Statement of
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Summary

Good morning, Chairman Walden, Chairman Pitts, Ranking Member Eshoo, Ranking Member Pallone, and Members of the Subcommittees. It is an honor to testify.

I am a serial entrepreneur, Founder of Health Fidelity, a leading big data analytics company, and consulting faculty at Stanford University School of Medicine. In addition, I am a practicing physician, board certified in surgery, critical care, palliative care, and clinical informatics. I also serve on the eHealth Initiative Leadership Council and collaborated with Bipartisan Policy Center on their Oversight Framework for Assuring Patient Safety in Health Information Technology.

I have been fortunate to succeed as an entrepreneur, educator, and surgeon and I am grateful to the federal government for contributing to my success. I have been awarded and named principal investigator on multiple grants from the National Institutes of Health and National Science Foundation, each grant resulting in creation of multiple long-term high-paying skilled jobs. For every federal dollar received, I have secured at least $15 in follow-on private sector investment. These efforts have led to companies and products used at Harvard, Stanford, and other leading institutions to benefit patients and enhance

medical knowledge.

My background has afforded me unique insight into healthcare innovation in practice. Entrepreneurship in healthcare is difficult work and requires an ecosystem of expert talent, venture and strategic financing, broad-minded health systems, and engaged patients.

21st century technology in healthcare includes devices, data, and information-enabled workflow. This industry disruption is sometimes termed data-driven healthcare. Data-driven healthcare not only assures the right information is available for the right patient at the right time, but also provides pathways for information to be used in less traditional ways, such as population health and patient engagement.

The goal in data-driven care is not to capture healthcare data electronically or enhance reporting of information, though these are necessary steps along the way. The goal is rather a more efficient, effective, and approachable healthcare system that provides high quality care at an affordable price. Although great strides have been made, achieving our common goal will require collaboration and innovation from all involved parties. The government has a critical role to play.

Today, I will focus on three actionable recommendations to promote safe and meaningful innovation in healthcare. These include redefining interoperability to share the information that is needed for clinical analytics and population health, revising our

approach to quality to better align with improved outcomes and reduced costs, and research to better understand safety in healthcare IT.

I recently cared for a very nice woman who was failed by our healthcare system. A heart murmur had been noted during physical exam years earlier. Unfortunately, on changing her insurance, the information was buried and lost in medical documentation. Her failing heart valve was only discovered years later when she presented to the emergency department unable to breath. She required an emergency operation, leading to an extended ICU stay and millions of dollars of taxpayer expense. If her condition had been recognized early and treated electively, the likely cost would have been far lower and she and her family would have been spared a month-long stay in the hospital. I will discuss recommendations in the context of her case.

The first actionable recommendation is a better definition of interoperability. Current efforts and proposed regulations focus on sharing patient summaries. Unfortunately, there is simply not enough information in these summaries for innovative analytics companies to promote data-driven healthcare. In this clinical case, an exam finding was documented in a physician narrative, but did not show up on the problem list and would not be present in an interoperable summary. To support interoperability of summaries only, as is proposed in currently regulation, is to ignore critically important information such as home environment, medication compliance, exam findings, and hospital course. Innovation and care improvement will be hobbled for years to come by such an arbitrary limitation. Through the Meaningful Use program, our country has footed much of the

cost for electronic capture of clinical data. Why wouldn't we require that all the data we capture be available for use by innovative companies and technologies to improve care?

The second actionable recommendation is an enhanced definition of quality. This patient's care met all process measures required. She had routine tests, documented smoking cessation counseling, and weight documented and trended. But, did she receive great care? Quality measures are increasingly selected for feasibility, meaning we often select for what is easy to measure rather than what really influences outcome. In this case, a relevant measure of quality would have been whether the patient received appropriate clinical follow up for her heart murmur. These types of clinical measures are hard to measure and track, but foundational for good care. If quality measures are our national target, this is the time to refine our approach and require accurate and meaningful quality measures in healthcare.

Finally, my patient's information was exposed to many healthcare IT software systems. Were these systems safe and effective? While the country defines a first pass approach to healthcare IT safety, we must acknowledge that these IT systems are new, innovative, and rapidly evolving. Not only must we understand the efficacy of the technology, we must also ensure proper integration into clinical workflow. Technology creates a new way of providing care that should be based on real science, not trial and error. To refine our regulatory approach over time, we will need information on how and when healthcare IT is safe versus potentially dangerous. Support of academic and clinical research on healthcare IT benefits and risks would go a long way to help us refine regulation over

time.

We're going in the right direction. Health systems, payers, and vendors are collaborating over new financing models with newly available data and with new enthusiasm. Venture financing in healthcare is at its highest level since 2001 and growing. Innovation in healthcare is being rewarded with a robust acquisition and IPO market. But, there is a great deal of work left to do if we are to bridge the gap from electronic information to better and more efficient care. I look forward to continuing to work with you to leverage our national healthcare IT investment to create data-driven healthcare. The US is well poised to revolutionize healthcare to benefit our people and economy at home while showing global leadership in a critical industry.