Testimony of

Matthew Quinn, Federal Solutions Director

Health and Life Sciences

Intel Corporation

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Oversight and Government Reform

Opportunities and Challenges in Advancing Health Information Technology

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Good Morning Chairman Hurd, Ranking Member Cummings and other esteemed members of the House Oversight and Government Reform Committee. I appreciate the opportunity to testify today on behalf of Intel Corporation. Thank you for your leadership in focusing on this important topic. The health of our nation literally hinges on our ability to seize the opportunities and overcome the challenges related to the promise of health information technology.

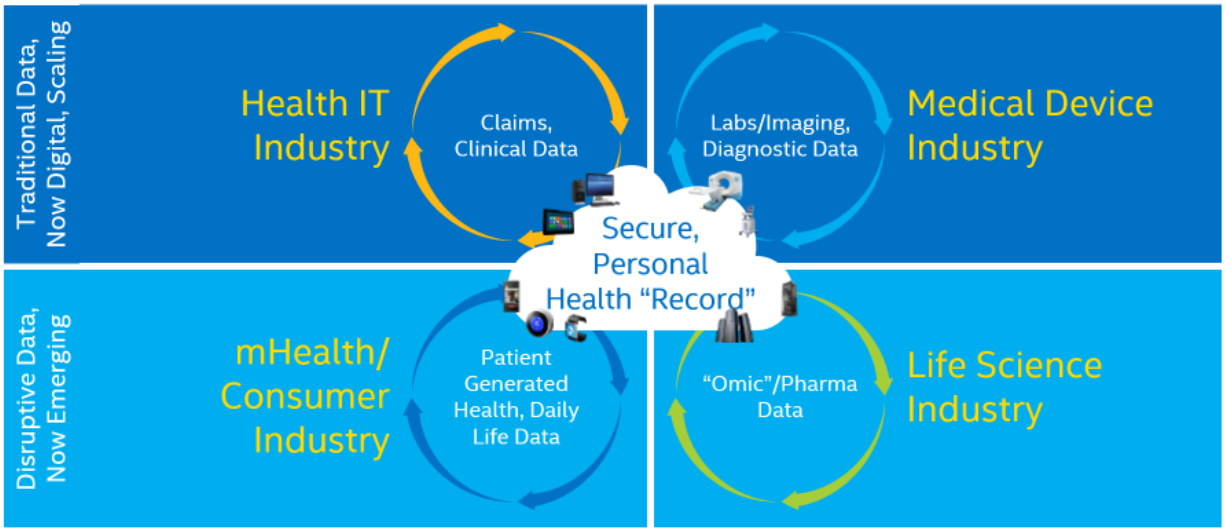
Today I will share some tangible examples of how Intel is working with public and private organizations across the care and research continuum to make good on the promise of today's health technologies and to pave the way toward tomorrow's.

We'll start with an overview of Intel's own Connected Care Program, an initiative for value-based care, in which we're leveraging our purchasing power to both directly contract with healthcare providers and also facilitate secure, standards-based data sharing among hundreds of care delivery organizations and 150 different EHR vendors for over 33,000 employees across the country.

Next, I'd like to highlight three key initiatives that illustrate the promise – and some challenges – of what's ahead with Precision Medicine and "The Internet of Things" or IoT: Our Collaborative Cancer Cloud platform, collaboration with the Michael J Fox Foundation and "You 24x7" employee wellness pilot.

I will focus on two foundational principles – full data interoperability and deep patient engagement – throughout, as solutions or approaches that are required to achieve a high functioning health care system and will also focus on where government should – and as importantly, should not – play in advancing the ecosystem.

Let's begin by thinking of the constellation of our health data over the course of a lifetime. Most familiar are the **clinical and claims data** captured at clinics, hospitals, pharmacies, insurers, etc., including such information as diagnosis codes, prescriptions, program notes, claims, vital signs, and test results. Secondly, there is **diagnostic data** captured by medical devices and imaging equipment. Adding to this now are two new data streams that are rapidly increasing in importance and opportunity: **consumer-generated health data**, captured outside the traditional health system and including such information as patient diaries, observations of daily living, vital sign monitors, fitness wearables, online and smartphone apps, social media and gaming and **'omics** — vast amounts of information contained in each person's genome (and proteome, metabolome) that will increasingly be used to attack disease at its molecular roots. By their very nature, these diverse data (coming from what we at Intel call the "Four Circle Model" depicted below) are collected at multiple sites, across long spans of time, and in a vast array of structured and unstructured formats.



The reality is that personal, precision health in the 21st century will need to make sense of all of this information for deeper insights into population health and individual treatment. These data tell us critical things about one of the most important aspects of anyone's life — our very health and well-being. To me, it's just unthinkable that we would architect a health system — a whole health economy — without

facilitating each person's access to one's own data, as well as the ability to contribute meaningful data about oneself back to researchers and data scientists to gain insights into population health and wellness.

Sharing of interoperable data must be the foundation of targeted, individual care.

The US has made great strides to ensure that each patient has an electronic health record. Today, 8 out of 10 physicians are using an EHR, with 79% of primary care physicians adopting a certified EHR through the Meaningful Use program.[1] Yet the goal of point of care access to comprehensive patient records has not been achieved. Through research in the studies of patient experiences that Intel has done across more than 20 countries—we see three recurring barriers that often limit data sharing among institutions and patients:

1) Medical institutions using **privacy/security policies and laws like HIPAA as excuses** for why they cannot risk sending patients their data;

2) Medical professionals **lacking easy, affordable, interoperable tools to share patient data**, especially because app and device vendors fail to use—or correctly implement—standards;

3) **Payment reforms that reimburse for new care delivery models** that will improve health and reduce the overall "total cost of care" as evidenced by telehealth and remote patient monitoring.

Revisiting the four-circle model described earlier, we can see that, despite a great deal of progress, each type of data is still not readily available to individuals—or even their clinicians—in most cases:

- **Electronic health record data and claims**: Under the Health Insurance Portability and Accountability Act (HIPAA), patients have a right to see and obtain a copy of their medical records. The American Recovery and Reinvestment Act (ARRA) extends those rights through modifications to HIPAA, requiring healthcare providers who utilize EHRs to give patients copies of their medical records in an electronic format, to another person or entity like a doctor, caregiver, a personal health record or mobile health application. The information is typically

[1] https://www.healthit.gov/sites/default/files/briefs/oncdatabrief28_certified_vs_basic.pdf, September, 2015.

provided on paper or through a flash drive or CD, or an online clinic portal. Unfortunately, the regulations have two significant loopholes. First, patients can receive the information in their preferred electronic format *only if* the provider is capable of producing the copy in the requested format; and second, providers *have 30 days* (and an additional 30 if the information is stored off-site) to make the information available to the patient. (Certification for Meaningful Use Stage 2 is a huge improvement by requiring the information to be made available within 4 business days.) Congress must have envisioned a much easier and faster method for patient access to data. This could be much more readily achieved with today's technology, particularly if more of the information was captured as common data sets in standardized formats.

- **Consumer-generated health data:** Today, there is a plethora of apps and services that collect health and wellness data from devices we wear, carry around with us, or use in our homes and workplaces. However, generally speaking, each have different logins, different and confusing user interfaces, and different calibration of sensors, different apps and services. Very few integrate with the systems used by clinicians who make up an individual's care team. And consumers have a very difficult time pulling this information into one repository, controlled by them, that will outlast the particular device, app, employer, or insurance company with which they are currently associated.

  As a founding member of Continua (http://www.continuaalliance.org/), Intel supports a developing ecosystem of certified devices that "plug and play" to give consumer-friendly connectivity to individuals who wish to better manage their health and wellness no matter where they are. If industry adopts common standards, the information from the various devices can be curated and exchanged with the goal of helping individuals understand their information, track their progress, stay on track with their care plans, and generally take more ownership of their health. The potential is enormous for remote monitoring of patients with chronic diseases, with continuous feedback and more efficient, two-way communication between the patient and clinicians, but only if these data are securely shareable and interoperable.

- **Imaging and diagnostic data:** Medical images make up a large percentage — estimated as high as one-third — of all stored data in the world. Although storage demands are high, fortunately, cloud-computing environments enable much more cost-effective storage of medical imaging, transitioning the hosting of medical images to the cloud for electronic retrieval through healthcare provider systems. However, providing *individuals* with convenient, on-the-go access to these often-large data files remains nascent. Think of the advantage to you as a patient if you were able to log on to access all your X-rays, MRIs, ultrasounds, etc., any time you go to a new provider or the ER, instead of filling out request forms and waiting for the files to be shipped, or paying for an expensive test to be unnecessarily repeated. Since these data types are not usually part of the official EHR per se, the progress on patient access to their own data misses important classes of personal information today.

- **Genomics and other 'omics:** The data from whole human genome sequencing are so large they are impractical to send back and forth across institutions, and we are in the early days of having tool for clinicians—let alone consumers—to make use of this data. As these new data types begin to scale, it is important that we *start* with commitments to—and validation of—interoperability and standards from the outset so we do not recreate the problems that have plagued us with EHR data. Also, new tools for big data analytics are necessary to scale the potential for precision medicine, such as the Collaborative Cancer Cloud described below.

Because each of these data streams is important to understand each person's whole health picture, providing the individual with access to parts of electronic health record (EHR) systems is necessary but not sufficient. As the National Institutes of Health builds out the extremely promising Precision Medicine Initiative, the 1 million person cohort, and our national strategy to compete globally in the economic opportunity that precision medicine will present, let's make sure we build an architecture for individual access to personal health information from the beginning. It cannot be an afterthought, or it will never

happen. We need to learn from the hard lessons of the nation's multibillion investments in subsidies for EHRs and grants for health information exchanges. We must think about interoperability in much broader terms than merely the doctor-to-doctor exchanges of EHR data. We need to continue to support the concept of individual's having personal health records available to them and their care team, anytime and anywhere, and not tied exclusively to a particular institution or company.

To help show what's possible today within the current healthcare ecosystem, with currently available EHRs, data standards, health information exchanges and , I'd like to share what Intel is doing in its own journey to make health care more effective and affordable.

Intel's Connected Care Program – an employer initiative for value-based purchasing:

The Connected Care vision is to improve Intel employees and families' healthcare experiences, outcomes, and reduce costs over time and EHR interoperability plays an important role to help Intel achieve this vision. In 2013, Intel launched the Connected Care program in Albuquerque, New Mexico. It is essentially an employer-sponsored and -facilitated accountable care organization (ACO). In focus groups, we heard from our employees and families that they wanted streamlined access to primary care and specialists. In response, Intel significantly changed its relationship with the healthcare system in the Connected Care Program. We contracted directly with the healthcare supply chain, removing middle men. We built a network of 11 primary care medical homes, including an onsite clinic, and medical neighborhood of specialists and facilities. To ensure timely access to care, Intel and Presbyterian Health Services agreed on protocols for call responsiveness and established acceptable levels of appointment availability. We contracted directly with Presbyterian Health System in an arrangement that aligned incentives and shared risk, with outcomes measured according to the following accountability metrics:

- **Right care:** Use of evidence-based medicine to improve population health, focusing on diabetes, hypertension and depression.
- **Right time:** Timely access to care in the optimal setting, including a nurse hot line.

- **Best outcome:** Patient satisfaction 100 percent of the time.
- **Right price:** Material decrease in the cost of care, per patient per month.
- **Best life:** Rapid return to productivity.

Employee response has been excellent: More than 3 in 4 eligible employees opted to join the Connected Care Program. So far, major successes have included greater member engagement with the healthcare system, very high satisfaction ratings, and statistically significant improvements in diabetes control. We have yet to demonstrate an improvement in costs. In the long term, we believe that promoting proactive primary care with deep patient engagement and accountability should improve health outcomes *and* costs as we iterate this program.

Successful preliminary results in New Mexico drove the decision to scale Connected Care to Oregon and Arizona. These locations which integrated multiple institutions and sites had a deeper need for sharing of our employees' electronic health records. With our healthcare partners, we addressed the data liquidity problem head-on through contracts that called for seamless care that required data sharing across institutional boundaries.

The Connected Care interoperability team at Intel selected the Direct messaging standard and the Healtheway eHealth Exchange (recently renamed The Sequoia Project) to support the business and clinical requirements for coordinated care. The Connected Care data exchange model utilizes the HL7 Consolidated Clinical Documentation Architecture (C-CDA), which is a key part of the data interoperability specifications in Meaningful Use. The EHR interoperability model in Oregon is nationally recognized for having an innovative approach for point-of-care access to electronic health records. New care coordination workflows are using data exchange with healthcare information coming to them in real time, resulting in quicker access to care with less work for everyone involved. Having the

most up-to-date healthcare data means a more efficient model where physicians and patients can now make the best possible choices about their care planning, leading to lower costs over time. And, critically, this data exchange model is enabling consumer health pilots that will improve Intel employee experience and improve health engagement.

We relied upon the security, authorization and privacy measures governed by national standards (eHealth Exchange/NHIN and Direct messaging), and HIPAA for exchange of clinical records. This includes end-to-end encryption of data, authorization, PKI/digital signatures and appropriate access controls. The underlying technology standard is called SAML, which is used to assert authentication of the user. Members of the eHealth Exchange secure their communications using x.509 certificates whose chain-of-trust begins with the same Root Certificate Authority (CA), thus facilitating trust between organizations without the need to exchange certificates.

Results: Tens of thousands of records are being queried and exchanged for our 33,000 employees in the Connected Care Program. For more specific information on the interoperability challenges and the value provided from joining Healtheway/Sequoia for a query-based system, Intel, Kaiser Permanente, and Providence Health and Services, The Portland Clinic and Premise Health have produced a white paper accessible at the following URL: https://www-ssl.intel.com/content/www/us/en/healthcare-it/advancing-interoperability-healthcare-paper.html. I'd like to re-iterate that Intel is making this happen as we speak – with today's EHRs, today's standards, today's health information exchanges and as an employer within today's healthcare system.

How could the federal government use its contracting power to achieve interoperability for beneficiaries of the Department of Defense, Department of Veterans Affairs, Centers for Medicare and Medicaid and Office of Personnel Management or for the hundreds of thousands of

government workers receiving federal health benefits? We have a tried and tested playbook for federal provider contracting that could be a model for both government and private industry.

Next I'd like to shift toward enabling the future. Precision medicine is an emerging approach for disease treatment and prevention that takes into account the individual variability in genes, environment, and lifestyle for each person.

Intel's work in precision medicine

Intel and Oregon Health & Science University (OHSU) recently announced the Collaborative Cancer Cloud, a precision medicine analytics platform that allows medical institutions to securely share insights from their private patient genomic data for potentially lifesaving discoveries. Intel announced that key technology components of the Collaborative Cancer Cloud (CCC) will be opened sourced. Hospitals and research institutions of all sizes could use the technology to advance personalized cancer research. They can also apply it to advance personalized research in other diseases that are known to have a genetic component, including Alzheimer's, diabetes, and more. Intel and OHSU also announced that they will partner with two other large cancer institutions to extend this capability in 2016.

The project combines next-generation Intel technologies and bioscience to enable solutions that can be used to make it easier, faster, and more affordable for developers, researchers, and clinicians to understand any disease that has a genetic component, starting with cancer. It will enable large amounts of data from sites all around the world to be analyzed in a distributed way, without having to move the data itself, preserving the privacy and security of that patient data at each site. The end goal is to empower researchers and doctors to help patients receive a diagnosis based on their genome and potentially arm clinicians with the data needed for a targeted treatment plan. By 2020, we envision this happening in 24 hours — a challenge to the computing and life science industries that we call All in One Day. The focus is to help cancer centers worldwide — and eventually centers for other diseases — share with one another the insights that reside in their private clinical and research data without having to share the data itself.

This approach is designed to protect data privacy and the business models of the research centers while at the same time unlock the insights from far larger datasets to benefit research and inform the specific treatment of individual patients.

Building and Accelerating the Health and Healthcare Internet of Things

Today, we often think of EHRs or health and medical devices in isolation or closed networks: Can we get the EHR from one clinic or hospital to talk to the one across the street? Does that infusion pump talk to that monitor? And we build and maintain a lot of interfaces.

But that's all changing as the Internet of Things takes hold and we connect "smart" devices to the internet in ways that generate data that can be analyzed and turned into valuable insight. Driven by dramatic reductions in the cost of sensors, computing and bandwidth and the drive for improved cost and efficiency, we will have a smart energy grid, smart transportation network and…we hope…a smart healthcare system. All in all, these trends will unleash the IOT opportunity impacting the way we work and the way we live. Some estimate that by 2020, there will be 50B smart devices with 212B sensors generating 44 ZB of data.

Intel and key global partners collaboratively identified five critical IoT tenets which describe how endpoint devices should connect to the cloud:

- Security as the Foundation: With billions of internet-connected devices by 2020, it is important that IoT is secure from the sensor to the cloud, including all hardware and software.
- Connectivity, Device Discovery, and Provisioning: Billions of devices cannot be managed manually. Rather, devices need to be able to communicate their "status" to the rest of the system independently.
- Data Normalization: With so many different data types, there must be some level of interoperability between devices such that they are speaking the same language.

- Actionable Analytics: The data must be turned into meaningful information through analytics.
- Monetize Hardware, Software, and Data Management: The IoT infrastructure must be built to allow developers to manage and monetize innovative applications and services.

To better illustrate these principles, let's look at Intel pilots with specific healthcare applications.

Intel's work with consumer-generated health data:

The Michael J. Fox Foundation for Parkinson's Research (MJFF) and Intel Corporation are collaborating on improving research and treatment for Parkinson's disease — a neurodegenerative brain disease second only to Alzheimer's in worldwide prevalence. The collaboration includes a multiphase research study using a new big data analytics platform that detects patterns in participant data collected from wearable technologies used to monitor symptoms. This effort is an important step in enabling researchers and physicians to measure progression of the disease, improve medication adherence and speed progress toward breakthroughs in drug development.

With wearable technology, the potential to collect and analyze data from thousands of individuals on measurable features of Parkinson's, such as slowness of movement, tremors and sleep quality, could enable researchers to assemble a better picture of the clinical progression of Parkinson's and track its relationship to molecular changes. Wearables can unobtrusively gather and transmit objective, experiential data in real time, 24 hours a day, seven days a week. With this approach, researchers could go from looking at a very small number of data points and burdensome pencil-and-paper patient diaries collected sporadically to analyzing hundreds of readings per second from thousands of patients and attaining a critical mass of data to detect patterns and make new discoveries. It is a dramatic shift from data-poverty to data-wealth — and in my view it signals the future of research and discovery.

MJFF and Intel share a commitment to increasing the rate of progress made possible by open access to data. The organizations' aim to share data with the greater Parkinson's community of physicians and

researchers as well as invite them to submit their own de-identified patient and subject data for analysis. Teams may also choose to contribute de-identified patient data for inclusion in broader, population-scale studies.

What could government do to extend the Parkinson trial to the thousands of Medicare patients suffering from the disease?

Unfortunately CMS has virtually no payment codes to provide services for the MJFF trial described above. However, Congress is recognizing the need for payment reform to encourage Medicare reimbursement for wearables and remote patient monitoring devices for patients with chronic disease through legislation as outlined by HR 4442, the CONNECT for Health Act introduced by Reps. Black, Harper, Welch, Thompson and Blumenauer.

Intel's YOU.24X7 Study

The YOU.24x7 Study, a 6-month observational pilot study of nearly 500 participants uses an end-to-end prototype platform consuming patient-generated data for research into health trends and behaviors to analyze cardiovascular risk factors and potentially improve outcomes. Patient data are collected through a number of devices: a Basis watch to track sleep and activity, plus blood pressure and weight scales in the home. These data are combined with electronic medical record information, labs and other key metrics to give more holistic view of the population. Data scientists and cardiologists are using an advanced analytics platform created by Intel, looking at the de-identified data to gain trending and correlation insights into cardiovascular wellness. Meanwhile, the individual participant has 24x7 access to all of his or her own information through the secure personal health collaboration hub.

As an employer faced for years with unsustainable healthcare cost inflation for the 53,000 employees we are proud to employ in the United States and their 88,000 Intel Health Plan dependents, Intel has initiated these projects for business reasons — both to support a healthy, productive workforce and to grow the

global market for the powerful computing needed to scale precision medicine. We hope these programs can become examples for the rest of the country to build upon.

Congressional action is needed to ensure that these positive examples using Health IT innovation are options for Medicare patients across the country.

1) **Sustain momentum toward standards and interoperability for today and tomorrow:** As Intel's Connected Care Interoperability team demonstrated, a standards-based approach for health information technology enables quicker and more efficient deployments to share data from different sources. This provides scalability, interoperability, and innovation as new services can be built upon a common framework of standards, data models and clinical vocabularies. Intel supports an implementation specification compatible with baseline standards that are specific, well-documented, tested vigorously, and shared publicly, as described in HR 6, the 21st Century Cures Act.

   Intel invites policymakers to consider standards and interoperability efforts beyond EHRs (electronic health records) and into the domain of the health and healthcare Internet of Things (IoT) through encouraging recognition and active federal participation in industry-led initiatives such as Industrial Internet Consortium (IIC), OCF (Open Connectivity Foundation), ICE Alliance, Continua and other organizations.

2) **Encourage patient engagement by removing obstacles for patients to access and share their data.** With the adoption of electronic health records comes enormous potential for creating value from data held in millions of patient records. Today, the use of this information is regulated by a series of highly regulated consent requirements constructed by not only the federal government, but by states. Intel invites policymakers to partner with industry to pursue a standardized machine readable consent form to allow patients to donate their data to ongoing research without the need for securing and faxing consent forms each time patient data is requested. The International Rare

Disease Research Consortium has recognized this problem. The Consortium has assembled a task team from the Global Alliance for Genomics and Health to explore the machine readability of consent and its impact on data use and accessibility. PCORI has launched research into patient preferences for consent,[2] as well as other government and private industry initiatives.

3) **Continue to push toward value-based care:** We support the HHS goal announced last year to move 30 percent of care to alternative payment models by 2016 and to 50 percent by 2018. When incentives are aligned toward value-based care and managing population health, the demand for information-sharing goes up. Fee-for-service models work the opposite way, in which providers are paid based on the volume of service they deliver. Based upon Intel's experience with Connected Care, we have seen increased patient engagement and better outcomes based upon shared risk, shared goals and consistent metrics for success. As the U.S. healthcare system moves to outcome-based payments through the Medicare Access and Chip Reauthorization Act (MACRA), Congress can assist through providing funding for new care delivery tools for training and discovery until the 2019 implementation date for remote patient monitoring (RPM), which remains mostly unpaid in today's fee-for-service environment in spite of studies showing as much as a 75 percent reduction in hospital readmissions when provided to chronic care patients.[3]

4) **Facilitate the right mechanisms and incentives for managing and reducing cyber security risk:** Open collaboration and communication among regulators, industry medical and healthcare practitioners are key to managing and reducing cyber security risk. Public-private partnerships have proven to be successful in helping a wide range of industries improve their cyber security readiness and overall capabilities in the past. More recently, the NIST Cybersecurity Framework has provided a tool for healthcare organizations to review their security posture with a focus on risk management. The Framework provides an organization the ability to evaluate its current security posture, create a

[2] http://www.pcori.org/research-results/2014/demonstrating-respect-and-acceptable-consent-strategies-what-matters-patients

[3] http://healthaffairs.org/blog/2014/04/04/the-role-of-remote-care-management-in-population-health/ o http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/snell-smalley_hospital_-physician-summit-feb-2013.pdfr

target for risk tolerance and allow the organization to develop a path towards achieving the target. The U.S. Department of Health and Human Services' (HHS) mapping between the HIPAA Security Rule and the Framework through an effort developed in conjunction with NIST and the Office of the National Coordinator for Health IT (ONC) provides a means for healthcare organizations who have aligned their security programs to the HIPAA Security Rule to be able to use the Framework to identify and address gaps in their security. Collaboratively developed efforts such as the NIST Cybersecurity Framework provide real benefits to healthcare organizations wishing to better understand and improve their organization's cyber risk management processes and posture. Security must be stressed at the outset, rather than **as an afterthought in the design process.**

Cyber security must be baked into the equipment, systems and networks at the very start of the design process - intrinsic to an organization's thought processes, its business processes, and its design, development, and manufacturing processes. It must be embedded in a product or network element so that it becomes an integral part of the product's or element's functioning. This approach is not only more effective; it is less cumbersome and less expensive than trying to lock down systems that are inherently insecure after the fact, as has happened all too often in the past in a wide variety of industries, including health care.

While Information Sharing and Analysis Organizations (ISAOs) and associated liability protection for participation have been proposed to allow increased sharing of information on cyber threats among private sector participants, such proactive information sharing could be a valuable tool in preventing cybercrimes. Gaining active participation in such organizations – whether in support of cybersecurity or patient safety – will require carefully crafted mechanisms and incentives.

5) **Ensure privacy as an enabler of innovation**: Intel believes that privacy is a key enabler of innovation in this sector. If individuals are to feel at ease with these technologies and data uses, they

must trust that their devices are secure and data about them is protected and used in privacy respectful ways. Intel endorses the application of long recognized, proven principles of fair information practices to address concerns about data practices and privacy. Intel further endorses implementation of "privacy-by-design" - that is, addressing privacy and building in privacy solutions throughout the design cycle of technologies and data applications.

Privacy and progress in this sector are not values to be balanced or traded off - they are goals that must be pursued in tandem if we are to realize the benefits these technologies promise.

We thank the Committee for inviting Intel to address Congress on the important contributions being made today in the diverse realm of Health IT and for considering our recommendations on how to accelerate deployment.

Matthew Quinn. Federal Solutions Director
Health and Life Sciences
Intel Corporation

Matt Quinn – Bio

Matt Quinn manages Federal Healthcare Solutions and was previously Intel's East Coast Managing Director for Intel's Healthcare and Life Sciences business. He joined Intel from the Federal Communications Commission (FCC), where he was the Commission's first Director of Healthcare Initiatives. Prior, he led efforts at NIST and AHRQ to improve the usability and accessibility of health IT and to realize the value of health IT in emerging models of care delivery. In addition, Matt served as program management lead for the National Resource Center for Health IT, as lead staff for the National Committee on Vital and Health Statistics (NCVHS) and as Co-Chair of the Assistive Technology Subcommittee of the Interagency Committee for Disability Research (ICDR). Before joining government, Mr. Quinn was the Healthcare Industry Manager for Teradata, responsible for healthcare strategy and partnerships. Prior, he led marketing for Quantros, a patient safety and clinical outcomes improvement software company, managed GE Healthcare's "Six Sigma for Healthcare" consulting services and data analytic products, helped build an early Personal Health Record (PHR) company, and served as an Army Engineer Officer. Matt earned an engineering degree from the United States Military Academy at West Point and an M.B.A. from Colorado State University.