms and CAT Scans*, 65 S. Cal. L. Rev. 529, 530 (1991).

devices used to diagnose, treat, and cure.

The influence of ever-evolving technologies is not a new phenomenon. In fact, technology has not only influenced but has largely shaped the development of medicine and the healthcare field for centuries. In ancient Egypt, Imohep was not only a trusted advisor to the pharaoh Djoser and the architect of his tomb, he was one of the world's first physicians.<sup>6</sup> Around 2600 BC, Imohep recorded the identification of and treatment for two hundred diseases, and extracted medicines from plants.<sup>7</sup> Throughout the centuries that followed, scholars continued to study human anatomy and disease.<sup>8</sup>

In the modern world, significant technological advances began around 1800. The stethoscope, for example, was invented in Paris in 1816 by French physician René Laennec.<sup>9</sup> Prior to Laennec's invention, doctors would listen to a patient's heart by placing their ear against the patient's chest, an act especially uncomfortable – and sometimes flat-out unacceptable – between male physicians and female patients, especially in the case of young female patients.<sup>10</sup> When presented with one such patient whose “great degree of fatness” interfered with Laennec's ability to listen to her faltering heart, he used what he knew about acoustics and sound to develop an instrument which has evolved into the heart-listening device that we call a stethoscope today.<sup>11</sup> Although once a novelty, a stethoscope can now be seen hanging around the necks of nearly every physician walking the halls of a hospital.

Despite the continuous influence of technology on medicine for centuries, between 1890

---

<sup>6</sup> *Imohep*, BBC, [http://www.bbc.co.uk/history/historic\\_figures/imhotep.shtml](http://www.bbc.co.uk/history/historic_figures/imhotep.shtml); Imohep, WIKIPEDIA, <http://en.wikipedia.org/wiki/Imhotep>; *Timeline of Medicine and Medical Technology*, WIKIPEDIA [http://en.wikipedia.org/wiki/Timeline\\_of\\_medicine\\_and\\_medical\\_technology](http://en.wikipedia.org/wiki/Timeline_of_medicine_and_medical_technology).

<sup>7</sup> *Imohep*, *supra* note 6.

<sup>8</sup> *Timeline of Medicine and Medical Technology*, *supra* note 6.

<sup>9</sup> Austin Flint, *Notices of Books: The Life and Labors of Laennec*, 3 N.Y. MED. PRESS 1, 109 (1860), available at <https://play.google.com/store/books/details?id=isJXAAAAMAAJ&rdid=book-isJXAAAAMAAJ&rdot=1> (summarizing the publication of Laennec's 1859 address at the New Orleans School of Medicine).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

and 1930, science became more central to the practice of medicine, and with that, technology consequently became a significantly more integral part of the field.<sup>12</sup> This fact is hardly surprising; during this same period, people worldwide became fascinated by science and innovation as it brought them the telephone, automobile, and airplane.<sup>13</sup> Indicative of the growing interest in – and excitement about – the role of science in medicine, noted physician Benjamin Rush stated that “medicine is my wife, but science is my mistress.”<sup>14</sup> Physical machines, such as the x-ray machine, were physical manifestations of this science.<sup>15</sup> These devices were used by both practicing physicians and medical students, and bridged the gap between the study of medicine in laboratories and textbooks and in the field at a patient’s bedside.<sup>16</sup>

## **B. How Informed Consent Helped To Push The Integration Of Technology And Medicine**

Furthermore, not only did physicians become more interested in the use of technology and machines in their field, patients began to *expect* doctors to use these tools in caring for them.<sup>17</sup> In fact, it was during this period that patients’ rights began to be acknowledged by U.S. courts.<sup>18</sup> Although informed consent and patient participation are expected parts of healthcare today, both are relatively new ideas in the history of medicine. In ancient Greece, it was considered undesirable for patients to be involved in the decision making process with regards to their health because, it was feared, information about potential negative consequences would

---

<sup>12</sup> Howell, *supra* note 5, at 531.

<sup>13</sup> *Id.* at 531-32.

<sup>14</sup> *Id.* at 531.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> Peter M. Murray, M.D., *The History of Informed Consent*, 10 IOWA ORTHOPEDIC J. 104, 104-08 (1990), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2328798/pdf/iowaorthj00024-0107.pdf> (citing numerous cases that showcase courts’ increasing recognition of patient rights).

erode patients' trust in the physicians.<sup>19</sup> During medieval times, although doctors were encouraged to offer patients comfort and hope, they were actively encouraged to be deceitful and manipulative with patients.<sup>20</sup> A shift began during the Era of Enlightenment when views emerged that patients were able to listen to and understand doctors, and were therefore capable of taking a more active role in their healthcare.<sup>21</sup> The dominate view persisted however, and many continued to believe that deception was necessary for successful patient care.<sup>22</sup> In the 1800s, the medical world became split over whether or not patients should be informed about an unfavorable prognosis.<sup>23</sup>

Under the English common law, the torts of assault and battery formed the basis for today's informed consent doctrine.<sup>24</sup> Battery is a criminal offense involving unauthorized contact, and assault is an attempt to commit a battery or the intention or creation of an apprehension in the mind of the victim of such unlawful contact.<sup>25</sup> Thus, if a patient does not consent to procedures by his doctor, such as a surgery, he should have recourse under the doctrine of battery.

Throughout the twentieth century, the concept and duty of informed consent – and a patient's right to informed consent – gained acceptance.<sup>26</sup> Courts began to recognize a patient's right to be involved and make decisions about his health.<sup>27</sup> In a 1914 opinion, Justice Benjamin Cardozo expressed his position that a patient should play an active role in the decision making process about his health, stating that:

---

<sup>19</sup> *Id.* at 104.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Murray, *supra* note 18, at 104, 109.

<sup>25</sup> Model Penal Code §§ 210-213 (1962); Restatement (Second) of Torts §§ 13, 21 (1965).

<sup>26</sup> Murray, *supra* note 18, at 104-08 (citing numerous cases that showcase courts' increasing recognition of patient rights).

<sup>27</sup> *Id.*

every human being of adult years in sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits a battery for which he is liable in damages.<sup>28</sup>

Despite Justice Cardozo's statement and similar court holdings in following decades,<sup>29</sup> it was not until 1973 that the American Hospital Association instituted a Patient Bill of Rights.<sup>30</sup>

Today's informed consent doctrine is a patient-centered approach whereby both general risks, and risks that may be of importance to the specific patient, are disclosed. Such factors that must be revealed include a patient's diagnosis, the nature and purpose of the proposed treatment, potential risks, and possible alternatives.<sup>31</sup> The Institute of Medicine, a non-profit organization that aims to advise decision makers and the public,<sup>32</sup> views this patient-centeredness approach as representing "care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions."<sup>33</sup> Furthermore, the American Board of Internal Medicine includes patient autonomy as one of the three fundamental principles of its new definition of physician professionalism.<sup>34</sup> Patients now have a voice. Although the physicians of centuries past worried that this unveiled approach would weaken the doctor-patient relationship, it in fact strengthens it and increases the likelihood that decisions will more accurately reflect the needs, preferences, and values of each individual patient.<sup>35</sup>

Just as early-twentieth-century patients began to expect their doctors to use the latest

---

<sup>28</sup> *Schloendorff v. Soc'y of N.Y. Hosp.*, 211 N.Y. 125, 129-30 (N.Y. 1914).

<sup>29</sup> *See, e.g., Canterbury v. Spence*, 464 F.2d 772 (D.D.C. 1972) (holding that doctors must disclose to patients any potential harms and benefits of a surgery before the operation and in plain English).

<sup>30</sup> Michael L. Millenson & Juliana Macri, *Will the Affordable Care Act Move Patient-Centeredness to Center Stage?*, URBAN INST. (2012), available at <http://www.rwjf.org/qualityequality/product.jsp?id=74054>.

<sup>31</sup> Kristin Madison, *Patients as "Regulators?" Patients' Evolving Influence Over Health Care Delivery*, 31 J. OF LEGAL MED. 9, 11 (2010).

<sup>32</sup> *About the IOM*, INST. OF MED., <http://www.iom.edu/About-IOM.aspx> (last visited Mar. 27, 2013).

<sup>33</sup> INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> CENTURY* 3 (2001).

<sup>34</sup> Millenson & Macri, *supra* note 30 (citing Amer. Board of Internal Med., et al., *Medical Professionalism in the New Millennium: A Physician Charter*, ANNALS OF INTERNAL MED. (2002), available at <http://annals.org/article.aspx?articleid=474090>).

<sup>35</sup> Madison, *supra* note 31.

technology, today's patients will likewise expect healthcare providers to keep up with technology. In fact, a recent study by the Optum Institute, an organization aimed at reshaping healthcare systems around the world,<sup>36</sup> found that patients are more willing and able than their healthcare providers to use the latest medical-related technology.<sup>37</sup> In fact, Americans today are seeking more high-tech medical tests and surgeries than ever before.<sup>38</sup> The increased use of technology via computers and the internet will only further strengthen the patient-physician bond and ultimately improve patient care and have a positive impact on the U.S. healthcare system.<sup>39</sup>

### **C. Current Use Of The Internet And Technology In Today's Society**

The demand by patients that their healthcare providers utilize the internet and new internet-related technologies is no surprise: these patients likely access the internet for a variety of daily activities. In fact, Nielsen recently reported that “[e]ach month consumers are spending more time with more media, across all devices under the sun.”<sup>40</sup> The number of Americans with internet access has more than doubled since 2000.<sup>41</sup> According to a 2012 Nielsen report, approximately 274 million Americans – or nearly ninety percent of the population – now have access to the internet.<sup>42</sup> In fact, a Google executive recently estimated that every person on Earth

---

<sup>36</sup> *About, OPTUM*, <http://www.optum.com/about/> (last visited Mar. 27, 2013).

<sup>37</sup> *Patients Expect More From Physicians' Health IT Offerings*, MEDIVO (Oct. 3, 2012) <http://www.medivo.com/2012/10/patients-expect-more-from-physicians-health-it-offerings/>.

<sup>38</sup> Sharyn Alfonsi & Courtney Hutchinson, *More Americans Using High-Tech Medicine, CDC Finds*, ABC World News (Feb. 7, 2010), <http://abcnews.go.com/Health/Wellness/technology-medicine/story?id=9864930> (citing that the number of high-tech medical tests and surgeries dramatically increased between 1996 and 2006).

<sup>39</sup> *See, e.g.*, Interview by Mayo Clinic with Dr. Farris Timimi, Director, Mayo Clinic Center for Social Media, Rochester, Minn. (Mar. 24, 2012), <http://newsblog.mayoclinic.org/2012/03/24/farris-timimi-m-d-discusses-the-role-and-use-of-social-media-in-healthcare/> (stating that, today, there is great interest in healthcare being a shared process between physicians and patients, and that new tools like social media help make this a reality).

<sup>40</sup> Nielsen, *Exploring the Consumer Media Universe*, NIELSEN WIRE (Jan. 7, 2013), <http://www.nielsen.com/us/en/newswire/2013/exploring-the-consumer-media-universe.html>.

<sup>41</sup> Nielsen, *Detailing the Digital Revolution: Social, Streaming and More*, NIELSEN WIRE (Feb. 24, 2012), available at [http://blog.nielsen.com/nielsenwire/media\\_entertainment/detailing-the-digital-revolution-social-streaming-and-more/](http://blog.nielsen.com/nielsenwire/media_entertainment/detailing-the-digital-revolution-social-streaming-and-more/).

<sup>42</sup> *Id.*; U.S. & World Population Clock, U.S. CENSUS BUREAU (last visited Mar. 28, 2013 12:25 AM), <http://www.census.gov/main/www/popclock.html>.



will be “online” by the year 2020.<sup>43</sup> Americans spend on average three hours and fifty-eight minutes per week accessing the internet on a computer, while Americans age 25-34, 35-49, and 50-65 spend approximately six, six, and five hours per week on the internet, respectively.<sup>44</sup> Furthermore, between February 2011 and March 2012, the percent of U.S. mobile subscribers that use smartphones as opposed to simple cellular phones that do little more than make and receive calls and text messages increased thirty-eight percent.<sup>45</sup> As of Nielsen’s January 2013 report, fifty-six percent of U.S. mobile subscribers use smartphones.<sup>46</sup> Of those Americans who acquired a new mobile device between December 2011 and February 2012, more than two-thirds chose smartphones over simple cellular phones.<sup>47</sup> Unsurprisingly, some of these Americans are healthcare providers; one such physician recently told the New York Times that he carries with him and uses his iPhone while at work.<sup>48</sup>

The use and dependency on the internet in the U.S. will likely only continue to increase. As a result, the internet is increasingly becoming a key new way technology can be utilized in the healthcare field. The internet has already become a source for health-related information for general American public. Search engines such as Yahoo! and Google put a wealth of information from a variety of sources at the patient’s fingertips in seconds. A Google search for

---

<sup>43</sup> Doug Gross, *Google Boss: Entire World Will be Online by 2020*, CNN (Apr. 15, 2013), [http://www.cnn.com/2013/04/15/tech/web/eric-schmidt-internet/index.html?hpt=hp\\_t3](http://www.cnn.com/2013/04/15/tech/web/eric-schmidt-internet/index.html?hpt=hp_t3).

<sup>44</sup> Nielsen, *State of the Media: Consumer Usage Report 2011*, NIELSEN WIRE, available at <http://www.slideshare.net/infopik/state-of-media-consumer-usage-report-nielsen-2011> (last visited Mar. 28, 2013).

<sup>45</sup> Nielsen, *Smartphones Account for Half of all Mobile Phones, Dominate New Phone Purchases in the US*, NIELSEN WIRE (Mar. 29, 2012), [http://blog.nielsen.com/nielsenwire/online\\_mobile/smartphones-account-for-half-of-all-mobile-phones-dominate-new-phone-purchases-in-the-us/](http://blog.nielsen.com/nielsenwire/online_mobile/smartphones-account-for-half-of-all-mobile-phones-dominate-new-phone-purchases-in-the-us/); Milt Freudenheim, *As Smartphones Become Health Aids, Ads May Follow*, N.Y. TIMES (Apr. 1, 2012), <http://www.nytimes.com/2012/04/02/technology/as-smartphones-become-health-aids-ads-may-follow.html>.

<sup>46</sup> *Exploring the Consumer Media Universe*, supra note 40; Nielsen, *State of the Media: Consumer Usage Report 2012*, NIELSEN WIRE, available at <http://www.slideshare.net/Briancrotty/nielsen-us-consumer-usage-report-2012>.

<sup>47</sup> *Smartphones Account for Half of all Mobile Phones*, supra note 45.

<sup>48</sup> Katie Hafner, *Redefining Medicine With Apps and iPads*, N.Y. TIMES (Oct. 8, 2012), available at [http://www.nytimes.com/2012/10/09/science/redefining-medicine-with-apps-and-ipads-the-digital-doctor.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2012/10/09/science/redefining-medicine-with-apps-and-ipads-the-digital-doctor.html?pagewanted=all&_r=0).

“abdominal pain,” for example, provides the searcher with over 9.3 million links.<sup>49</sup> Three of the top four links are to information on the websites of reputable healthcare websites, namely WebMD, the governmental National Institutes of Health (NIH), and the Mayo Clinic; the fourth link is to an article on Wikipedia, an online encyclopedia of user-generated content that is arguably becoming a more trusted site.<sup>50</sup> Moreover, what is unique about this search is that, next to the top search results, a framed box – created by Google – appears; this contains a brief description of “abdominal pain,” links to various related pages on the trusted NIH website, potential related conditions, and a warning to consult a doctor if you have a medical concern.<sup>51</sup>

Various websites have also been developed to cater to internet users who seek information regarding medical issues. One in particular is the aforementioned WebMD, a U.S. corporation that is funded by advertising on its site, sponsorships, and third-party contributions.<sup>52</sup> In 2012, it generated \$469.9 million in revenue.<sup>53</sup> Its dominance in the field is evidenced by the more than 117 million people that visit the site each month.<sup>54</sup> WebMD provides patients with a wealth of information that ranges from the serious (“What is Type 2 Diabetes?”) to the less serious (“Keys to a Successful Nose Job”).<sup>55</sup> The information that WebMD provides is a

---

<sup>49</sup> Search for Abdominal Pain, GOOGLE, google.com (enter “abdominal pain” in search bar; then follow search hyperlink).

<sup>50</sup> *Id.* When conducting a Google search, a user is most likely to click on one of the first three results; if the user researching abdominal pain strays from this and chooses the fourth result, he will still be led to accurate information. Danny Goodwin, *Top Google Result Gets 36.4% of Clicks*, SEARCH ENGINE WATCH (Apr. 21, 2011), <http://searchenginewatch.com/article/2049695/Top-Google-Result-Gets-36.4-of-Clicks-Study>.

<sup>51</sup> Search for Abdominal Pain, *supra* note 49.

<sup>52</sup> *WebMD Announces Fourth Quarter and Year End Financial Results*, PR NEWswire, Feb 23, 2012, <http://www.prnewswire.com/news-releases/webmd-announces-fourth-quarter-and-year-end-financial-results-140202573.html>.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* After enjoying several years of dominance in the market, WebMD was surpassed in advertizing revenue, and thus traffic, by newbie Everyday Health. EVERYDAY HEALTH, <http://www.everydayhealth.com/>; Matthew Flamm, *Everyday Health Closes in on WebMD’s Online Dominance*, CRAIN’S N.Y. (June 10, 2012), <http://www.craigslist.com/article/20120610/SUB/306109984>.

<sup>55</sup> See generally WEBMD, [www.webmd.com](http://www.webmd.com).

combination of original material and material from other providers it deems credible.<sup>56</sup> Its staff is comprised of both medical and non-medical professionals who provide information and frequently check the site for accuracy to ensure that its readers receive the right information.<sup>57</sup> Patrons of WebMD can search the site with the same ease and expediency that they can with Google, and be confident that the information they receive is reliable. Sites like WebMD also allow users to participate in interactive blogs on which they can discuss health concerns with healthcare professionals and other site users. To cater to the millions of smartphone users, these sites also offer “apps,” often for free, that allow a user to easily access their information from virtually anywhere.<sup>58</sup> Today’s patients can easily access information – relatively accurate information – regarding an array of medical conditions in a matter of seconds. The mounting use of the internet and technology by Americans to access medical-related information suggests a general approval of and encouragement that healthcare professionals follow suit. Such use can improve the quality and efficacy of patient care, and effectuate an overall improvement in the U.S. healthcare system.

## **II. CURRENT USE OF COMPUTER APPS IN HEALTHCARE**

### **A. Increasing Use Of Mobile Technology By Healthcare Professionals At Work**

The website Wikipedia, previously mentioned in Part I.C, has an article entitled “Timeline of Medicine and Medical Technology.”<sup>59</sup> As is obvious from its title, that article lists

---

<sup>56</sup> *What We Do For Our Users*, WEBMD, <http://www.webmd.com/about-webmd-policies/about-what-we-do-for-our-users> (last modified Nov. 22, 2011).

<sup>57</sup> *Editorial Policy*, WEBMD, <http://www.webmd.com/about-webmd-policies/about-editorial-policy> (last modified May 11, 2012).

<sup>58</sup> WebMD, for example, offers several free “apps,” including ones specifically for pregnancy, allergies, and pain control. *Experience WebMD on the Go Via Your Smartphone or Tablet*, WEBMD, <http://www.webmd.com/mobile> (last visited May 9, 2013). The WebMD app was recently named one of the top fifty must-have iPad apps. Doug Aamoth, *50 Must-Have iPad Apps*, TIME (Apr. 12, 2013), <http://techland.time.com/2013/04/15/50-must-have-ipad-apps/slide/webmd/>.

<sup>59</sup> *Timeline of Medicine and Medical Technology*, *supra* note 6.

dozens of major technological advances in medicine since 2600 BC.<sup>60</sup> On that timeline, sandwiched between the 1968 development of controlled drug delivery, and the 1969 invention of the balloon catheter, is the Advanced Research Project Agency's creation of the internet.<sup>61</sup> As detailed in Part I.C, above, patients already realize the internet's ability to impact their personal participation in their own health (or that of a friend or relative). Based on the statistics that indicate high and frequent internet use among Americans,<sup>62</sup> it is highly likely that healthcare professions are internet users in their personal lives. Yet, despite this high level of tech-intelligence, healthcare professionals have yet to fully harness the power of the internet and computer programs in their work. For purposes of this paper, the term "computer app" will refer to any program, typically downloaded from the internet onto a mobile device (smartphone or tablet computer) and run by computer software that allows its user to search the program's content and/or perform a function that, after inputting data, will yield a result.<sup>63</sup> This definition is not restricted to only those apps that require internet-access to function.

The notion that computer apps are the next new frontier in medical technology is becoming more realized by the healthcare field. While only fifty-nine percent of physicians used smartphones in 2006, a 2010 study revealed that that figure jumped to ninety-four percent; this statistic today is nearly one hundred percent.<sup>64</sup> Furthermore, the overwhelming majority of

---

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *See supra* Part I.C.

<sup>63</sup> For purposes of this paper, this definition excludes programs used to create and maintain patient charts, input and analyze patient data, and other similar internal programs used by healthcare facilities. Such programs, however, may still be mentioned herein.

<sup>64</sup> Elizabeth Armstrong Moore, *Study: Doctors Choosing iPhone Over Blackberry*, CNET (Jul. 27, 2010), [http://news.cnet.com/8301-27083\\_3-20011813-247.html](http://news.cnet.com/8301-27083_3-20011813-247.html); *Vitera Healthcare Solutions Study Indicates That the Majority of Healthcare Professionals Are Interested in a Mobile EHR Solution*, VITERA HEALTHCARE SOLUTIONS (Aug. 13, 2012), [http://www.viterahealthcare.com/company/Pages/pr\\_ViteraHealthcareSolutionsStudyIndicatesThattheMajorityofHealthcareProfessionalsAreInterestedinaMobileEHRSolution.aspx](http://www.viterahealthcare.com/company/Pages/pr_ViteraHealthcareSolutionsStudyIndicatesThattheMajorityofHealthcareProfessionalsAreInterestedinaMobileEHRSolution.aspx).

smartphone-using physicians prefer the app-friendly iPhone and iPad over the Blackberry.<sup>65</sup> The iPhone's biggest competitors, such as Samsung's Galaxy phones and Android phones, are also app-compatible and provide the user with easy access to the internet. Moreover, approximately seventy-two percent of physicians already use their mobile device in some professional capacity, twenty-percent of whom use their devices to perform medical research.<sup>66</sup>

Additionally, a recent study found that seventy-one percent of nurses already use their smartphones on the job, while sixty-six percent of nursing students reported using their smartphones in their studies.<sup>67</sup> Eighty-five percent of the nurses and students polled in 2012 also reported that they wanted an app version of the Nursing Drug Handbook. In response, publisher Lippincott Williams & Wilkins released the 2013 edition of the handbook both in print and as an app, which is available for purchase and download from a number of sites, including the Apple App Store, Amazon for download to a Kindle, and Google Play for non-Apple phones.<sup>68</sup>

Healthcare facilities are also encouraging their employees to log on to this technology. The Beaumont Health System in Metro Detroit, Michigan, for example, gave an iPad to each of its more than three thousand physicians in 2012.<sup>69</sup> The Beaumont network includes three hospitals and numerous nursing homes, outpatient facilities, and doctors offices throughout the

---

<sup>65</sup> Moore, *supra* note 64; *Vitera Healthcare Solutions Study*, *supra* note 64.

<sup>66</sup> *Vitera Healthcare Solutions Study*, *supra* note 64.

<sup>67</sup> *As Smartphone Usage Expands, Survey Says Nurses and Nursing Students Want Mobile Access to Credible Drug Data*, WOLTERS KLUWER HEALTH (Apr. 26, 2012), <http://www.wolterskluwerhealth.com/News/Pages/As-Smartphone-Usage-Expands,-Survey-Says-Nurses-and-Nursing-Students-Want-Mobile-Access-to-Credible-Drug-Data.aspx>.

<sup>68</sup> *Nursing 2013 Drug Handbook*, [https://www.lww.com/webapp/wcs/stores/servlet/product\\_Nursing2013-Drug-Handbook\\_11851\\_-1\\_12551\\_Prod-9781451150230?cm\\_sp=PE-NSG-Pharmacology--Bestseller-Nursing--Two-NoPromo-NDH13-NoOffer](https://www.lww.com/webapp/wcs/stores/servlet/product_Nursing2013-Drug-Handbook_11851_-1_12551_Prod-9781451150230?cm_sp=PE-NSG-Pharmacology--Bestseller-Nursing--Two-NoPromo-NDH13-NoOffer). Rival publisher McGraw-Hill also created the Nurse's Drug Handbook and Nurse's Drug Pocket Guide apps last year. *Nurse's Drug Handbook*, [https://play.google.com/store/apps/details?id=com.mobisystems.msdict.embedded.wireless.mcgrawhill.ndh2011.full&feature=related\\_apps#?t=W251bGwsMSwyLDEwOSwiY29tLm1vYmlzeXN0ZW1zLm1zZGljdC5lbWJlZGRlZC53aXJlbGVzcy5tY2dyYXdoaWxsLm5kaDIwMTEuZnVsbCJd](https://play.google.com/store/apps/details?id=com.mobisystems.msdict.embedded.wireless.mcgrawhill.ndh2011.full&feature=related_apps#?t=W251bGwsMSwyLDEwOSwiY29tLm1vYmlzeXN0ZW1zLm1zZGljdC5lbWJlZGRlZC53aXJlbGVzcy5tY2dyYXdoaWxsLm5kaDIwMTEuZnVsbCJd).

<sup>69</sup> Telephone Interview with Dr. Timothy Schmale, Anesthesiologist, MEDNAX, INC. (Mar. 24, 2013); Beaumont Physician Practice Opportunities, BEAUMONT HEALTH SYS., <http://www.beaumont-doctor.com>.

several counties it serves.<sup>70</sup> Beaumont is arguably on the forefront of healthcare’s technology movement; its patient records are fully electronicized and accessible by all company physicians in all Beaumont-affiliated facilities.<sup>71</sup> Although the iPads the physicians received were not pre-loaded with any apps other than those that come standard on all iPads, likely for liability reasons, Beaumont’s actions clearly send the message to its doctors that it expects them to keep up with the newest technology available in medicine.<sup>72</sup> Other healthcare facilities have followed suit. Cedars-Sinai Medical Center, Doylestown Hospital, and Mt. Sinai Medical Center are all “iPhone hospitals.”<sup>73</sup> Thus, as healthcare professionals and facilities see the potential impact mobile devices can have on their field, the next step is for companies and software developers to bring them the apps that can make this happen.

## **B. Useful Apps For Healthcare Professionals**

As Americans increasingly use – and, sometimes, depend on – various apps throughout their personal lives, it is no surprise that healthcare professionals are looking for this type of technology for use in the workplace. Medical apps generally can be divided into four categories: reference tools, diagnostic tools, education, and patient records,<sup>74</sup> and there currently are thousands of healthcare-related apps available for download.<sup>75</sup> In fact, there are so many medical apps available that one company released a review in late-2012 of what it considers the

---

<sup>70</sup> *Centers & Services*, BEAUMONT HEALTH SYS., <http://www.beaumont.edu/services-programs> (last visited Mar. 28, 2013).

<sup>71</sup> Interview with Dr. Timothy Schmale, *supra* note 69.

<sup>72</sup> *Id.*

<sup>73</sup> Brian Dolan, *AT&T Highlights 3 iPhone Hospitals*, MOBIHEALTH NEWS (Feb. 3, 2010), <http://mobihealthnews.com/6379/mhi-att-highlights-3-iphone-hospitals/>; *see also* iPhone in Business, *Profile: Doylestown Hospital*, APPLE, <http://www.apple.com/iphone/business/profiles/doylestown/> (last visited Mar. 28, 2013).

<sup>74</sup> Dolan, *AT&T Highlights 3 iPhone Hospitals*, *supra* note 73.

<sup>75</sup> Benjamin Jelle Visser & Jonathan Bouman, *There’s A Medical App For That*, MEDSCAPE NEWS (May 8, 2012), <http://www.medscape.com/viewarticle/763009> (citing the availability of over 10,000 apps for Apple devices and over 3300 Android apps for non-Apple devices at time of publication).

top *eighty* healthcare apps.<sup>76</sup> Whether this list is exhaustive of all healthcare apps currently available, or is truly a list of the top apps among dozens more that did not make the cut, it is clear that healthcare professionals already have a variety of programs to choose from to aid their work – and a single iPhone has the capability of storing dozens of apps at once.

In addition to the growing availability of digital copies of medical books, such as The Merck Manual,<sup>77</sup> a plethora of apps currently in regular use by healthcare professionals are information-based. Medscape Mobile, by WebMD, a trusted company in the healthcare field, is a favorite encyclopedia-type app among physicians and millions of medical students.<sup>78</sup> As the top medical app download of 2010,<sup>79</sup> Medscape enable its user to research medical conditions and procedures, has a drug interaction checker, and provides users with medical formula calculators.<sup>80</sup> As physicians in the past would have to retreat to a backroom to flip through medical books and journals when confronted with a difficult question at a patient’s bedside, healthcare professionals with an iPhone with Medscape Mobile can perform a quick search on the app and provide answers to patients who, in today’s internet-connected world, do not expect to wait for answers. Because of the plethora of information in medicine today, and the sheer volume of information taught during medical and nursing school, a healthcare professional can “know” and be able to dispense more information to patients regarding diagnosis, prognosis, and treatment than ever before. This is especially true if a doctor of nurse is confronted with a

---

<sup>76</sup> Brian Dolan, *Apple’s Top 80 Apps For Doctors, Nurses, Patients*, MOBIHEALTH NEWS (Nov. 27, 2012), <http://mobihealthnews.com/19206/apples-top-80-apps-for-doctors-nurses-patients/>.

<sup>77</sup> *Id.*

<sup>78</sup> Interview with Dr. Timothy Schmale, *supra* note 69 (reporting that Medscape is a popular tool among his colleagues); Telephone Interview with Andrew Schmale, Student, MICHIGAN STATE UNIVERSITY SCHOOL OF MEDICINE (Mar. 26, 2013); Visser & Bouman, *supra* note 75; *Medscape – Probably The Best Android Medical App of All Time*, DOCTOR TIPSTER, <http://www.doctortipster.com/13232-medscape-probably-the-best-android-app-of-all-time.html> (last visited Mar. 28, 2013). Another similar popular reference app is Epocrates; it claims that it is used by over fifty percent of physicians. Interview with Dr. Timothy Schmale, *supra* note 69 (reporting that Medscape is a popular tool among his colleagues); Dolan, *Apple’s Top 80 Apps For Doctors, Nurses, Patients*, *supra* note 76.

<sup>79</sup> Dolan, *Apple’s Top 80 Apps For Doctors, Nurses, Patients*, *supra* note 76.

<sup>80</sup> *Medscape Mobile Tools & Features*, MEDSCAPE MOBILE, <http://www.medscape.com/public/mobileapp/features#drugReference> (last visited Mar. 28, 2013).

condition beyond the scope of his or her specialty: in using reference apps, a physician of specialty A may detect symptoms that should be reviewed by a physician of specialty B, thereby enabling the patient to receive a diagnosis and treatment earlier than he would have otherwise received, potentially saving his life.

Not only can reference apps help healthcare professionals diagnose and treat patients, they can also help improve the quality of treatment dispensed. There are several free apps on the market that assist users in calculating and converting units of drugs.<sup>81</sup> MedCalc, developed by two physicians, is available in both a \$1.99 basic version and \$4.99 “Pro” version.<sup>82</sup> It provides users with over two hundred formulas, scales, scores, and classifications, into which users can plug data to get the required result.<sup>83</sup> Although this app was simply created by two physicians, and not a top medical organization or company, it is highly rated – and trusted – by physicians.<sup>84</sup> Apps like MedCalc provide healthcare professionals with more formulas, and thus the ability to dispense more drugs and other treatments, more quickly and accurately than they otherwise would be able to. Furthermore, even for simple or common calculations, physicians can use MedCalc to further ensure their accuracy and limit errors.<sup>85</sup> In past years, by far the most common mistakes made in medicine have been dosage errors made in dispensing medication.<sup>86</sup> With the advent of and easy access to apps like MedCalc, such errors will likely be limited.

Furthermore, apps that target specific specialties that inherently involve a lot of calculations and

---

<sup>81</sup> Interview with Dr. Timothy Schmale, *supra* note 69.

<sup>82</sup> *App Reviews from Practicing Physicians: Medcalc*, MED. ECON. (Sept. 10, 2012), <http://medicaleconomics.modernmedicine.com/medical-economics/news/modernmedicine/modern-medicine-now/app-reviews-practicing-physicians-0>.

<sup>83</sup> *Development, MEDCALC FOR IOS*, [http://medcalc.medserv.be/iphone\\_credits.html](http://medcalc.medserv.be/iphone_credits.html) (last visited Mar. 28, 2013); *Description, MEDCALC FOR IOS*, [http://medcalc.medserv.be/iphone\\_description.html](http://medcalc.medserv.be/iphone_description.html) (last visited Mar. 28, 2013).

<sup>84</sup> *App Reviews from Practicing Physicians: Medcalc*, *supra* note 82; Interview with Dr. Timothy Schmale, *supra* note 69.

<sup>85</sup> *MedCalc*, iTUNES PREVIEW, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm> (last visited May 3, 2013).

<sup>86</sup> Interview with Dr. Timothy Schmale, *supra* note 69 (based on his knowledge and experience as a physician for nearly forty years).



formulas, such as anesthesia and chronic pain management, will further improve physician efficiency and accuracy, thereby enhancing the quality of patient care.

A third type of app, diagnostic tools, has begun to be developed but is not currently widely used in healthcare. Despite being an advocate for utilizing technology in medicine, Dr. Timothy Schmale, an anesthesiologist who has practiced at Beaumont for nearly four decades, is skeptical of the iPhone's diagnostic abilities.<sup>87</sup> When asked about the ability of the iPhone to replace his stethoscope, Dr. Schmale commented that,

I just don't see how the iPhone can work as well as the machines we have in the hospital. Sure, I always carry my iPad or iPhone with me, and they have a speaker and may have the ability to pick up a heartbeat, but I don't know how well that would work; I'm going to use my stethoscope.<sup>88</sup>

Recent advances in the creation of these apps, however, indicate that their use in the healthcare field may be closer than many think. One such app is the Remotoscope, an accessory that attaches to an iPhone and turns the device into an otoscope for inspecting inside a person's ear canal.<sup>89</sup> After inserting the accessory into the ear, the iPhone user can use the phone's camera function to view and snap photos of the inside of the patient's ear.<sup>90</sup> The Remotoscope may especially appeal to parents of children prone to ear infections. These parents can simply use the Remotoscope to take photos of their child's inner ear and send them to a pediatrician who can then make a diagnosis and, if necessary, call in a prescription to a pharmacy for the child. It is in this way that a patient can receive a diagnosis and treatment for a common condition, which, had a physical appointment with the doctor been made, would have been diagnosed in a matter of seconds. The use of apps like the Remotoscope will allow doctors to diagnose and

---

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> Andrew Liszewski, *Using Your iPhone to Detect Ear Infections Also Keeps the Doctor Away*, Gizmodo (Oct. 12, 2012), <http://gizmodo.com/5951195/using-your-iphone-to-detect-ear-infections-also-keeps-the-doctor-away>.

<sup>90</sup> *Id.*

treat more efficiently, providing them with more time for patients whose conditions require face time with a doctor.

Diagnostic apps also enable healthcare professionals to carry multiple tools contained in a single, four-ounce device in the palm of their hand.<sup>91</sup> The iStethoscope, for example, replaces the tool nearly all healthcare professionals own and use: the stethoscope. The app costs less than \$0.99 on iTunes and uses the iPhone's built-in microphone to detect, play, and record a patient's heartbeat.<sup>92</sup> The app also has a Heart Murmur Interpreter, Lung Sounds Interpreter, and Bowel Sounds Interpreter; these three functions lead the user through a step-by-step diagnosis process, which ends in an encyclopedic-like entry of the specific condition detected and suggested treatment options.<sup>93</sup> With the iStethoscope, the healthcare provider can save the file containing the patient's heartbeat to the patient's electronic medical record, or easily e-mail the file to another physician for a second opinion or to transfer the patient to a specialist.<sup>94</sup> The process can get the patient a faster and more accurate diagnosis and treatment, potentially saving his life. The ease of carrying a single, compact device with multiple functions will also permit healthcare providers to better assist patients in an emergency before additional help is available to them, and in rural or low-income areas where medical equipment is scarce or outdated.<sup>95</sup> This technology

---

<sup>91</sup> Figure based on the weight of an iPhone 5. *iPhone Tech Specs*, APPLE, <http://www.apple.com/iphone/specs.html> (last visited May 3, 2013).

<sup>92</sup> *iStethoscope Pro*, iTUNES PREVIEW, <https://itunes.apple.com/us/app/istethoscope-pro/id322110006?mt=8> (last visited May 3, 2013); Peter J. Bentley, *iStethoscope Pro*, PETER J. BENTLEY ONLINE, <http://www.peterjbentley.com/istethoscopepro.html> (last visited May 3, 2013). The "Expert Pro" version of the software is also available for download from iTunes for \$1.99. *iStethoscope Expert Pro*, iTUNES PREVIEW, <https://itunes.apple.com/us/app/istethoscope-expert-pro/id447933327?mt=8> (last visited May 3, 2013).

<sup>93</sup> See, e.g., Professor Nathan Cortez, Professor, Southern Methodist Law School, Mobile Health, Disruptive Innovation, and Regulatory Fortitude (Sept. 28, 2012), available at <http://prezi.com/arr5dspsyjaww/medical-apps-disruptive-innovation-and-regulatory-timing/> (displaying screenshots of these functions in use).

<sup>94</sup> Bentley, *supra* note 92.

<sup>95</sup> In fact, earlier this year, a physician named Eric Topol used the iPhoneECG app – an app similar to the iStethoscope that uses a sensor attachment to measure vital signs – on a man experiencing chest pains during a flight. Kevin Bostic, *Doctors See Apple's iPhone as Life Saver in "the Future of Medicine,"* APPLE INSIDER (Jan. 25, 2013, 2:37 pm), <http://appleinsider.com/articles/13/01/25/doctors-see-apples-iphone-as-life-saver-in-the-future->

will thus improve patient care in a variety of facilities across the entire country in a multitude of scenarios. This influence of medical apps will consequently make a positive impact on the future of the U.S. healthcare system.

### **III. THE REGULATION OF MOBILE MEDICAL APPS**

#### **A. Regulatory Background**

The U.S. Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services and is charged by Congress with the protection, promotion, and advancement of the U.S. public health.<sup>96</sup> As part of its responsibilities, the FDA regulates health- and wellness-related products, including vaccines, dietary supplements, pharmaceuticals, and medical devices.<sup>97</sup>

The regulation of medical devices is overseen by the Center for Devices and Radiological Health (CDRH), a division of the FDA.<sup>98</sup> This regulation includes issuing approvals and clearances for medical devices and alerting the public – and healthcare facilities and providers – to product recalls and other safety concerns.<sup>99</sup> The FDA defines a medical device as “an instrument, apparatus, implement, machine, contrivance . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . .”<sup>100</sup> A medical device can be a simple tool made for use at home, a surgical

---

of-medicine. Using the app, Dr. Topol detected that the man was having a heart attack and that an emergency landing was necessary. *Id.* Dr. Topol’s actions, and the iPhoneECG app, ultimately saved the man’s life. *Id.*

<sup>96</sup> 21 U.S.C.S. § 393 (2011).

<sup>97</sup> *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last modified June 21, 2012).

<sup>98</sup> *About the Center for Devices and Radiological Health*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm> (last modified Sept. 7, 2012). In this paper, when referring to the regulation of medical devices and mobile medical apps, the FDA and CDRH will be used interchangeably.

<sup>99</sup> *About the Center for Devices and Radiological Health*, *supra* note 98.

<sup>100</sup> 21 U.S.C.S. § 321(h)(2) (2013); *Is the Product a Medical Device?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm> (last modified Feb. 8, 2013).

instrument, or a state-of-the-art diagnostic machine.<sup>101</sup> Whether a device is subject to FDA regulation typically hinges on its intended use.<sup>102</sup> A device's intended use is determined by the objective intent of the person or entity that labels the device.<sup>103</sup> This and can be indicated by the device's advertising, statements made about the device, or other circumstances which indicate the intended purpose of the device.<sup>104</sup> If it is determined that a device's use is intended to aid in "the diagnosis . . . cure, mitigation, treatment, or prevention of disease," then it is a medical device subject to FDA regulation.<sup>105</sup>

The level of FDA regulation a device is subject to loosely correlates to its classification into one of three tiers of devices according to the risk associated with the device's use, with the Class III label designating the devices of the highest risk.<sup>106</sup> Most medical devices are classified as Class II devices.<sup>107</sup> Higher risk associated with a device generally indicates greater FDA oversight prior to market and commercial distribution.<sup>108</sup>

In addition to listing the device with the FDA and adhering to manufacturing controls, there are two pathways a medical device can take to effectuate proper registration prior to entry into the marketplace.<sup>109</sup> First, the device can receive 510(k) premarket clearance.<sup>110</sup> In order to

---

<sup>101</sup> *Products and Medical Procedures*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm> (last modified May 3, 2013).

<sup>102</sup> 21 C.F.R. § 801.4 (2013); *Classify Your Intended Use*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last modified Dec. 3, 2012).

<sup>103</sup> 21 C.F.R. § 801.4.

<sup>104</sup> *Id.*

<sup>105</sup> 21 U.S.C.S. § 321(h)(2).

<sup>106</sup> 21 U.S.C.S. § 360c; COMM. ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS & INST. OF MED., *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* 1, 3 (2011) [hereinafter IOM REPORT]; *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last modified Dec. 3, 2012).

<sup>107</sup> *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/resourcesforyou/consumers/ucm142523.htm> (last modified Apr. 24, 2009).

<sup>108</sup> IOM REPORT, *supra* note 106, at 3.

<sup>109</sup> 21 C.F.R. § 807.20; *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm> (last modified Mar. 5, 2013). *See generally* 21 U.S.C.S. § 360 (outlining the requirements necessary prior to commercial distribution).

receive 510(k) clearance, the device must be “substantially equivalent” to a predicate device.<sup>111</sup> To meet this requirement, the intended use of the new device must have the same intended use as that of a predicate device.<sup>112</sup> The new device and the predicate device must also have the same technological characteristics, as defined by the statute.<sup>113</sup> Alternatively, the FDA Secretary reviewing the application may find that the application demonstrates, through clinical or scientific data, that the device is a safe and effective device that will not raise safety or efficacy concerns not already addressed by the predicate device.<sup>114</sup> Once the FDA issues a letter of substantial equivalence, the device can be commercially distributed.<sup>115</sup> 510(k) clearance is the more common route for medical devices.<sup>116</sup>

The second path a medical device can take to get to market is Premarket Approval (PMA).<sup>117</sup> A mere one percent of devices enter the market via PMA.<sup>118</sup> All Class III devices must submit an application for PMA.<sup>119</sup> There is no substantially equivalent device on the market or listed by the FDA for devices that require PMA.<sup>120</sup> The PMA process is more in-depth than the 510(k) clearance process and requires clinical trials that demonstrate the safety and efficacy of the device.<sup>121</sup> In determining whether or not to approve an application for PMA, the reviewing Secretary will consider the conditions of use contained in the proposed labeling to

---

<sup>110</sup> 21 C.F.R. § 807.81; *Overview of Device Regulation*, *supra* note 109; *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last modified Sept. 3, 2010).

<sup>111</sup> 21 U.S.C.S. § 360c(i); *Overview of Device Regulation*, *supra* note 109.

<sup>112</sup> 21 U.S.C.S. § 360c(i)(1)(A).

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Overview of Device Regulation*, *supra* note 109.

<sup>116</sup> IOM REPORT, *supra* note 106, at 3, 85.

<sup>117</sup> 21 C.F.R. § 814; 21 U.S.C.S. § 360e.

<sup>118</sup> IOM report at 4.

<sup>119</sup> 21 U.S.C.S. § 360e.

<sup>120</sup> 21 C.F.R. § 814; *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm> (last modified Jan. 24, 2012).

<sup>121</sup> 21 C.F.R. §§ 814.2, 814.20(b)(3)(iv); *Premarket Approval (PMA)*, *supra* note 120.

evaluate the safety and effectiveness of the device.<sup>122</sup>

Most Class I and some Class II medical devices are exempt from establishing registration and thus do not require either 510(k) clearance or PMA.<sup>123</sup> Most Class II devices require 510(k) clearance and most Class III devices require PMA, however there is some overlap between the classes and requirements for registration.<sup>124</sup> If a device does not fall under the FDA definition of a medical device, then it is not subject to FDA regulation.<sup>125</sup>

### **B. Medical Mobile Apps And FDA Medical Device Regulation**

On its website, the FDA acknowledges that it is responsible for “oversee[ing] the safety and effectiveness of a *small subset* of mobile medical applications that present a potential risk to patients if they do not work as intended.”<sup>126</sup> This statement indicates that the FDA plans to regulate only a small portion of medical apps on the market. Considering the number of medical apps already on the market, a plethora of easily-accessible, unregulated medical apps could lead to inaccurate diagnoses and treatments.

Furthermore, although the FDA is aware of the existence and proliferation of mobile medical apps, it currently has no set policy on their regulation. The FDA defines a mobile app “as software programs that run on smartphones and other mobile communications devices.”<sup>127</sup> In July 2011, in a step toward defined regulation, the FDA released proposed draft guidelines on the regulation of mobile medical apps.<sup>128</sup> Through these draft guidelines, the FDA stated that,

---

<sup>122</sup> 21 U.S.C.S. § 360e(d)(1)(ii).

<sup>123</sup> *Class I/II Exemptions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm> (last modified Dec. 12, 2012).

<sup>124</sup> IOM REPORT, *supra* note 106, at 1, 3; *Overview of Device Regulation*, *supra* note 109.

<sup>125</sup> IOM REPORT, *supra* note 106, at 4.

<sup>126</sup> *Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm> (Dec. 22, 2011) (emphasis added).

<sup>127</sup> *Id.*

<sup>128</sup> U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF

for purposes of determining whether a medical app is an FDA-defined medical device, the “intended use” of a mobile app can be shown by “labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.”<sup>129</sup> The draft guidelines merely state that the FDA will regulate apps that meet the statutory definition of a medical device, and do not provide the public with examples of regulation-subject apps or intended uses.<sup>130</sup> The guidelines do, however, provide examples of apps that the FDA does not intend to regulate.<sup>131</sup> These excluded apps include electronic textbooks, apps that merely record or track a person’s general health or wellness, and apps that function as an electronic health record system or personal health record system.<sup>132</sup>

Although the FDA originally planned to release its final set of guidelines by October 2011, it has yet to do so; the FDA recently stated in a special hearing before Congress that it hopes to release them by September 2013.<sup>133</sup> The lack of set guidelines and uncertainty surrounding the FDA’s intended regulation scheme of medical mobile apps causes numerous problems for app developers, manufacturers, and users alike. First, this uncertainty makes it difficult for software developers to create apps that will meet the FDA’s standards, if necessary. Second, the lack of FDA guidelines lowers economic incentives for creators and inventors, and thus is likely to deter app developers from creating medical apps and stifle innovation.

To date, FDA has reviewed approximately one hundred applications for mobile medical

---

– MOBILE MEDICAL APPLICATIONS (Jul. 21, 2011), *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm> [hereinafter DRAFT GUIDELINES]; Regina V. Ram, *FDA Guidance on Mobile Medical Apps*, HEALTH REFORM WATCH (Sept. 1, 2011), <http://www.healthreformwatch.com/2011/09/01/fda-drafts-guidance-on-mobile-medical-apps/>.

<sup>129</sup> Ram, *supra* note 128.

<sup>130</sup> DRAFT GUIDELINES, *supra* note 128, at IV.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.* This is of little concern, at least with respect to textbooks, because textbooks are typically written, published, and distributed by reputable sources.

<sup>133</sup> Brian Dolan, *Five Things We Learned from the FDA’s Medical App Testimony*, MOBILE HEALTH NEWS (Mar. 21, 2013), *available at* <http://mobihealthnews.com/21202/five-things-we-learned-from-the-fdas-medical-app-testimony/>.

apps, or approximately twenty each year; all have been either Class I or Class II medical devices that have entered the market via the 510(k) clearance process.<sup>134</sup> This accounts for only one half of one percent of all the total medical device applications the FDA reviews each year.<sup>135</sup> This number is likely to increase once the final FDA guidelines are released and the certainty incentivizes app developers to create. However, this may not occur if the FDA's definition of an app as a medical device is narrowly construed so as to include only a small percentage of apps created and on the market. FDA oversight of an app will mitigate healthcare professionals' liability concerns. Without FDA regulation, healthcare professionals may find an app too risky for use, thereby decreasing the economic incentives for software developers to create apps that fall outside the FDA's domain. These non-FDA regulated medical apps could benefit patients, and their absence in the marketplace will have a detrimental effect on healthcare.

Two medical apps, both Class II medical devices, have received 510(k) clearance from the FDA for use by physicians.<sup>136</sup> The first, AirStrip OB, which received 510(k) clearance in 2009,<sup>137</sup> allows obstetricians to remotely access and analyze real time information for mothers and babies that is collected by fetal monitors and other labor and delivery machines.<sup>138</sup> The app's iTunes page explicitly states that it is "intended for use by Obstetricians who deliver

---

<sup>134</sup> *Id.* It is unlikely that a medical app will be classified as a Class III medical device. *Id.*

<sup>135</sup> *Id.*; Alexis Fotiu & Bronwyn Spira, *Regulation of Medical Apps by the FDA: What Qualifies as a "Medical Apps"*, FORCE THERAPEUTICS (Apr. 4, 2013), <http://blog.forcetherapeutics.com/regulation-of-medical-apps-by-the-fda-what-qualifies-as-a-medical-app/>.

<sup>136</sup> Ram, *supra* note 128. According to a 2012 report by Mobile Health News, an additional seventy-five medical devices with a mobile software component or companion app have received 510(k) clearance. Brian Dolan, *Analysis: 75 FDA-Cleared Mobile Medical Apps*, MOBILE HEALTH NEWS (Dec. 20, 2012), <http://mobihealthnews.com/19638/analysis-75-fda-cleared-mobile-medical-apps/>.

<sup>137</sup> Letter from Janine M. Morris, Acting Director, Division of Reproductive, Abdominal, and Radiological Devices, Office of Device Evaluation, Center for Devices and Radiological Health, to Mark Job, Reviewer, Airstrip Technologies, LP (Feb. 13, 2009), *available at* [http://www.accessdata.fda.gov/cdrh\\_docs/pdf9/K090269.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090269.pdf) [hereinafter FDA Airstrip Letter].

<sup>138</sup> AirStrip OB, iTUNES PREVIEW, <https://itunes.apple.com/us/app/airstrip-ob/id309381240?mt=8> (last visited May 3, 2013); *Sequoia Hospital Introduces Breakthrough Technology Connecting Doctors to Moms in Labor*, SEQUOIA HOSP. (Jul. 7, 2011), [http://www.sequoiahospital.org/Who\\_We\\_Are/Press\\_Center/216850](http://www.sequoiahospital.org/Who_We_Are/Press_Center/216850).



babies.”<sup>139</sup> The second app that has received 510(k) clearance by the FDA is Mobile MIM.<sup>140</sup> This app allows healthcare workers, such as radiologists and dosimetrists, to send and view medical images, such as X-rays or CAT scans, to physicians’ mobile devices.<sup>141</sup> It is not meant to replace a physical radiology workstation at a healthcare facility.<sup>142</sup>

While these apps are comparable to the aforementioned Remotoscope and iStethoscope in that they allow physicians to analyze a collection of patient data remotely on the iPhone, they differ in one key aspect. Neither AirStrip OB nor Mobile MIM actively retrieves data from the patient as both the iStethoscope and Remotoscope do. Furthermore, while the AirStrip OB app description states that its intended use is for an obstetrician<sup>143</sup> and the Mobile MIM app is intended to be used by those who review radiological medical images,<sup>144</sup> it can easily be argued that the Remotoscope is intended for use by a pediatrician or an Ear-Nose-Throat physician and thus requires 510(k) clearance. Consequently, it is difficult to imagine an app used by a physician in any way other than as a textbook or encyclopedia as not subject to FDA regulation. As technology improves, medical apps will become more innovative and advanced, and FDA regulation of medical apps will be of increasing importance.

Given the existence of apps that are arguably more invasive, and thus higher risk, than the two apps that have already received FDA 510(k) clearance, it appears doubtful that the FDA will – or should – regulate a mere “small subset” of mobile medical apps. Apps like the iStethoscope and Remotoscope have the ability to make a great impact on the U.S. healthcare

---

<sup>139</sup> AirStrip OB, *supra* note 138.

<sup>140</sup> Letter from Mary S. Pasel, Director, Division of Radiological Devices, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, to Lynn Hanigan, Quality Manager, MIM Software Inc. (Dec. 2, 2011), *available at* [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K112930.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/K112930.pdf) [hereinafter FDA MIM Mobile Letter].

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> FDA Airstrip Letter, *supra* note 137.

<sup>144</sup> FDA MIM Mobile Letter, *supra* note 140.

system by improving efficiency and streamlining patient care. Because FDA regulation helps ensure a device's safety and efficacy, and because healthcare providers are less likely to use non-FDA regulated devices, limited FDA regulation of mobile medical apps would stifle the potential effect app technology can have in healthcare.

### **C. The Importance of Regulation of Medical Apps Will Benefit Patients and the U.S. Healthcare System**

Medical Apps can – and, likely, will – play a vital role in the next frontier of U.S. healthcare. As a result, proper regulation is key to ensuring that this technology is optimized.<sup>145</sup> Because of the potential risks involved in medicine, and in light of both the FDA's and the CDRH's responsibility “for protecting and promoting the public health,”<sup>146</sup> the FDA should play an active role in the regulation of mobile medical apps.

FDA regulation of medical apps will encourage their use among healthcare providers. Although medical apps have the ability to impact patient care and physician efficiency, this will only occur if the apps dispense the correct information and work properly. An app that uses outdated information or improper formulas will thwart the positive impact of medical apps and could be dangerous. While trial and error will help weed out these apps, especially in the age of online product reviews, this is not enough and may occur only after someone is injured by improper or inaccurate treatment. As a result, medical professionals will be cautious when choosing whether or not to use a specific app, or any app at all, especially if they are worried about liability. FDA review and 510(k) clearance or PMA signals to healthcare providers that

---

<sup>145</sup> Proper privacy controls must also be used in conjunction with medical apps. This topic, however, is beyond the scope of this paper.

<sup>146</sup> *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last modified June 19, 2012).

the device is safe to use, and counters their liability concerns.<sup>147</sup> It also signals to patients that the app their physician is using has passed some level of scrutiny and is trustworthy.

In addition to FDA regulation, oversight by non-governmental entities in the healthcare field, such as the American Medical Association and American Nurses Association, can provide additional assurance of medical apps.<sup>148</sup> These organizations can test, rate, and review apps, recommend that certain apps be used (or not used), and communicate the healthcare field's needs to app developers and manufacturers. The organizations can also communicate with healthcare facilities when there is a vital problem with an app or a necessary software update available, and the facilities can, in turn, alert their employees. The FDA itself also has post-market surveillance controls in place to continue to monitor the safety and efficacy of medical device.<sup>149</sup> Increased oversight will improve the overall efficacy of medical apps. Involvement by agencies that healthcare providers trust will further encourage physicians and nurses to use these advantageous tools to make the impact that they are capable of.

## **CONCLUSION**

Technology and mobile apps are playing an increasing role in our everyday lives, and it comes as no surprise that apps for use in the healthcare field are the next frontier of healthcare. Medical apps are becoming more technologically advanced and thus more capable of making a greater impact on patient care and the U.S. healthcare system. In order to make such an impact, however, FDA regulation of the distribution and use of medical apps is of utmost importance to ensure an app's safety and efficacy. This will increase app use by healthcare providers, thereby

---

<sup>147</sup> Interview with Dr. Timothy Schmale, *supra* note 69 (explaining his colleagues' liability concerns with using medical apps).

<sup>148</sup> The involvement of such organizations in the development, manufacturing, and distribution of medical apps will also signal an app's dependability to a potential user. The Remotoscope, for example, was developed by researchers at Emory University and Georgia Tech. Liszewski, *supra* note 89.

<sup>149</sup> See generally *Strengthening Our National System for Medical Device Postmarket Surveillance*, U.S. FOOD & DRUG ADMIN. (Apr. 2013), <http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf>.

incentivizing the creation of more groundbreaking medical apps. Regulation and oversight will also help guarantee the accuracy of data and information used by apps, further ensuring that patients receive the right diagnoses and treatments. Utilizing the advantages of this technology can help improve the efficiency and effectiveness of medicine and patient care, and consequently alleviate the overburdened U.S. healthcare system.

Consequently, this article recommends that the final FDA guidelines on mobile medical apps clearly define a medical app subject to FDA medical device regulation, and that this definition encompasses more than a small subset of apps. This article also encourages oversight and review of medical apps by other organizations and individuals in the healthcare field, and advocates the continued development and use of medical apps by healthcare professionals for the advancement of patient care and the improvement of the U.S. healthcare system.