Testimony of

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Health Information Technologies: Harnessing Wireless Innovation

before the

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Introduction

Chairman Walden, Ranking Member Eshoo and members of the Subcommittee, I am Dr. Teo Forcht Dagi, Partner of HLM Venture Partners, based in Boston, MA. I am a board certified neurosurgeon trained at Johns Hopkins and the Massachusetts General Hospital. I hold a professorial appointment at Harvard Medical School and served as President of the Georgia Neurosurgical Society and as a Director of the American Association of Neurological Surgeons. I also sit on the steering committee of the Harvard-MIT Program in Biomedical Entrepreneurship, and was a director of the Goergen Institute for Entrepreneurship at the Wharton School of the University of Pennsylvania. I also chair the Committee on Perioperative Care for the American College of Surgeons and serve as a director and officer of the Council for Surgical and Perioperative Safety and a director of the Anesthesia Patient Safety Foundation.

Prior to joining HLM, I raised a venture capital fund focused on very early stage ventures in the Southeast. By investing $17 million in 11 early stage companies focused on healthcare and the life sciences, the fund yielded over a 300-fold increase in value. It participated in the development of drugs and devices that benefit millions of patients world-wide and created numerous new jobs.

HLM Venture Partners is a leading dedicated health care venture capital firm providing over $400 million in capital to some of the most dynamic, innovative companies nationwide. HLM is focused on building sustainable, profitable companies to the advantage of patients, healthcare professionals, entrepreneurs and investors in the Health Care Information Technology, Health Care Services and Medical Device sectors. HLM was established in 1983 and qualifies as one of the most experienced healthcare funds in the industry. Because of its experience and its focus, it is uniquely positioned to provide insightful guidance on a range of health care industry issues. We take pride in partnering with exceptionally talented entrepreneurs and with strategic partners from the industry to develop emerging companies. Over the course of my 15 year venture capital career, which overlaps with over 30 years in the practice of clinical and academic surgery, I have worked side-by-side with entrepreneurs to create and finance many start-ups.

In addition to representing HLM Partners and its portfolio companies, I also am testifying on behalf of the National Venture Capital Association (NVCA) based in Arlington, Virginia. NVCA represents nearly 400 U.S. venture capital firms and empowers its members and the entrepreneurs they fund by advocating for policies that encourage innovation and reward long-term investment.

On behalf of HLM Venture Partners, the venture industry and entrepreneurs, it is my privilege to share our perspective on the current state of investment in the Health Information Technologies and Health Care Services Sectors and how emerging technologies are positioned to improve patients' access to better

health care, achieve improvements in patient outcomes, provide greater efficiencies and drive down costs in the overall healthcare system.

Venture Capital Plays a Key Role in Innovation

According to a 2011 IHS Global Insight report, companies that were founded as small start-ups with venture capital accounted for 12 million jobs and $3.2 trillion in revenues in the United States. These figures equate to 11 percent of private U.S. employment and 21 percent of our country's GDP.

Venture-backed companies are responsible for the creation of entire industry sectors here in the United States including semiconductors, biotechnology, Internet content and software. Today, we are creating the companies that will serve as cornerstones for cloud-based computing, internet security, healthcare, social media and new energy. Many companies founded with venture capital are household names today, including Apple, Genentech, Starbucks, Facebook, Home Depot and FedEx. With more than 18,000 companies having received venture funding in the last five years, the next generation of successful companies innovating in healthcare, the life sciences, high technology, and new energy are poised to follow in their footsteps.

The Healthcare and Life Sciences sectors account for 25 percent of all venture capital (VC) dollars invested. The majority of dollars are invested in the biopharma (60%) and medical devices (26%) sectors. A smaller portion is invested in the Health Care Services and Health Care Information Technology (4%). (PwC/NVCA Money Tree Report based on Thomson Reuters)

Venture capitalists are committed to funding America's best and most innovative entrepreneurs. They work with them closely to transform breakthrough ideas into emerging growth companies that drive job creation and economic growth in the United States. One of the top priorities for healthcare and life sciences investors such as myself is to work with healthcare focused entrepreneurs to develop new treatments and technologies for patients and discover innovative solutions that address unmet medical needs, enhance healthcare outcomes, and lower overall healthcare costs without compromising the safety and the quality of the American healthcare system.

For investment to grow in the formative stages of emerging medical mobile applications, which, as a group, stand to make a significant contribution to these goals, there need to be well defined pathways to market that balance patient safety and efficacy with rewards for undertaking investment risk in healthcare innovation. Uncertainties in the regulatory environment create significant risk for investors and deter investment in many promising ideas. We believe that regulatory pathways should be risk-based, transparent, consistent and predictable.

Bringing Promise to our Healthcare System

I believe that medical mobile applications (MMAs) will prove to be a central, important and potentially critical tool in optimizing and integrating communications among clinicians and between clinicians and patients, and will help broaden and sustain shared decision making. MMAs will prove invaluable for patient engagement and education and have the potential to materially enhance integrated strategies for patient care, coordination of the management of chronic disease, improve healthcare outcomes, promote patient safety, and lower healthcare costs. In fact, MMAs are already playing a critical role in patient care. MMAs are in development and in use to help diabetics follow and refine their insulin regimens; to screen for diabetic disease of the retina; for telemedical consultations in remote areas; to help patients with congestive heart failure avoid readmission; to diagnose moles and screen for melanoma; to exchange diagnostic images and obtain consultations; and to coordinate and integrate care across groups of physicians in different institutions. MMAs also provide a means for sending sentinel alerts to providers. They help patients adhere to medication protocols. They facilitate home health care as well as remote patient monitoring in other settings, like the intensive care unit. All in all, MMAs hold tremendous promise with respect to improving patient safety, increasing the quality of care and helping to contain the costs of delivering effective healthcare.

The Medical Device Tax is Impacting Investment in Health Care Innovation

I would like to also express my concerns about the medical device tax is having regarding medical innovation and U.S. job creation. MMAs that are listed as a device with the FDA under section 510(j) of the Federal Food, Drug and Cosmetic Act, and 21 CFR part 807, pursuant to FDA requirements are subject, under the provision of the Accountable Care Act (ACA), to a 2.3% medical device excise tax on revenues. The tax is intended to raise approximately $30 billion to help pay for the implementation of the ACA.

As you know, there was a lengthy debate during the ACA legislative deliberations regarding which products should pay the 2.3% tax. We believe Congress did not intend to burden emerging MMA companies with this new tax since their products aren't included in "traditional" medical devices. The 2.3% tax on revenue has already started to have a detrimental effect on early stage medical device companies. It creates a major market inefficiency by increasing the capital intensity of innovation, and affects the ability of venture capitalists to invest in these companies in the future. This tax would be even more devastating for companies developing MMAs.

The tax of 2.3% sounds modest, but is it not. This is a tax on revenue, not profits. The vast majority of entrepreneurial ventures developing MMAs are very small and very early start-up companies. Most of the

companies in which we invest may generate some revenue, but likely not profit. Revenues are plowed back into the company for development and for growth. Therefore, the 2.3% tax on small start-up companies delays their ability to reach profitability and increases the amount that must be invested before a company can become cash flow positive.

Even when profitability is attained, a company in this space might deliver profits of no more than 10% of revenue. A tax of 2.3% on revenue at that stage is the equivalent of a 23% tax on profits, over and above the corporate state and federal income tax companies are already obligated to pay. The effect on after-tax profits is material and severe. This tax dramatically reduces after tax profits. Correspondingly, it chokes the company, and can be expected to reduce the value of the company to prospective acquirers or public market investors. Thus, as you can see, more has to be invested for a smaller return, reducing the incentive for investors to support high risk, early stage companies working to bring important and innovative solutions to patients with unmet medical needs, and depriving the healthcare system of valuable tools and expedients. Rather than growing and creating new jobs, companies will be increasingly and unreasonably constrained. To pay the tax, they must cut R&D budgets and cut jobs.

As we have noted, these early-stage companies form the core of the ecosystem that has resulted in leading and sustainable medical innovation and in a brilliant American success story for patients and the economy alike.

We believe MMAs that are defined as medical devices should be exempted from the medical device tax. And more generally, we believe that Congress should repeal the entire tax because of the impact it is having on emerging growth companies that are focused on fueling medical innovation and job creation.

Recommendations to help drive investment in Health Care Services

Venture capitalists and entrepreneurs stand ready to participate, along with other public and private stakeholders, to find solutions that will help move these important innovations into the health care system. We would like to offer the following recommendations to help stimulate investment in this important sector.

- Promote a regulatory framework that is predictable, consistent, transparent and risk-based. The Food and Drug Administration (FDA) issued draft guidance for mobile medical applications on July 21, 2011 that addresses some regulatory concerns and reduces some regulatory uncertainty, but leaves open questions around enforcement discretion decisions. FDA's delay in finalizing this guidance document has had deleterious effects on the industry. It has prolonged ambiguity, impaired the ability of investors and innovators to evaluate regulatory risk, and discouraged investment. The lack of definitive guidance has

also affected the consistency of decisions made within the FDA by its reviewers. We also note that the FDA has broad discretion with respect to enforcement decisions that determine the regulatory status of MMAs--whether they are listed as medical devices and whether they are subject to the 2.3% excise tax. The FDA should publish final guidance documents regarding MMAs in order to shrink the grey area into which many of these applications fall. Publication will serve to reduce the current state of procedural and regulatory ambiguity, and relieve at least some of the burden of liability for the medical device excise tax. We believe there should be a risk-based approach to regulating mobile medical devices that balances protecting patient safety with fostering innovation. The regulatory environment should be rational, transparent, consistent and predictable.

- FDA and other stakeholders should collaborate and formulate alternative oversight frameworks that meet the goals of patient safety in mobile medical applications, but also encourage and foster innovation and invention. While the FDA remains the gold standard in the protection of patient interests, with unique credibility and expertise, it is essential that the pace of regulation keep up with the pace of innovation. Both are critical. Nevertheless, in order to address the healthcare challenges facing our nation, we must ensure that proposed alternatives to regulation of mobile medical devices by the FDA are feasible in today's resource-constrained environment, that they do not lead to duplicative or increased regulation, and that they neither slow innovation and nor create confusion through the implementation process.

- Solicit broad input, in evaluating new regulatory frameworks, especially from those at the forefront of innovation that promotes healthcare transformation. We are pleased that a working group is being convened to aid the Secretary of Health and Human Services in formulating a strategy and recommendations for an appropriate, risk-based regulatory framework pertaining to health information technology, including MMAs. Given the importance of this task and the need to optimize future applications of health IT, we encourage the Secretary to gather input through public forums beyond this working group so that all stakeholders might be heard.

- Medical mobile applications that are defined as medical devices should be exempted from the 2.3% medical device tax.

Thank you for the opportunity to testify. I look forward to working with you to address these critical issues.