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"Health Information Technologies: How Innovation Benefits Patients"

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Chairman Pitts, Ranking Member Pallone and members of the Subcommittee, thank you for the opportunity to testify about the important topic of health information technology (IT). My name is Joseph Smith, and I am the Chief Medical and Science Officer of the West Health Institute, a non-partisan, non-profit, applied medical research organization. In addition to my current role, I have spent the last 28 years at the intersection of medicine and innovative technology, practicing and teaching medicine and clinical cardiac electrophysiology in academic and private practice settings, as well as designing and developing novel medical device technology.

Our nation's health care system is in dire need of dramatic change. The subtitle of the Institute of Medicine's (IOM) recent publication on U.S. health says it all: "Shorter Lives, Poorer Health."[1] The report illustrates that Americans are living sicker and dying quicker than citizens of peer nations that spend far less for higher quality outcomes. The economics are unsustainable. As we approach spending nearly 20

[1] Institute of Medicine of the National Academies, *U.S. Health in International Perspective: Shorter Lives, Poorer Health* (January 9, 2013). Available: http://www.iom.edu/Reports/2013/US-Health-in-International-Perspective-Shorter-Lives-Poorer-Health.aspx.

percent of our gross domestic product [GDP][2] and our family budgets[3] on health care, we risk foreclosing on the American Dream, hindering our international competitiveness, and potentially compromising our national security. The logistical challenges of extending our current model of care delivery to an aging population, with a growing shortage of physicians, only make the need for change more clear. Further evidence of the enormity of this challenge was provided in the recent IOM report as it described that the time required for a family physician to deliver guideline-based care to one-day's patient panel requires an impossible 21.7 hours.[4] Our health care delivery system is clearly exceeding our nation's budget and our providers' bandwidth.

Faced with this crisis of cost and the unsustainability of our health care delivery system, the Gary and Mary West Foundation started the West Health Institute in 2009. The West Health Institute is an applied medical research organization dedicated to lowering the cost of health care by driving patient-centered solutions that make quality health care more affordable, more accessible, and more efficient.

We see an enormous opportunity to use information technology, device innovation, and smart/learning systems to transform health care delivery and create empowered, informed consumers of health care. Health care must be allowed and encouraged to rapidly evolve using the same innovations that have already revolutionized other industries. Banking, education, retail, computing, photography, and communication have all been transformed in our lifetimes, lowering their complexity and cost while improving efficiency and ease of use. Health care has avoided this modernization, persisting in a model of delivery that to our grandparents is as recognizable as it is complex and unaffordable. We must take

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[2] Centers for Medicare & Medicaid Services, *National Health Expenditure Data 2010-2011*. Available: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

[3] Commonwealth Fund, *2003 and 2010 Medical Expenditure Panel Survey -- Insurance*

[4] *Id. Page S-5*

proactive steps to assure that the disruptive forces of decentralization, democratization, automation, and personalization - that have beneficially revolutionized other aspects of our lives and our economy - have the same beneficial impact on health care.

This is about much more than electronic health records (EHRs). The conversation needs to be elevated to one of enabling the vision and promise of medical information and device technology to create integrated, interoperable learning systems to dramatically improve outcomes, lower costs, and create a higher-value health care system. Importantly, the technological elements required to realize this transformation in health care delivery are close at hand, but our regulatory and reimbursement systems frustrate the innovation, development, and adoption required to realize the full vision.

We believe three key enablers of the needed transformation are:

- Streamlined, predictable, transparent, risk-based regulation that fosters innovation and investment for the benefit of patients, as well as our ailing health care system;

- A proactive regulatory and reimbursement stance on true functional interoperability, not just the semantic interoperability of our electronic health records, but also medical device interoperability -- to take full advantage of the medical technology that we have to create an integrated, coordinated health care system; and

- Reimbursement policy that aligns stakeholder incentives and drives adoption of appropriate technology to improve the safety, efficiency, and cost of health care delivery.

The first priority addresses the essential need for innovation and the chilling effect that unclear, unpredictable, or heavy-handed regulation can and does have in this critically important intersection of mobile technology, medical information, and clinical decision support. At this point in time, when health care is a true "burning platform," we need to stimulate innovation and experimentation. To do so, we need a clear and consistent approach for when regulation enters the process, as well as how far-reaching it should be. Outside of health care, we have witnessed a revolution in information and communication technology driven by innovation and investment, and a similar dramatic increase in the capability and economy of ubiquitous (non-medical) electronic devices, all encouraged by a predictable regulatory posture. Within health care, however, we have yet to fully exploit the potent intersection of these technologies. Even with respect to 'medical apps,' the overwhelming majority of offerings are health and wellness applications, , and the bulk of the available 97,000 mobile health apps are dedicated to medical providers as opposed to consumers or patients. Unfortunately, there is relatively little activity in the critically important - but more heavily regulated - areas of remote monitoring, diagnosis, and treatment of those chronic diseases that burden patients and make up the lion's share of our health care spending.

Tele-dermatology represents an interesting case study. The lightly regulated smart phone with its integrated camera can be readily used to photograph a suspicious mole and transmit a picture to a dermatologist, and there is no additional regulatory burden encountered by its use. Yet, when this becomes packaged as a specific, user-friendly, documented, and downloadable app from the app store, purpose-built for use in tele-dermatology, it requires FDA approval. By 2017, more than 3.4 billion people will have smartphones or tablets with access to mobile applications: we must encourage innovation from all corners for use in solving our most pressing and burdensome health care needs.

We need to recognize that our current regulatory environment favors the large incumbents that already have the domain expertise and financial resources to navigate the ambiguity, complexity and, quite often, modified guidelines that unpredictably "move the goal posts." If we are to have any hope of democratizing and decentralizing health care, we need to encourage the disruptive innovation required to transform it to a sustainable enterprise. We need to "free" the innovation cycle with predictable and transparent risk-based regulation so that the full benefits of these emerging and rapidly evolving technologies can be realized. Specifically for medical apps and clinical decision support, it is an open question whether the existing medical device regulatory framework can be modified to provide sufficient applicability, clarity, and predictability, or whether we need to consider an alternative, less burdensome framework to spur innovation. The FDA's draft guidance on mobile medical apps offered some improved clarity, but still described significant areas of "regulatory discretion," and now after lengthy delay without becoming finalized, has left an industry in limbo. And going forward, considering the frequency with which both apps and medical treatment guidelines used in clinical decision support algorithms are routinely updated, the prospect of having all such changes subject to the complex regulatory process for medical device revision seems more than daunting. As we address this, we must learn to move regulation at the pace of innovation and not vice-versa.

The second priority is to use regulatory and reimbursement policy to encourage true functional interoperability of information systems and medical devices. We view interoperability as the ability of medical devices and health care systems to seamlessly communicate and exchange information to improve the delivery of care. This connected and coordinated net can be seen as originating at the patient and surrounding or even implanted medical devices, with seamless sharing of relevant information among all such devices and the background EHR. The current lack of such true, functional interoperability results in safety hazards and inefficiencies that we do not tolerate in

other, less critical settings and it creates additional barriers for new, innovative entrants. One need only consider the democratizing influence of the Internet communication protocols and the resulting deluge of innovation to understand the full impact of interoperability. And today, while all of our Internet-enabled devices freely and instantaneously share e-mail and information, the medical devices that surround our most acutely ill patients most often function completely blinded of the critically important information being collected by other such devices only inches away. Standards-based interoperability allows e-mail to work seamlessly across different servers, cars to fill-up their gas tanks at different filling stations, phone calls to be completed between different head-sets, and yet, when it comes to our health care, information is stuck in multiple non-communicating silos as lifesaving devices are forced to work independently. We can do better.

An analysis (attached) conducted by the West Health Institute, which was released to the public today, shows that the delivery of quality patient care could be enhanced and made dramatically more affordable by medical device interoperability. Our analysis suggests that true functional medical device interoperability improves patient care, increases efficiency, and results in more than $30 billion a year in health care savings.

To realize these benefits, providers, payers, medical device manufacturers, and the government will need to collaborate to promote the development, testing, certification, labeling, and adoption of seamlessly interoperable devices. Industry trends are already driving providers and payers to converge and share risk through care coordination, clinical integration, and improved population health management. Stakeholder collaboration will provide a strong platform for accelerating adoption of medical device interoperability and realizing its associated benefits.

The third priority area is policy that promotes aligned incentives. We are starting to see the unintended consequences of well-meaning policy. For example, the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations were intended to protect consumers, but are complicated and sometimes mistakenly applied as a reason not to share patient data. Fear of HIPAA violations results in onerous requirements for sharing. Patient care suffers when providers experience delays in receiving needed information. We must ensure that policies enable requisite data sharing across traditional and emerging participants in the health care ecosystem. The financial services industry has developed secure approaches to privacy and security that, while imperfect, provide sufficient protection to enable a revolution in banking and retail services. Health care should learn from this example and allow the Internet, which changes everything, to change health care.

Reimbursement systems that disproportionately reward hospital-based procedures over office-based procedures, or face-to-face encounters over remote encounters, need to give way to reimbursement based on outcome, not process, and value, not volume. Only in this way will we unleash the power of information, communication, and medical device technology. Enabling technologies and disruptive care delivery models exist; however, until incentives are aligned, they will not be broadly embraced. Telemedicine is one such example where the technology allows remote care, but reimbursement mechanisms frustrate full and best use as practitioners are often not paid for the care they can provide remotely, providing perverse incentives for unneeded patient travel and excessive costs of care.

In closing, the West Health Institute believes the following are imperatives in order to reach our nation's health IT goals and create a model of health care delivery in service of the patient:

- Streamlined, predictable, transparent, risk-based regulation;
- A proactive regulatory and reimbursement stance on medical device interoperability; and
- Realistic and actionable policy to align stakeholder incentives.

Thank you for your time. This is an important conversation and, on behalf of the West Health Institute, we look forward to advancing these imperatives for patients and our health care system. I am happy to answer any questions.