

Congress of the United States  
U.S. House of Representatives  
Committee on Small Business  
2361 Rayburn House Office Building  
Washington, DC 20515-6515

**Memorandum**

**To: Members, Small Business Subcommittee on Health and Technology**  
**From: Committee Staff**  
**Date: June 24, 2013**  
**Re: Hearing: "Mobile Medical App Entrepreneurs: Changing the Face of Health Care"**

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On Thursday, June 27, 2013 at 10:00 am in Room 2360 of the Rayburn House Office Building, the Small Business Subcommittee on Health and Technology will meet for the purpose of receiving testimony on mobile medical applications ("apps") founded by small businesses. The Subcommittee will hear testimony from witnesses on the growth of the industry and challenges faced by small app developers.

**I. Introduction**

For the first time, a majority of adults now own a smart phone,<sup>1</sup> an increase from 46% in 2012.<sup>2</sup> Our overall economy has yet to regain its footing, but the wireless communication sector appears to be thriving. Mobile devices and the apps related to them are said to have created over 500,000 jobs,<sup>3</sup> and global revenue for mobile apps<sup>4</sup> alone rose to \$25 billion<sup>5</sup> last year. Apps to help individuals monitor their health are a growing part of the industry; a recent survey found 11% of adults with cellular phones downloaded an app last year to help them manage their health.<sup>6</sup> Many of these innovations have been founded by entrepreneurs and small businesses. In the next few months, the Food and Drug Administration is expected to finalize some of its Food Drug and Cosmetic Act<sup>7</sup> and Patient Protection and Affordable Care Act<sup>8</sup> regulations that could affect these small businesses. This hearing will examine some of these innovators and their apps that are changing the face of health care.

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<sup>1</sup> See PEW INTERNET & AMERICAN LIFE PROJECT, PEW RESEARCH CENTER, ADULT GADGET OWNERSHIP (June 2013), *available at* [http://www.pewinternet.org/Static-Pages/Trend-Data-\(Adults\)/Device-Ownership.aspx](http://www.pewinternet.org/Static-Pages/Trend-Data-(Adults)/Device-Ownership.aspx).

<sup>2</sup> *Id.*

<sup>3</sup> CTIA AND THE APPLICATION DEVELOPERS ALLIANCE, *The Geography of the App Economy 2* (Sept. 2012), *available at* [http://files.ctia.org/pdf/The\\_Geography\\_of\\_the\\_App\\_Economy.pdf](http://files.ctia.org/pdf/The_Geography_of_the_App_Economy.pdf).

<sup>4</sup> The industry uses the terms "applications" and "apps" interchangeably. This memorandum will use the term "apps" unless quoting a source that uses the term "application."

<sup>5</sup> GARTNER CONSULTING INC. STUDY,<sup>5</sup> *available at* <http://my.gartner.com/portal/server.pt?open=512&objID=202&mode=2&PageID=5553&ref=webinar-rss&resId=2003121>.

<sup>6</sup> PEW INTERNET & AMERICAN LIFE PROJECT, PEW RESEARCH CENTER, HIGHLIGHTS OF THE PEW PROJECTS RELATED TO HEALTH AND HEALTH CARE, *available at* <http://www.pewinternet.org/Commentary/2011/November/Pew-Internet-Health.aspx>.

<sup>7</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938).

<sup>8</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter "health care law"].

## II. Mobile Medical Apps

Mobile medical apps are software programs that enable other hardware or software functions, such as smart phones and the Internet.<sup>9</sup> These apps did not exist before the iPhone was introduced in 2007.<sup>10</sup> According to one study, 500 million smartphone users will be using a health care app by 2015.<sup>11</sup>

The use of mobile medical apps for health-related purposes has increased as more individuals have taken an interest in managing their health. Apps are now available for everything from assisting with general health and wellness, such as tracking the distance and pace of running and walking,<sup>12</sup> to monitoring or measuring bodily functions, such as heart rate,<sup>13</sup> to diagnosing whether a skin lesion presents a risk.<sup>14</sup> Whether these products and services are or will be regulated by the FDA depends in large part on their intended use.

## III. Federal Regulation

At least three federal agencies, the FDA, along with the Office of the National Coordinator (ONC) for Health Information Technology in the Department of Health and Human Services, and the Federal Communications Commission, have roles in the regulation of health information technology. In addition, the Internal Revenue Service (IRS) will implement the health care law's medical device tax.

### A. Food and Drug Administration (FDA)

The FDA has been regulating medical devices for many years and medical device software for mobile platforms for many years.<sup>15</sup> With the prevalence of medical technology, FDA can be expected to increase its role.

FDA has the authority to regulate mobile medical apps that meet the definition of a medical device. According to the Food Drug and Cosmetic Act (FDCA), a medical device is:

An instrument, apparatus, implement, machine, contrivance,

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<sup>9</sup> W. ANDREW H. GANTT III, E-HEALTH, PRIVACY AND SECURITY LAW 298, American Bar Association Health Law Section (2<sup>nd</sup> ed. 2011) [hereinafter "E-HEALTH, PRIVACY AND SECURITY LAW"].

<sup>10</sup> DR. MICHAEL MANDEL, WHERE THE JOBS ARE: THE APP ECONOMY (Feb. 7, 2012), available at <http://www.technet.org/wp-content/uploads/2012/02/TechNet-App-Economy-Jobs-Study.pdf>.

<sup>11</sup> RESEARCH2GUIDANCE, GLOBAL HEALTH MARKET REPORT 2013-2017, available at <http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/>.

<sup>12</sup> One such app is RunKeeper, which calls itself "the personal trainer in your pocket," and states that it "makes tracking your workouts fun, social and easy to understand so you can improve the quality of your fitness," available at <http://runkeeper.com/>.

<sup>13</sup> An example is digifit, which says it "tracks cardio exercise, blood pressure, weight and sleep patterns" to provide "a complete view of essential aspects of your health." It is available at <http://www.digifit.com/>.

<sup>14</sup> Christopher Weaver, Apps Aim to Detect Skin Cancer, WALL ST. J., Jan. 18, 2013, available at <http://online.wsj.com/article/SB10001424127887323783704578245973988828066.html>. An example of this technology is skinvision, available at <https://skinvision.com/>.

<sup>15</sup> *Health Information Technologies: Administration Perspectives on Innovation and Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 113<sup>th</sup> Cong., (statement of Christy L. Foreman 5 (2013), available at <http://docs.house.gov/meetings/IF/IF02/20130321/100544/HHRG-113-IF02-Wstate-ForemanC-20130321-U1.pdf>).

implant, in vitro reagent, or other similar or related article, including any component, part, accessory, which is...intended [either] for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease... [or] to affect the structure or any function of the body of man or other animals....<sup>16</sup>

Whether a medical device should be regulated by FDA, then, turns on the product's intended use.<sup>17</sup> On July 21, 2011, FDA released draft guidance on the regulation of mobile medical apps.<sup>18</sup> In the guidance, FDA stated that it intended to regulate only mobile medical apps that meet the definition of "device" in the FDCA, and either: 1) is used as an accessory to a regulated medical device, such as a mobile app that allows medical personnel to view x-rays on a tablet to assist in making a diagnosis;<sup>19</sup> or 2) transforms a mobile platform into a regulated medical device.<sup>20</sup> The FDA also said that it does not consider mobile apps that are copies of medical textbooks, used to track health information, or to automate general office operations to be mobile apps.<sup>21</sup> Manufacturers of mobile medical apps are interested in preserving the ability of entrepreneurs to innovate and, at the same time, ensuring the health and safety of the public. Most would prefer not to have to submit products for FDA approval, since the average time to gain approval is about three years, and the average cost is \$75 million or more.<sup>22</sup>

In its effort to issue guidance that helps to clarify the products and services that it intends to regulate, FDA created additional issues. The initial guidance has been criticized by some stakeholders as confusing, vague, and a hindrance to small innovators and their funding.<sup>23</sup> It has now been nearly two years since the initial guidance was issued, and the lack of final guidance has also been cited as a problem. In March of 2013, FDA has said it hopes to issue final guidance by the end of the year.<sup>24</sup>

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<sup>16</sup> 21 U.S.C. § 321(h).

<sup>17</sup> E-HEALTH, PRIVACY AND SECURITY LAW at 299.

<sup>18</sup> FDA, DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF – MOBILE MEDICAL APPLICATIONS (July 21, 2011), *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm>.

<sup>19</sup> FDA, CONSUMER UPDATES, FDA PROPOSES HEALTH 'APP' GUIDELINES, *available at* <http://www.fda.gov/forconsumers/consumerupdates/ucm263332.htm>.

<sup>20</sup> *Id.* at 7. In the guidance, FDA defines mobile platform as "commercial, off-the-shelf (COTS) competing platforms, with or without wireless connectivity, that are handheld in nature." *Id.* Examples of mobile platforms are iPhones, Android phones, Blackberry phones, or tablet computers. A mobile application is defined as "a software application that is tailored to a mobile platform, but is executed on a server."

<sup>21</sup> *Id.* at 10.

<sup>22</sup> Joel White, *FDA's Assault on Mobile Technologies*, THE WASH. TIMES, Feb. 7, 2012, *available at* <http://www.washingtontimes.com/news/2012/feb/7/fdas-assault-on-mobile-technologies/>.

<sup>23</sup> IHEALTHBEAT, STAKEHOLDERS CONCERNED ABOUT FDA'S REGULATION OF MOBILE MEDICAL APPS, June 29, 2012, *available at* <http://www.ihealthbeat.org/articles/2012/6/25/stakeholders-concerned-about-fdas-regulation-of-mobile-medical-apps.aspx>. See also WHEN DOES AND APP NEED FDA'S BLESSING? NPR BLOGS, July 10, 2012, *available at* <http://www.npr.org/blogs/health/2012/07/10/155977692/when-does-an-app-need-fdas-blessing> (quoting American Enterprise Institute's Scott Gottlieb: "The problem is, if FDA steps into this field, it's going to create so much uncertainty for product developers that it's going to discourage a lot of investment and it's going to discourage a lot of programmers from getting into this space"). Presumably, many of these developers are entrepreneurs.

<sup>24</sup> *Hearing Before Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce*, 113<sup>th</sup> Cong. (2013) (statement of Christy L. Foreman, Director, Office of Device Evaluation, Center for Devices and

## B. Internal Revenue Service (IRS)

If mobile medical apps are subject to FDA regulation, they may also be subject to the Patient Protection and Affordable Care Act's<sup>25</sup> new 2.3% tax on the sale, importation or production of medical devices, which became effective on January 1, 2013.<sup>26</sup> The statute defines "taxable medical device" as any device (as defined in FDCA § 201(h)) intended for humans.<sup>27</sup> It exempts certain retail products that are generally purchased by consumers for individual use, such as eyeglasses, contact lenses and hearing aids (the "retail exemption"). IRC § 4191(b)(2). Other exemptions from the tax in the final rule are: products exported or destined for export; components sold for further manufacture; and products intended for nonhuman use.

On December 7, 2012, the IRS issued a final rule implementing the medical device tax.<sup>28</sup> Like the statute, the final rule limits the application of the tax and defines a taxable medical device as "a device listed with the FDA under 510(j) of the FDCA and 21 C.F.R. Part 807"<sup>29</sup> that is intended for humans. It, too, provides an exemption for eyeglasses, contact lenses, and hearing aids, and exempts items generally available to the public at retail for individual use.<sup>30</sup> In making the determination of whether a device qualifies for this exemption, the final rule retains the facts and circumstances test.<sup>31</sup> That test requires a balancing of factors, such as whether the device is purchased at retail, requires minimal or no training or is administered by a medical professional.<sup>32</sup> The final rule also stipulates that medical device tax payments must be made semi-monthly.<sup>33</sup> Taxpayers will report the tax on IRS Form 720 (Quarterly Federal Excise Tax Return).<sup>34</sup>

## C. Federal Communications Commission (FCC)

In 2012, FCC Chairman Julius Genachowski announced that the Commission would work toward implementing recommendations proposed by the mHealth Task Force, a group of wireless technology experts that FCC convened to facilitate the adoption of mobile medical technology.<sup>35</sup> The recommendations included urging FCC to continue its role in leading the adoption of mobile health technology and developing a health care stakeholder outreach plan.<sup>36</sup>

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Radiological Health, United States Food and Drug Administration), *available at* <http://www.fda.gov/NewsEvents/Testimony/ucm344395.htm>; *see also* WHEN DOES AN APP NEED FDA'S BLESSING? NPR BLOGS, July 10, 2012, *available at* <http://www.npr.org/blogs/health/2012/07/10/155977692/when-does-an-app-need-fdas-blessing>.

<sup>25</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter "health care law"].

<sup>26</sup> IRC § 4191 (2010).

<sup>27</sup> The statutory definition of "taxable medical device" is referenced in section III(A) of this memorandum.

<sup>28</sup> Taxable Medical Devices, 77 Fed. Reg. 72,924 (Dec. 7, 2012) (to be codified at 26 C.F.R. pt. 48), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29628.pdf>.

<sup>29</sup> *Id.* at 72,934.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 72,927.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 72,924.

<sup>34</sup> IRS Form 720 is available at <http://www.irs.gov/pub/irs-pdf/f720.pdf>. The instructions for IRS Form 720 are available at <http://www.irs.gov/pub/irs-pdf/i720.pdf>.

<sup>35</sup> FEDERAL COMMUNICATIONS COMMISSION, MHEALTH TECHNOLOGY TASK FORCE RECOMMENDATIONS (2012), *available at* <http://www.fcc.gov/document/fact-sheet-mhealth-task-force-recommendations>.

<sup>36</sup> *Id.*

The FCC recently released a new rule designed to promote innovation by encouraging a flexible approach in which the radio spectrum is made available. For example, under the rule, the agency will grant a new license to allow health care facilities such as hospitals to participate in clinical trials of new wireless medical technologies.<sup>37</sup> The FDA and FCC will be working together to formulate suggestions for a regulatory strategy.

#### IV. A Regulatory Framework for Mobile Medical Apps

The Food and Drug Administration Safety and Innovation Act,<sup>38</sup> enacted in 2012, requires the Secretary of Health and Human Services, through the FDA and in consultation with the Office of the National Coordinator for Health Information Technology and Federal Communications Commission, to prepare a report by January 2014 with a proposed strategy and recommendations for “an appropriate risk-based regulatory framework pertaining to health information technology, including mobile apps, that promotes innovation, protects patient safety and avoids regulator duplication.”<sup>39</sup> FDA and FCC have formed a working group to solicit input from stakeholders and others on regulatory options.<sup>40</sup>

#### V. Small Businesses and Mobile Medical Apps

According to a recent study, the market for mobile health services is likely to reach \$26 billion globally by 2017.<sup>41</sup> The same study reports that although the benefits of the industry have been discussed for years, developers are commercializing their products in high numbers.<sup>42</sup> According to the United States Small Business Administration, small firms created 67% of the net new jobs from 2009-2011.<sup>43</sup> Clearly, the app market is one that holds great promise for small businesses and job creation.<sup>44</sup>

App industry jobs can be found at both small and large businesses, in both tech and non-tech capacities, and in diverse locations.<sup>45</sup> One report concluded that most mobile apps are developed by one or two entrepreneurs,<sup>46</sup> and another found that the vast majority of the top app developers – 78% --

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<sup>37</sup> *Id.*

<sup>38</sup> Pub. L. No. 112-144, 126 Stat. 993 (2012).

<sup>39</sup> Pub. L. No. 112-144, § 618(a), 126 Stat. 993, 1063 (2012).

<sup>40</sup> *Health Information Technologies: Administration Perspectives on Innovation and Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 113<sup>th</sup> Cong.*, (statement of Christy L. Foreman 7-8 (2013), available at <http://docs.house.gov/meetings/IF/IF02/20130321/100544/HHRG-113-IF02-Wstate-ForemanC-20130321-U1.pdf>).

<sup>41</sup> RESEARCH2GUIDANCE, GLOBAL MOBILE HEALTH MARKET REPORT 2013-2017 (Mar. 2013), available at <http://www.research2guidance.com/the-market-for-mhealth-app-services-will-reach-26-billion-by-2017/>.

<sup>42</sup> *Id.*

<sup>43</sup> OFFICE OF ADVOCACY, UNITED STATES SMALL BUSINESS ADMINISTRATION, FREQUENTLY ASKED QUESTIONS (SEPT. 2012), available at [http://www.sba.gov/sites/default/files/FAQ\\_Sept\\_2012.pdf](http://www.sba.gov/sites/default/files/FAQ_Sept_2012.pdf).

<sup>44</sup> APPS ACROSS AMERICA, ASSOCIATION FOR COMPETITIVE TECHNOLOGY 3, July 18, 2012, available at <http://actonline.org/files/Apps-Across-America.pdf>

<sup>45</sup> DR. MICHAEL MANDEL, THE GEOGRAPHY OF THE APP ECONOMY 4 (Sept. 30, 2012), available at [http://files.ctia.org/pdf/The\\_Geography\\_of\\_the\\_App\\_Economy.pdf](http://files.ctia.org/pdf/The_Geography_of_the_App_Economy.pdf),

<sup>46</sup> Katie McAuliffe, CongressBlog, THE HILL, March 2013, available at <http://thehill.com/blogs/congress-blog/healthcare/286923-dont-allow-medical-device-taxation-on-smartphones-tablets-and-apps>.

are small businesses, with large businesses comprising only 22%.<sup>47</sup> However, this data also showed that many of the apps credited to “large businesses” were not built in-house, but were instead sub-contracted out to smaller app development companies.<sup>48</sup>

American developers make up 59% of apps sold here, but foreign developers are gaining ground.<sup>49</sup> There is particular opportunity for small app developers in international markets such as China. In fact, in a recent study, the 35<sup>th</sup> most popular paid app in China was designed by an American small company.<sup>50</sup> Although concern has been expressed about the lower prices developers are paid each time an app is purchased in China, they still see the enormous potential in that market.<sup>51</sup>

Although the industry has rapidly developed, it is far from mature.<sup>52</sup> Some startups have emerged solely to help app developers launch their companies.<sup>53</sup> And some small mobile app developers are targeting small businesses in the health sector that might benefit from their apps.<sup>54</sup> Because entrepreneurs have found innovating in the digital health industry especially challenging, there are accelerators and incubators to assist them with mentoring, strategy and sometimes office space and funding.<sup>55</sup> Small app developers seem poised to capitalize on an industry that is robust, rapidly expanding and creating jobs.

## VI. Conclusion

The increasing prevalence of mobile devices and medical apps for them reflects the public’s desire to take a more active role in managing their health. Because this is such a burgeoning field, and so many developers of apps are entrepreneurs, it is particularly important to balance the need for protecting the public’s safety with the need for innovation.

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<sup>47</sup> ASSOCIATION FOR COMPETITIVE TECHNOLOGY, APPS ACROSS AMERICA: THE ECONOMICS AND ECOSYSTEM OF THE MOBILE APP MARKET 2, July 18, 2012, available at <http://actonline.org/files/Apps-Across-America.pdf>. In the United States, employment by app developers appears to be greatest in California, New York, and Washington. DR. MICHAEL MANDEL, WHERE THE JOBS ARE: THE APP ECONOMY 10 (Feb. 7, 2012), available at [http://files.ctia.org/pdf/The\\_Geography\\_of\\_the\\_App\\_Economy.pdf](http://files.ctia.org/pdf/The_Geography_of_the_App_Economy.pdf).

<sup>48</sup> *Id.* at 4.

<sup>49</sup> *Id.* at 7.

<sup>50</sup> The app is “tap tap tap,” created by Camera+ in San Francisco. *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 2.

<sup>53</sup> Main Street Apps in Jersey City, New Jersey helps developers customize an app and pay based on the number of customers they have. Stacy Jones, *Jersey City Startup Creates Build-An-App Platform for Small Business Owners*, N.J. STAR-LEDGER, March 24, 2013, available at [http://www.nj.com/business/index.ssf/2013/03/jersey\\_city\\_startup\\_wants\\_apps.html](http://www.nj.com/business/index.ssf/2013/03/jersey_city_startup_wants_apps.html).

<sup>54</sup> *Id.*

<sup>55</sup> One such organization is Blueprint Health in New York: <http://www.blueprinthealth.org/>; another is RockHealth in San Francisco: <http://rockhealth.com/>.