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**Written Statement of**

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**Before the**

**House of Representatives**

**Committee on Energy and Commerce**

**Subcommittee Communications and Technology**

**Hearing on**

# "Health Information Technologies: Harnessing Wireless Innovation"

**March 19, 2013**

# Testimony of George S. Ford, PhD

## Chief Economist, Phoenix Center for Advanced Legal & Economic Public Policy Studies

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### I. Introduction

Mr. Chairman, Ranking Member Eshoo, and members of the Subcommittee, good morning and thank you for inviting me to testify once again before the Committee today.

My name is George S. Ford, and I am the Chief Economist of the Phoenix Center for Advanced Legal and Economic Public Policy Studies. I hold a Ph.D. in Economics from Auburn University, and the economics of the communications industry has been the focus of my career. Prior to joining the Phoenix Center full-time, I worked at the Federal Communications Commission as well as for several companies in the telecommunications industry. I have written numerous research studies that explore this industry, and many of these studies were subsequently published in peer-reviewed academic journals, books and other academic outlets. Recently, my work has evaluated

the effect of Internet use on health outcomes, and the results reveal the potential for the Internet to improve the health of Americans and reduce healthcare expenses.[1] I am pleased that the Sub-Committee has asked for my insight on the issue of health information technologies.

By means of introduction, the Phoenix Center is a non-profit 501(c)(3) organization that studies broad public policy issues related to governance, social and economic conditions, with a particular emphasis on publishing academic-quality research about the law and economics of regulated industries. Among other activities, the Phoenix Center publishes a PUBLIC POLICY PAPER SERIES, a POLICY BULLETIN SERIES, a POLICY PERSPECTIVES SERIES, and our blog @LAWANDECONOMICS, where we provide real-time comment on current events, as well as to highlight market examples of the relevancy of our research. We also sponsor Congressional briefings, Policy Roundtables, educational retreats, as well as our Annual U.S. Telecoms Symposium. The Phoenix Center makes it a policy not to endorse or support any particular piece of federal or state legislation or proposed rule. Our primary mission is not to tell you *what* to think about an issue but *how to think* about it. As such, our contributions to communications policy are decidedly more analytical than most, and we refuse to ignore the institutional realities and economic constraints of the communications business and related sectors

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[1] *See, e.g.*, George S. Ford and Sherry G. Ford, *Internet Use and Depression Among the Elderly*, 23 PHOENIX CENTER POLICY PAPER NO. 38 (October 2009) (available at: http://www.phoenix-center.org/pcpp/PCPP38Final.pdf) and published as 28 COMPUTERS IN HUMAN BEHAVIOR 496 (2012).

including the health care industry. I have attached to my testimony a bibliography of our work, all of which is available at www.phoenix-center.org.

## II. Summary of Testimony

My testimony today consists of three basic parts: First, I point out that in any discussion of regulatory intervention by the FDA into mHealth, we must remember that this intervention will have a direct effect on the broader U.S. mobile industry. Second, I explain that not only could regulation of mHealth slow down the rate of innovation and growth of the wireless industry, but mHealth regulation of mobile devices could also trigger the 2.3% medical excise tax required by the Affordable Care Act, which could also slow innovation and, worse yet, impose a regressive tax on those Americans who could most benefit from the efficiencies and breakthroughs created by mHealth. Given the nature of regulation, the costs to innovation and competition may not be offset by improvements in safety and efficacy. Finally, I would like to highlight some of the specific language in the FDA's 2011 *Draft Guidance* that I believe an over-zealous regulator or tax collector could use to make a legally-defensible argument that mobile handsets, tablets and other devices, or even the entire mobile network, was a medical device and thus subject to regulation or the medical device tax.

## III. Background

At issue in this hearing is the role of FDA oversight of health-related applications for mobile devices, commonly referred to as (or included in the class of) "mobile-Health" or "mHealth." Mobile health applications are believed to have great potential to promote better heath care through improved communications between doctors and

patients, better decision-making by health professionals and patients, the encouragement of active and healthy lifestyles, and better access to medical and health information. mHealth also promises to improve the efficiency of health care operations and thus reduce the costs of providing health care to Americans. While much attention is directed at the benefits of mHealth in less advanced economies,[2] the use of mobile telecommunications in health care is rapidly growing in advanced economies. Patient monitoring systems alone are expected to be a $21 billion market by 2016.[3] Even in advanced economies, mHealth can help address the documented health disparities in lower-income segments of the population where the provision of health services and treatment compliance can be challenging.[4]

In this set of hearings, I am certain you will hear of the many actual and potential benefits of mHealth technologies. Suffice it to say that the present and future benefits derived of mHealth are (for now) not much disputed and potentially large, though there are challenges in widespread and effective implementation.

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[2] World Health Organization, *eHealth Tools and Services: Needs of Member States* (2005) (available at: http://www.who.int/kms/initiatives/tools_and_services_final.pdf); Vital Wave Consulting, *mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World* (2009) (available at: http://www.unfoundation.org/news-and-media/publications-and-speeches/mhealth-for-development-mobile-technology-for-healthcare.html).

[3] N. Versel, Wireless patient monitoring to be $20.9B business in U.S. by 2016, MOBIHEALTHNEWS (July 18, 2012) (available at: http://mobihealthnews.com/17951/wireless-patient-monitoring-to-be-20-9b-business-in-u-s-by-2016).

[4] *CDC Health Disparities and Inequalities Report – United States, 2011*, Center for Disease Control and Prevention, 60 MORBIDITY AND MORTALITY WEEKLY REPORT (January 14, 2011) (available at: http://www.cdc.gov/mmwr/pdf/other/su6001.pdf); B.D. Smedley, *Addressing Racial and Ethnic Health Care Disparities*, Testimony to the House Energy and Commerce Committee, Health Subcommittee (March 2009) (available at: http://www.jointcenter.org/hpi/sites/all/files/Smedley%20testimony.pdf).

By its very nature, a discussion of the regulatory intervention into mHealth by the FDA has direct implications for the nation's mobile communications industry. Mobile applications, mobile devices, and mobile networks are all part of the mobile communications ecosystem. The United States mobile wireless industry is a true American success story. As FCC Chairman Julius Genachowski just testified before your colleagues in the Senate Commerce Committee earlier this month, the United States has as many LTE subscribers as the rest of the world combined.[5] Moreover, Mr. Genachowski further testified that while mobile infrastructure investment in Europe and Asia has been roughly flat since 2009, annual mobile investment in the U.S. is up 40% over this period.[6] And, according to statistics compiled by CTIA—The Wireless Association, not only does the U.S. wireless industry directly/indirectly employ more than 3.8 million Americans, which accounts for 2.6% of all U.S. employment, but these wireless employees are paid 65% higher than the national average for other workers. Finally, and particularly germane to my testimony today, CTIA reports that the "mobile app" economy employs 519,000 developers and related jobs, and grew from almost zero to nearly $10 billion in four years.[7]

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5 Prepared Statement of FCC Chairman Julius Genachowski Before the United States Senate Committee on Commerce, Science, and Transportation, "Oversight of the Federal Communications Commission" (March 12, 2013) at 1 (available at http://transition.fcc.gov/Daily_Releases/Daily_Business/2013/db0312/DOC-319476A1.pdf).

6 *Id.*

7 CTIA, *50 Wireless Quick Facts* (available at: http://www.ctia.org/media/industry_info/index.cfm/AID/10377); M. Mandel, *Where the Jobs Are: The App Economy,* TECHNET (February 7, 2012) (available at: http://www.technet.org/wp-

Footnote Continued…

Many believe that the continued growth in the mobile sector, both in size and innovative capacity, is critical for the U.S. economy. The deployment of new mobile technologies brings significant benefits. For example, last year a study—*The Employment Effects of Advances in Internet and Wireless Technology: Evaluating the Transitions from 2G to 3G and from 3G to 4G*—considered the impact of progress in mobile technology on jobs.[8] This study reports that the investment in mobile network upgrades, and the resulting adoption of smarter devices and the apps that ride on them, have stimulated significant job creation in the US. Indeed, the authors of the study conclude, the "shift from 2G to 3G Internet and wireless network technologies led to the creation of nearly 1.6 million new jobs across the United States, between April 2007 and June 2011—even as total private sector employment fell by nearly 5.3 million positions." Based on computations using their estimated relationship between employment and wireless technology diffusion, the authors conclude that the advancement of wireless technology created

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content/uploads/2012/02/TechNet-App-Economy-Jobs-Study.pdf); M. Mandel and J. Scherer, *The Geography of the App Economy*, CTIA: The Wireless Association (September 20, 2012) (available at: http://files.ctia.org/pdf/The_Geography_of_the_App_Economy.pdf); *Creating Jobs Through Innovation*, Apple (available at: http://www.apple.com/about/job-creation); *but c.f.,* D. Streitfeld, *As Boom Lures App Creators, Tough Part is Making a Living,* NEW YORK TIMES (November 17, 2012) (available at: http://www.nytimes.com/2012/11/18/business/as-boom-lures-app-creators-tough-part-is-making-a-living.html?pagewanted=2&hp&_r=0).

[8] R. Shapiro and K. Hasset, The Employment Effects of Advances in Internet and Wireless Technology: Evaluating the Transitions from 2G to 3G and from 3G to 4G (January 2012) (available at: http://ndn.org/sites/default/files/blog_files/The%20Employment%20Effects%20of%20Advances%20In%20Internet%20and%20Wireless%20Technology_1.pdf.

about 400,000 jobs annually (1.585 million jobs over about four years). This is a big number, which is a good thing given current economic conditions.[9]

Accordingly, regulating mobile applications is not only a healthcare issue but a much broader economic one. Healthcare and information technology, as well as related industries such as retail and manufacturing, are significant economic sectors upon which the growth of the U.S. economy depends. The difference between a good decision and a bad decision regarding the FDA's regulation of the mobile sector may have significant economic impacts. I commend this Committee for taking this issue seriously.

## IV. Discussion

### A. *The Law of Unintended Consequences*

The "app economy" is a fast growing segment of the U.S. economy. Health-related applications are a significant part of this growth and offer significant promise for improved health care. Perhaps billions of dollars are at stake. In some cases, these medical applications can directly and materially influence health outcomes. Naturally, concerns have arisen regarding the largely unregulated nature of these mobile health applications. In July 2011, the FDA issued a *Draft Guidance* on how the agency plans to

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[9] Similar results are found in T.R. Beard, G.S. Ford, and H. Kim, *Jobs, Jobs, Jobs: Communications Policy and Employment Effects in the Information Sector*, PHOENIX CENTER POLICY BULLETIN No. 25 (October 2010) (available at: http://phoenix-center.org/PolicyBulletin/PCPB25Final.pdf). Mobile Internet use has also been shown to have a large and statistically significant effect on sustaining active job search, cutting in half the probability an unemployed person abandons efforts to find new employment due to discouragement about labor market prospects. In fact, mobile use reduces labor market discouragement even more than broadband use at home. G. Ford, *Mobile Broadband and Job Search: An Empirical Test*, PHOENIX CENTER POLICY PERSPECTIVE NO. 11-05 (2011) (available at: http://www.phoenix-center.org/perspectives/Perspective11-05Final.pdf).

regulate, or not, mobile medical applications as medical devices.[10] Many praised the effort as a solid first step, but many questions remain as the guidance lacked specificity and clarity. It appears the industry is ready for further guidance. As noted in the Federal Communications Commission's *National Broadband Plan*, the "[p]otential lack of clarity about the appropriate regulatory approach to these convergent technologies threatens to stifle innovation, slow application approval processes and deter adoption."[11]

Without doubt, the scope of the FDA's regulation of mobile health applications is a complex issue on its own. Unfortunately, the regulatory decision is made even more complex by an important side effect of the regulation: specifically, the proper definition of a "medical device" for purposes of FDA regulation also affects the taxation of such devices under the Affordable Care Act ("ACA"), which levies a 2.3% excise tax on medical devices (subject to some exclusions). It is tempting to assume that a single operative definition of a medical device will do for both regulation and taxation. I urge Congress to resist this temptation. Regulation and taxation are completely different questions, and there is no reason to believe, and every reason to suppose, that the proper methodologies will be quite different in scope and severity. The taxation requirements are not insignificant, and economists would broadly agree that such taxes will reduce

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[10] U.S. Department of Health and Human Services, Food and Drug Administration, *Draft Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications* (June 11, 2011) (available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)

[11] *National Broadband Plan: Connecting America*, Federal Communications Commission (March 2010) (available at: http://www.broadband.gov/download-plan) at 207.

the introductions of new devices by lowering the returns the innovator can expect from them. Taxes may (or may not) raise revenues, and they always discourage the activity being taxed, but they are not very useful means of assuring the safety of the product being sold. Yet, the role of the FDA in assessing mobile health applications cannot be treated today as independent of the tax question, since defining applications as "medical devices" may very well lead to the taxation of such applications under the ACA. I examine the distinct issues of regulation and taxation on the mobile industry next.

1. *The Potential Effects of FDA Regulation on the Mobile Industry*

Many (but not all) believe that the regulation by the FDA of medical devices lies squarely within the sphere of FDA's traditional function of assuring the safety and efficacy of medical goods. Agreement on the specifics of the regulatory approach is not, however, universal. Some believe that the FDA should play no role in regulating medical applications, while others believe a balanced, risk-based framework is better for both consumers and the industry. Whichever side one takes, most agree that FDA regulation has implications not only for safety, but also for innovation and competition.

An inevitable and arguably intended effect of FDA involvement is to raise the cost of innovation and to alter the trajectory of innovation. Uncertainty, delays and the fixed costs related to the regulatory process reduce expected returns, and thus

discourage firms from participating in the healthcare industry.[12] As such, we must expect FDA review of mobile applications to slow innovation and to reduce competition. Also, the fixed cost of compliance will likely reduce participation in the market by small firms that cannot afford the overhead of dealing with a federal regulatory agency. As such, the regulations will likely favor large, incumbent firms that already have such apparatus in place. Given the nature of the app economy, where small firms are common, FDA oversight could materially alter the structure of the industry.

In a trade-off with efficacy and safety, these negative side effects may be acceptable. Improvements in safety and quality have benefits, and these gains may be sufficient to offset the lost innovation and higher prices from less competition. This trade-off is affected by the nature of the regulation. A risk-based approach to the problem, which is what is outlined in the *Draft Guidance*, is arguably a sensible approach. The devil is in the details, however, and those details remain unspecified. Regardless of the level of intervention, the industry will evolve into something different.

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[12] In one case, the FDA approval of a mobile application took two-and-one-half years and costs the applicant hundreds of thousands of dollars. J. Stossel, *The FDA Kills: How Government Regulations Raise Prices and Stifle Medical Innovations*, REASON (November 10, 2011) (available at: http://reason.com/archives/2011/11/10/the-fda-kills); *VCs Take Their Case For FDA Reform To Capitol Hill*, WALL STREET JOURNAL (October 6, 2011)(available at: http://blogs.wsj.com/venturecapital/2011/10/06/vcs-take-their-case-for-fda-reform-to-capitol-hill/); T. Hay, *Frustrated Investors Swap FDA War Stories, Share Advice*, WALL STREET JOURNAL (April 25, 2011)(available at: http://blogs.wsj.com/venturecapital/2011/04/25/frustrated-investors-swap-fda-war-stories-share-advice).

Merely determining whether regulations do or do not apply can be a complex problem,[13] and this alone may discourage participation in the industry.

These theoretical risks of intervention are understood by most persons familiar with the effects of regulation. In fact, the risk-based framework for determining what applications are to be regulated arises out of the desire to minimize the cost and maximize the benefit of regulatory intervention. There is, however, a fundamental error in the typical evaluation of the FDA's role in mHealth. For the health industry, the FDA's role is, put simply, to regulate private sector innovation, and the necessity for such intervention is based on the idea that the private sector may have inadequate incentives for safety and effectiveness. It is frequently argued that the FDA is needed to offset the incentive problem and by doing so the health products that hit the shelves in America are safer and more effective. However, to some extent, the argument is guilty of what economists refer to as the Nirvana fallacy.[14] The Nirvana fallacy is described by noted economist Harold Demsetz as follows:

> The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing 'imperfect' institutional arrangement. This nirvana approach differs considerably from a comparative institution approach in which the relevant choice is between alternative real institutional arrangements. In practice, those who adopt the nirvana viewpoint seek to discover

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13 B.M. Thompson, *FDA Regulation of Mobile Health, 2010 Report*, MOBIHEALTHNEWS (June 2010) (available at: http://mobihealthnews.com/wp-content/pdf/FDA_Regulation_of_Mobile_Health.pdf).

14 H. Demsetz, *Information and Efficiency: Another Viewpoint*, 12 JOURNAL OF LAW AND ECONOMICS 1 (1969), p. 2 (emphasis in original).

> discrepancies between the ideal and the real and if discrepancies are found, they deduce that the real is inefficient. Users of the comparative institution approach attempt to assess which alternative real institutional arrangement seems best able to cope with the economic problem; practitioners of this approach may use an ideal norm to provide standards from which divergences are assessed for all practical alternatives of interest and select as efficient that alternative which seems to most likely to minimize the divergence. The nirvana approach is much more susceptible than is the comparative institutional approach to committing three logical fallacies – *the grass is always greener fallacy, the fallacy of the free lunch, and the people could be different fallacy*.

The Nirvana fallacy points to the error of an unqualified belief that a regulated outcome will be superior to an unregulated outcome simply because the unregulated outcome is not to your liking. The grass is not always greener, and regulation has costs of its own. Instead, the proper comparison involves the economic well-being across the regulated and unregulated states as they can actually be expected to exist, rather than treating the regulated state as some perfection (i.e., nirvana) that solves the static defects of the market outcome. While it is true that market outcomes—which are simply the outcomes of interactions among buyers and sellers (that is, human beings)—sometimes may be sensibly labeled as inadequate in some regard, particularly when lives are at stake, the FDA is an institution run by human beings with their own incentives and limitations. Regulatory agencies, including the FDA, are imperfect, and the problems it attempts to solve are very complex. In some instances, the FDA's oversight may render positive outcomes, while in others the costs of its action may well exceed the benefits. As a life-saving treatment awaits approval, people die; when a dangerous treatment is rejected, people live. There are costs and benefits inherent in the process; there is no free lunch.

Research on the FDA, which is extensive, presents widely different assessments of the agency, many highly critical of the agency.[15] The Government Accountability Office ("GAO") has pointed to a number of shortfalls in the FDA's regulatory efforts.[16] Some economic research suggests that the lives lost from delay in approval may significantly overwhelm the lives saved from the FDA approval process.[17] Some studies say otherwise.[18] Recently, the FDA's own scientists and leadership describe the agency as "fundamentally broken" and "failing to fulfill its mission,"[19] and lament the agency's tendency to consider the "political consequences"[20] of its decisions. Some refer to the FDA as "government's most dysfunctional agency."[21]

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15 *See, e.g.*, S. Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 JOURNAL OF POLITICAL ECONOMY 1049–1091 (1973); F. Hawthorne, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT (2005); P. Hilts, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION (2004); B. Richards, FIGHT FOR YOUR HEALTH: EXPOSING THE FDA'S BETRAYAL OF AMERICA (2006); R. Higgs, HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS (1995).

16 *FDA Has Met Most Performance Goals but Device Reviews are Taking Longer*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-12-418 (February 2012) (available at: http://www.gao.gov/assets/590/588970.pdf).

17 D. Gieringer, *The Safety and Efficacy of New Drug Approval*, 5 CATO JOURNAL 177-201 (1985).

18 T. J. Philipson, E. R. Berndt, A. H. B. Gottschalk, M. W. Strobeck, *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts*, NBER Working Paper 11724 (2005) (available at: http://www.nber.org/papers/w11724).

19 A. Mundy and J. Favole, *FDA Scientists Ask Obama to Restructure Drug Agency*, WALL STREET JOURNAL (January 8, 2009) (available at: http://online.wsj.com/article/SB123142562104564381.html).

20 *Lamictal Efficacy Comparable to Carbamazepine in First-Line Epilepsy, Glasgow Study; Lamotrigine in Phase III for Monotherapy, Pediatrics,* PHARMACEUTICAL APPROVALS MONTHLY, F-D-C REPORTS (January 1996), at p. 29.

21 *See, e.g.*, J. Entine, *FDA SpyGate – New Revelations Challenge The New York Times Investigation of Agency "Enemies List," Raise More Questions About the "Government's Most Dysfunctional Agency,* FORBES (August 20, 2012) (available at: http://www.forbes.com/sites/jonentine/2012/08/20/fda-spygate-new-revelations-challenge-the-new-york-times-investigation-of-agency-enemies-list-raise-more-questions-about-the-governments-most-dysfunctional-agency); *Medical Device VCs Link FDA Dysfunction With Company*

Footnote Continued…

Put simply, some question whether the cost-benefit tradeoff for FDA involvement is favorable on average, and clearly the tradeoff could be net negative for any specific drug or device. It is possible that FDA intervention may do more harm than good due to the nature of the problems its tries to solve or to its alleged dysfunction. Even a well intentioned, perfectly functioning FDA may not improve matters through its regulation given the inherent uncertainty and complexity of its tasks.

Legislation and regulation would be easy if all one had to do was to vote for a policy of "safer products," but this is not possible. "Safety" is not a policy; it is an idea, or a goal. Too often the debate over regulation centers on ideas rather than policies. A policy is a set of legally-defensible and specific rules telling people what to and not to do. The policy is about how and when to move the box from pallet A to pallet B and who is to do it. Human implementation of a complex set of human-designed rules aimed at improving safety may, in the end, increase danger. We have made personal decisions that we thought wise, yet turned out be to otherwise; regulators are people too. Recognizing that regulation has shortcomings need not imply the regulators necessarily behave badly; rather, in my experience, regulatory solutions to even simple problems are hard enough to construct, implement, and enforce even under the best of intentions, and the FDA hardly ever deals with simple problems. Certainly, the FDA is not dealing in "safety." Rather, the FDA establishes very specific rules that firms must

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*Shutdowns,* VENTURE WIRE (June 23, 2011) (available at: http://www.atvcapital.com/technology-news/medical-device-vcs-link-fda-dysfunction-with-company-shutdowns).

follow in the hope that the rules will increase safety (or possibly serve some political end). Success is a probability; not a certainty.

On the issue of mobile health applications, even those that believe the FDA has an important role to play in the regulation of mobile health applications contend that the FDA has failed in the sense that it has acted too slowly or has failed in that it has provided too little guidance. "More action" or "more guidance" seems to flow naturally from such thoughts. In the course of these hearings, the testifying experts and some members of the Committee will likely say things like "the FDA should be doing" something it is not. But it is also important to recognize that the "should be doing it" implies necessarily that the FDA is not doing what it should be doing. Embedded in a call for "more" is the recognition of "failure." It is important to keep in mind we are not dealing the FDA we wish existed, but the FDA we have, including all of its warts. As we contemplate the role of the FDA in regulating mHealth applications and devices, we must not only consider the inevitable negative consequences on innovation and competition (and hopefully the benefits of safety and efficacy), but it is important to keep in mind that the actions of the agency may or may improve safety, efficacy or quality.[22] It is sensible to guard against letting hope overcome experience.

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[22] For example, the GAO has identified a wide variety of concerns related to FDA's ability to fulfill its mission of protecting the public health. *FDA's Premarket Review and Postmarket Safety Efforts*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-11-556T (April 13, 2011) (available at: http://www.gao.gov/products/GAO-11-556T); *FDA Should Expand Its Consideration of Information Security for Certain Types of Devices*, GOVERNMENT ACCOUNTABILITY OFFICE, GAO-12-816 (August 31, 2012) (available at: http://gao.gov/products/GAO-12-816). Also see M. Carey, *Medical Research, FDA and Mental Health Programs Face Budget Bite*, KAISER HEALTH

Footnote Continued…

2. *Medical Device Taxation: Is it a Regressive Tax?*

The Affordable Care Act levies a 2.3% excise tax on medical devices, and the FDA's regulation of mobile apps is likely to label such apps as medical devices. Whether or not these applications are taxed is an important consideration naturally flowing from the FDA's activity in this area. Economists would broadly agree that such taxes will reduce the rate of innovation and the introductions of new mobile applications and devices by lowering the returns on such innovations. Taxes may (or may not) raise revenues, but they always discourage the activity being taxed (other things constant). Taxes do nothing to improve safety or efficacy. Is it important that Congress and the FDA consider the implications of such taxation on the mHealth sector, the health sector broadly, and the mobile communications sector that is a perfect complement to these applications.[23] Clear guidance is needed to avoid unnecessary loss of innovative capacity in this sector.

Another significant concern with taxes on medical devices, particularly those in the mHealth space, is that such taxes could be regressive in nature. Government studies regularly document the health disparities in lower-income segments of the population.[24]

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NEWS (March 1, 2013) (available at: http://www.kaiserhealthnews.org/Stories/2013/March/01/health-programs-budget-cuts-sequester.aspx).

[23] D. Furchtgott-Roth and H. Furchtgott-Roth, *Employment Effects of the New Excise Tax on the Medical Device Industry*, Furchtgott-Roth Economic Enterprises (September 2011) (available at: http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf).

[24] *See supra* n. 4.

Studies also show that lower-income residents are also more likely to access the Internet using a mobile device, suggesting that mHealth will be particularly beneficial in improving health care for poorer Americans.[25] Indeed, mHealth is frequently targeted at lower income populations, whether in less-developed economies or within advanced economies. The combination of health disparities and use of mobile technology in lower-income populations suggests that the medical device tax could be regressive, with lower income Americans shouldering a relatively high tax burden. More research on this topic is obviously needed, particularly in light of universal health care, but the conditions appear suitable for such an outcome.

3. *The Odd Case of the Medical Device Tax*

Without dispute, taxes reduce the production and consumption of goods and services. "Sin taxes" are a clear manifestation of this fact, where goods that are deemed socially undesirable are taxed more heavily in order to curb their consumption (e.g., tobacco). With that in mind, it is interesting to consider the implication of taxing regulated medical devices, including mobile medical applications.

In order to market a "regulated medical device," the device must be reviewed or certified by the FDA. This "certification" by the FDA indicates that the medical device is a "good one," or one that is efficacious and safe and will improve the general well being

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[25] A. Smith, *35% of American Adults Own a Smartphone*, PEW INTERNET & AMERICAN LIFE PROJECT, Pew Research Center (July 11, 2011) (available at: http://pewinternet.org/~/media//Files/Reports/2011/PIP_Smartphones.pdf).

and health of society. If the device is not efficacious and safe, then it will not be certified; it is a "bad" device. It is only after receiving the FDA's stamp-of-approval as a "good" and "health improving" device is the ACA's excise tax applied. Oddly, the tax, which necessarily discourages the consumption of the "good" medical device, applies only to those medical devices which improve the well being of society. The ACA's medical device tax may thus be labeled a "virtue" tax, as opposed to a "sin" tax. Only those things society deems as desirable are targeted by the tax, thereby reducing the use of the desirable devices. By reducing the consumption of the "good" medical device, the tax reduces the social value of the FDA by reducing the benefits of the agency's efforts without affecting its costs.

When the medical device tax is contemplated within the context of its relationship to FDA approval, the ACA's medical device tax is a particularly odd form of taxation. I am not surprised that there is bipartisan support for a repeal of this "virtue" tax; there appears to be good reason to do so.[26]

**V. Is the iPhone a Medical Device?**

All of the mobile applications in question are running on mobile platforms like iPhones, Android phones, iPads, and so forth. Technological innovation in these

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[26] P. Kasperowicz, *GOP, Dems Call for Repeal of $30 Billion Medical Device Tax*, THE HILL (February 7, 2013)(available at: http://thehill.com/blogs/floor-action/house/281691-gop-dems-call-for-end-to-30-billion-medical-device-tax)("A bipartisan group of 180 House members — consisting of about 40 percent of the House — has reintroduced a bill to end the 2.3 percent tax on medical devices that was imposed under President Obama's healthcare law.")

platforms is rapid and provides substantial benefits to consumers. The ubiquity of such devices is amazing considering that the first iPhone was released in 2007. The most troubling (to me) about the FDA's *Draft Guidance* on the regulation of mHealth is the potential for inserting the FDA into the innovation flow of mobile handsets, tablets, and other devices. I suspect many would find a requirement for FDA approval on each new mobile device a scary thought. It would certainly curtail the pace of innovation. While many do not believe the FDA will regulate mobile platforms as a regulated medical device, some do, and I believe the *Draft Guidance* plainly leaves that door wide open.

In the FDA's *Draft Guidance*, it defines a "mobile platform" as "as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as the iPhone, BlackBerry phones, Android phones, tablet computers, or other computers that are typically used as smart phones or personal digital assistants (PDAs)."[27] As such, we can equilibrate the iPhone (for example) with the "mobile platform." The same document defines a mobile application as "as a software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server."[28] In turn, the "mobile medical application" that is to be subject to FDA regulation is a "mobile application" is defined as an application "that meets the definition of 'device' in Section

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27 FDA *Draft Guidance, supra* n. 10 at p. 7.

28 *Id.*

201(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act); and either (a) used as an accessory to a regulated medical device; or (b) transforms a mobile platform into a regulated medical device."[29] Per the *Draft Guidance*, the application would meet the definition of a "device" when "the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man."[30]

My initial concern about the treatment of handsets and tablets as regulated medical devices subject to FDA jurisdiction should be immediately apparent from these definitions. Specifically, a "mobile medical application" is one that "transforms a mobile platform into a regulated medical device," which (by substitution) could be read as saying it "transforms [an iPhone] into a regulated medical device." This language is troubling, and it may be that the specific words do not accurately reflect the intent of the FDA or could be interpreted differently. Nevertheless, the plain language suggests, at least to me, that the mobile platform can be a "regulated medical device" by implication of its complementary use with a mobile health application.[31]

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[29] *Id.*

[30] *Id.* at p. 8. For the full definition of a device, *see* http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm.

[31] Such language appears elsewhere in the *Draft Guidance* ("Mobile apps that transform the mobile platform into a medical devices by using attachments, display screens or sensors or by including funcationalities similar to those of currently regulated medical devices (*Draft Guidance, supra* n. 10 at p. 15).")

There is more to demand concern. In an attempt to clarify the guidance on mobile platform regulation, the FDA's *Draft Guidance* provides an example, stating "if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany with a medical device intended use, then BrandNameCompany would not be a medical device manufacturer."[32] Clearly, the example addresses the treatment of the "phone." The example reveals that whether the "phone" qualifies as a "medical device" depends on "intended use." Thus, the *Guidance* leaves open the question of whether the "phone" is a "medical device," which takes us back to the question of a "transformation" of the platform into a *regulated* medical device.

What is meant by "intended use" is obviously an important concept. Is it possible, for example, for a manufacturer of blood glucose meters to avoid FDA by describing its product as a paperweight? No. The term "intended use," as applicable to the FDA, "refer[s] to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."[33] Intent, therefore, may be

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[32] *Id.* at p. 10.

[33] 21 CFR § 801.4 (available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.4).

reflected not in specific labeling, but in other materials and actions. To clarify, consider the discussion provided in a paper written by my co-panelist Bradley Thompson[34],

> Figuring out the actual intended use of the article depends entirely on the facts. I teach this topic at Columbia Law School, and I generally begin the session by taking out a popsicle stick. To employ a case study, I tell the students that I'm the CEO of a company that makes these sticks, and I want to know whether I have to comply with FDA regulations. At that point I encourage them to ask questions of me in my hypothetical role as CEO, and then ultimately to advise me.
>
> If they have done their homework, they will start to ask me how I promote the stick. In my answers, I'm pretty coy at first, simply explaining that I sell sticks and what my customers do with them is their business. I explain that my labeling for the product merely identifies the product as a stick without going into its possible uses.
>
> Hopefully my students have read enough to know that the regulations define "intended use" as: "the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. …" So what I say in my labeling is not the last word, but ultimately what matters is the totality of what I have done to promote the article and to some extent what I know about how my customers are using it.
>
> Eventually my students start asking me about what trade shows I attend, what types of magazines I use to advertise the sticks, what my salesmen say to customers, and what I know about the actual usages of the sticks. And it turns out, in my hypothetical, I know that many of my customers are using them as pediatric tongue depressors, I promote them in advertisements in hospital journals, and at least some of my salesmen might encourage their use as tongue depressors. So eventually my

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[34] Thompson, *supra* n. 13.

> students come to the view that my simple popsicle sticks might in fact qualify as medical devices and be subject to FDA regulation.

As this discussion reveals, and the regulatory language infers, the term "intended use" is not the same as "stated use." Mobile platforms are typically sold as just that: general-purpose handsets, tablets, phones, and so forth. Yet, the manufacturers of such platforms frequently advertise the use of their products as health devices. For example, Apple's "iPhone in Business" and "iPad in Business" series describes the benefits of its handsets and tablets in healthcare systems, with the apparent intent of promoting its devices to healthcare organizations. These reports state, for example, the "iPhone is clearly helping to improve health care"[35] and is "helping doctors treat patients" and "take care of [] patients."[36] Apple has also made corporate announcements about its devices use for medical care with demonstrations from major medical companies.[37] (Many of the claimed usages are for records management, however, which is a largely unregulated field today.) Nor is it clear that such representations rise to the level of "intended use." Perhaps the critical question is could an over-zealous regulator or tax collector make a legally-defensible argument that devices or even the entire mobile network was a medical device and thus subject to regulation or the medical device tax?[38]

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35 http://www.apple.com/iphone/business/profiles/memorial-hermann.

36 http://www.apple.com/iphone/business/profiles/mt-sinai; also http://www.apple.com/ipad/business/profiles/dr-ferencz; http://www.apple.com/ipad/business/profiles/rehabcare/#video-rehabcare; http://www.apple.com/ipad/business/profiles/medtronic/#video-medtronic.

37 http://mobihealthnews.com/949/iphone-30-all-about-mhealth.

38 The platforms, as general purpose devices purchased by consumers, may qualify under the retail

Footnote Continued…

In an ecosystem, where all components are intertwined, where does the line get drawn on what is and what is not a medical device? Obviously, clarity is needed, and there needs to be some limitations on the scope of FDA's reach lest regulation taxation become very broad in the mobile ecosystem and due significant damage to innovation in the sector.

**VI. Conclusion**

Mr. Chairman, thank you again for the invitation to testify today. I would welcome any questions the Subcommittee might have.

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exemption.