July 21, 2014

The Honorable Fred Upton; Chairman
The Honorable Diana DeGette; Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

RE: Comments from UL in Response to 21st Century Cures White Paper on Digital Health Care

Dear Chairman Upton and Representative DeGette:

Underwriters Laboratories (UL) appreciates the opportunity to comment on the 21st Century Cures initiative White Paper on Digital Health Care. UL has been involved in the interoperability of electrical distribution systems and healthcare/medical devices interoperable systems from the start. Just as appliances can safely be plugged in to outlets without having to think about safety implications, UL would like to see that same level of confidence in safety brought to telehealth.

UL shares 21st Century Cure's desire to increase quality of care, decrease costs in healthcare, and provide mechanisms for increased innovation in health. UL applauds the goals of this initiative and believe they can be enhanced by including patient safety as a top concern for digital healthcare. As new technologies enter the health care ecosystem, there are new safety challenges that must be addressed and considered to ensure patient safety, safe living and working environments. UL is driven by our global safety mission, which promotes safe living and working environments by the application of safety science and hazard-based safety engineering. The application of these principles manifests itself in the evaluation of tens of thousands of products, components, materials, and systems for compliance to specific requirements. Through these activities, UL actively engages the US government in its development and administration of federal regulations and conformity assessment programs at the federal, state, and local levels.

As the health care system is becoming increasingly digital, health care providers and health care systems are facing new challenges. From things like interoperability challenges to data issues, the health care ecosystem is being faced with challenges that have never been seen before and that can impact patient safety. In this world, it is critical that patients receive innovative products in a timely manner that are also safe and interoperable. In order to facilitate new innovations getting to the market and to patients quickly, UL urges 21st Century Cures to consider other aspects of digital health that as critical to patient safety such as post market surveillance and full systems based risk classifications to balance the need for innovation with patient safety.

Introduction

UL is a premier global independent safety science company that has championed progress and safety for 120 years. UL's more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people. UL uses research, standards, and conformity assessment to continually advance and meet ever-evolving safety needs. We partner with businesses, manufacturers, trade associations, and international regulatory authorities to bring solutions to increasingly complex global supply chains.

UL Life & Health Sciences (LHS) is the focused on the healthcare sector, working on the safety of medical devices, software and the larger health environment. UL LHS is an internationally accredited and recognized third party authorized body (e.g.: PAL, Japan, CMDCAS, Canada) and Notified Body in Europe for CE marking certification. Leading global medical device manufacturers use UL to test and certify their products. As this division has evolved, UL LHS has recognized the increasingly integrated and digitized healthcare sector has new needs for standards and safety.

Additionally, UL is a Standard Development Organization (SDO) accredited by ANSI (American National Standards Institute) with a long history in standards development. As such, UL works to

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contribute to telehealth developments through the creation of standards focused on the safety aspects of medical devices interoperability. UL has partnered with the Association for the Advancement of Medical Instrumentation (AAMI) to develop standards in the area that are focused at achieving the goal of safety in the telehealth space.

Overview

While much has been accomplished to initiate interoperability and safety in healthcare, the infrastructure is in its infancy of deployment and still has to mature to achieve the same level of confidence in safety that is enjoyed with established technologies such as electricity, transportation, and telecommunications. UL believes that as conversations progress around telehealth and digital medicine, it is important to keep safety and certification of systems and components a paramount priority.

HIT Safety Should Be Focused on Full Healthcare Ecosystems

Throughout the 21st Century Cures round tables, hearings, and this White Paper, it is UL's interpretation that 21st Century Cures is focused on Electronic Health Records (EHR) systems and other singular digital health care products. UL recommends that 21st Century Cures look to shape the overall healthcare ecosystem: medical devices, infrastructure (e.g. medical device data systems), and EHRs, to help ensure that the unregulated domains of the ecosystem cannot compromise the safety of the regulated domains with which they are interconnected.

When looking at how technology is introduced into the HIT environment, particularly in situations where there are integrated devices from multiple vendors, the intended use for an individual device is often not as relevant for risk as the system integration and purpose (i.e. intended use) of the larger interoperable system is. For example, consider a situation where there are two individual standalone devices from separate manufacturers "A" and "B" that include indications for use in an integrated system. The ultimate clinical benefit of combining those two devices would be under the design of the system integrator. In this situation, the system integrator would determine the intended use and constraints associated with the emergent system that is neither a direct function of "A" nor "B." The intended use of a medical device, when planned for use in a broader, connected environment such as a HIT system, has to take into account certain connectivity and functionality. UL believes that risk needs to be assessed not only based on intended use, but also on the impact a device or system can have to patient safety in the context of the entire HIT ecosystem in which it is connected.

Additionally, there may also be risk from what certain regulators classify as "low risk systems" in terms of the movement of data. Data originating from one source, such as an EHR that would then enter another regulated device, like a medical device, could cause harm or damage to the second device if it was corrupted or malicious data. Such movement of malicious data can be part of a causal chain for harm to the patient. UL believes that all parts of this chain (including the nature of the movement of data) need to be considered when developing regulations or risk classifications.

One way to mitigate many of these challenges is through improving safety labeling requirements. The HIT industry can look to the factory automation industry for an example. In factories, there are safety systems that are put in place. These often involve things like punch presses and light curtains that shut down a machine if someone gets too close. The labeling on these two different products helps to capture key safety attributes and communicates those to the system integrator. This is very important for making sure the devices work together and keep the integrator informed. Applying this idea to the healthcare world, when there are products from disparate vendors and a separate systems integrator, having that minimum safety information available on labeling related to intended use and indications for use could be useful for safe systems integration.

Post-Market Surveillance is Key to Patient Safety

UL shares 21st Century Cures belief that providing new technologies to patients and doctors as quickly as possible is an important goal within healthcare. However, UL feels that this needs to be done with safety as a primary concern, even if pre-market regulations or testing requirements are modified. UL believes that post-market surveillance is a critical aspect of ensuring patient safety as new technologies (e.g. EHRs, etc.) that are, as yet, largely unproven in the field are deployed. UL feels

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that without mechanisms in place for correlating adverse events to specific technology deployments, it will become virtually impossible to determine whether (a) the technologies are implicated as "root causes" of adverse events, and (b) whether current risk controls are sufficient to meet societally tolerable risk targets from a risk/benefit perspective relative to the use of these new technologies. If the root cause of the potential hazard is related to a component that doesn't fall into the domain of regulated devices, then the traceability to that component will be a challenge. UL feels that the Committee should consider looking at ways to increase the use and effectiveness of post-market surveillance so that new health information technologies can enter the market quickly, but still be tracked and monitored once it is in use.

Private Sector Standards Activities and Third Party Testing Can Supplement Government Regulation

Similar to 21st Century Cures, UL is constantly looking for ways to improve the regulatory environment for manufactures, doctors, and patients. UL understands that there is currently a very intricate process of regulation around entering the market in many aspects of digital health, and feels that third party testing is a way to help lessen the government burden on this type of testing. Currently, there are often long backlogs for drugs, medical devices, and systems to enter the health market due to the limited resources of the government. By using third party testing organizations, innovations can be tested to the same high standards, but enter the market more quickly by using testing organizations with a smaller backlog. This balance of high standards and regulation with testing organizations that have the capacity and capability to do the testing could help 21st Century Cures to achieve the goals of quickly getting quality products in to the health care market.

UL believes that given the diverse landscape of issues surrounding HIT and regulation that third party testing and industry driven consensus standards can help to provide guard rails to the industry in terms of safety. UL believes this type of testing can provide confidence in the quality of products entering the market and provide a level of credibility for patients and doctors to reference, At present, three different agencies are engaged in creating standards and regulations around HIT. While the FDA Safety and Innovation Act (FDASIA) working group is focused on streamlining communication, the current regulatory system can be complex and burdensome on telehealth. At present, certain regulatory agencies rely on third party certification that's market driven to support the regulatory processes. We recommend that the Committee should consider at the possibility of those types of processes being introduced into the current HIT regulatory environment. For example, the principles of the National Technology Transfer and Advancement Act (NTTAA), enacted more than 15 years ago, states that federal agencies should utilize standards developed by private sector voluntary consensus standards bodies in lieu of developing unique proprietary, non-consensus, standards. The NTTAA goes on to direct Federal agencies to consult with standards development organizations (SDOs), and participate in standards development. Voluntary consensus standards reflect the interest of diverse stakeholders. They help to support and guide technical specifications and resulting conformity assessment. UL believes that standards have a dual function to meet evolving regulator needs: (1) They provide the reference for specifications and processes, allowing the industry to have a common set of standards upon which to develop products and support interoperability; and (2) They can help mitigate risk, while supporting safety and quality. Standards, however, should not impair or become obstacles to developing new and better technologies. UL supports regulator engagement with private sector SDOs to meet agency needs.

To supplement these types of standards, UL believes that the Committee should consider recommending the use of independent Third Party Certification via Nationally Recognized Testing Laboratories (NRTL) to supplement existing regulatory processes. Currently, regulators in the telehealth space are often overburdened with the scope of requirements placed on telehealth systems, and particularly EHR systems. UL believes that this burden can be eased and the process made more efficient through the use of Third Parties to complete verification and certification of telehealth products and systems. The Occupational Safety & Health Administration (OSHA) requires that specified equipment and materials (products) be tested and certified for safety by an OSHA-recognized organization, called a Nationally Recognized Testing Laboratory. OSHA's NTRL program fulfills this responsibility by recognizing the capabilities of private sector testing organizations to test and certify such products for manufacturers, according to a specifically pre-defined scope. The NRTL Program, in operation since 1988, is an effective public and private partnership. Rather than performing product testing and certification itself, OSHA relies on private sector organizations to do so. Using existing private sector systems to perform the work eliminates the need for creating and maintaining

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government facilities. Additionally, it drives down the costs for manufacturers as NRTLs complete for business. An organization must have the necessary capabilities both as a testing laboratory and as a product certification body, for the specific products covered within its scope of recognition, to be designated as a NRTL. UL believes this policy and precedent should be applied to HIT systems and products.

Continuing an International Perspective

At present, there is an environment where manufacturers are complying with largely internationally based standards for safety, quality, and performance. Additionally, from a technology perspective, the types of systems that are emerging are unconstrained by geographic boundaries. As a result, HIT is evolving into global communication systems that enable clinical capabilities. Considering those two things, while 21st Century Cures is a U.S. focused activity, UL believes it would be beneficial for Congress to be cognizant of how global regulatory authorities are addressing this issue.

Data in Digital Health

The issue of data is an important topic. At present, there is a growing need for data security and safe interoperability in the digital health space. There is a significant focus in the field of cyberphysical systems on reducing the threat surface (i.e. opportunities to attack these systems) and addressing security and safety aspects of system design as forethought rather than an afterthought. As such, UL believes that data integrity and security must be a primary concern in the digital health field.

As previously mentioned, UL/AAMI collaboration is intended to result in the jointly published AAMI/UL 2800 series of standards for safe interoperability of medical devices (including Mobile Medical Application software), with the intent of becoming an internationally adopted.. More information on this standard can be found in the Appendix.

Conclusion

UL commends the members of the 21st Century Cures initiative for working together on this important topic. Moving forward, HIT systems will continue to be an important aspect of how health care is delivered and UL believes that patient safety, the development of consensus based standards around such systems and their interoperability must continue to be paramount concerns.

UL looks forward to the opportunity to work with the Committee on these important issues. Please contact Abel Torres [redacted] if you have any further questions.

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Appendix: AAMI/UL2800

Health Information Technology Standards

UL is participating in the development of a safe and interoperable integrated clinical environment by working to demonstrate key aspects of safety assurance. We aim to facilitate interoperability that can be trusted from the perspectives of manufacturers, regulators, solution providers, healthcare providers, and patients. UL is engaged with multiple stakeholders from industry sectors relevant to health IT and mHealth. Stakeholders include: the healthcare and IT industry, medical device manufacturers, software and mobile application developers, healthcare provider organizations, standard development organizations, academia, and nonprofit stakeholders. UL has conducted significant research and been involved in case study work to support the pending development of a suite of consensus-based standards for interoperable medical device interface safety (AAMI/UL2800). This standard defines the safety and related specifications of interface(s) required when it is declared an interoperable medical device, thereby enabling manufacturers to design safer interoperable products and aid healthcare facilities in implementation. UL has facilitated the development of medical device interoperability safety based on sound research and concepts:

- Engaged in developing standards for “interoperable medical device interface safety,” which establish a link between the Medical Device domain and the HIT domain.
- The outcomes of these activities are intended to encompass safety concepts from a number of international medical device safety standards.
- These safety concepts are aligned with the essential requirements of multiple directives across several product safety engineering disciplines.

We are aligning with existing internationally accepted standards. The type of standards reflect the essential requirements of international directives so that essentially when these standards, like 2800, become adopted in regulatory processes they are effectively aligning with international philosophies.

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Response to House Energy and Commerce Committee request for suggestions for "21st Century Cures"

Submitted on behalf of Indiana University by Assistant Vice President got Federal Relations Doug Wasitis [redacted]

As House Energy and Commerce Committee Chairman Fred Upton has stated, "Advancements in technology and communications provide a gateway of opportunity as we work to accelerate the discovery, development, and delivery cycle for innovative cures and treatments. "

Healthcare institutions and academic information technology developers in Indiana have important problems to solve. Indiana University, IU Health, and their partners in the state of Indiana are at the forefront of using modern networks and information technology to accelerate discoveries in medicine and propel them into practice, thus improving the lives of Hoosiers. The approaches we are implementing in Indiana can serve as a model for the US generally.

Indiana: Challenges and opportunities in our history

For more than a century, Indiana's economy has centered on agriculture-, coal-, and heavy steel-based industries.

The economy of Indiana has struggled particularly following the decline of steel-based industries since the late 1990s. At one point or another since then, Indiana has led the nation in personal bankruptcies, unemployment, and mortgage defaults (all prior to the economic downturn in 2008). As the economy has lagged, many health problems in Indiana have worsened. Indiana now ranks amongst the lowest states in the US in health indicators such as obesity and smoking. In 2013, Indiana also led the nation in Methamphetamine-related drug arrests.

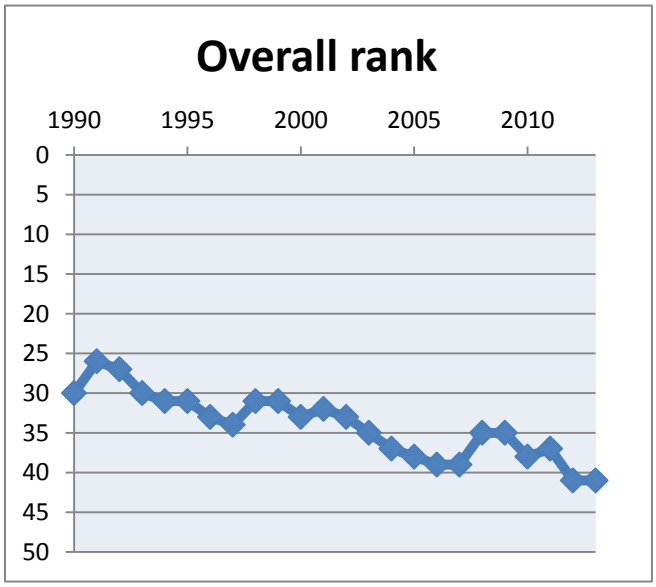

Figure 1. Indiana ranking among states in the US in terms of overall health. Data retrieved from americashealthrankings.org.

These factors and others have lowered Indiana's health ranking among US states from about the median in the nation to its current ranking of 41st in health indicators overall, as shown in **Error! Reference source not found.** at right.

For decades, Indiana University has led the nation in the creation of electronic health record systems.

The Regenstrief Institute – a medical research institute affiliated with IU – established the Regenstrief Medical Record System, which over time led to the creation of the HL7 medical records system that set international standards for transferring clinical and administrative data between hospital information systems. As a result of Regenstrief's leadership, the medical records of most Indianapolis-area hospitals were housed on the Indiana University-Purdue University Indianapolis (IUPUI) campus.

In recent years, IU has emerged as a leader in information technology and networking.

Since the mid-1990s, IU has established itself as a leader in advanced computing and networking. In 2001, the Indiana Legislature approved funding for a university-owned research network connecting Indiana and Purdue Universities. In 2010, the legislature approved expanding that network to every college, university, and university-operated medical research clinic in the state of Indiana. Furthermore, in 2007, all of IU's supercomputers and massive data storage systems were HIPAA aligned. IU was the first non-classified facility to achieve this status, which meant IU supercomputers could be used for analyzing protected, personal health information as part of clinical and translational research.

As a result of these factors, the state of Indiana constitutes a potential proving ground for new clinical and translational research and testing of new therapies in practice. Indiana has an unusual combination of a population with an abundance of people with health challenges (many lifestyle-induced), and excellent advanced networking and information technology systems supporting clinical and translational research and enabling new breakthroughs in healthcare.

Pursuing solutions that improve lives

In particular, within this challenging environment, the state of Indiana and IU have established a pipeline from basic laboratory research to clinical and translational research. Implementing scientific discoveries leads to better health in the community, as exemplified by the National Institutes of Health-funded Indiana Clinical and Translational Sciences Institute (CTSI).

Indiana University, IU Health, and partner research universities Purdue University and Notre Dame have distinguished themselves nationally through the use of advanced information networks and 21st century communications technology to promote and enable collaborative research. Figure 2 below briefly explains the concept of translational research – research that translates biomedical innovations into treatments that improve lives.

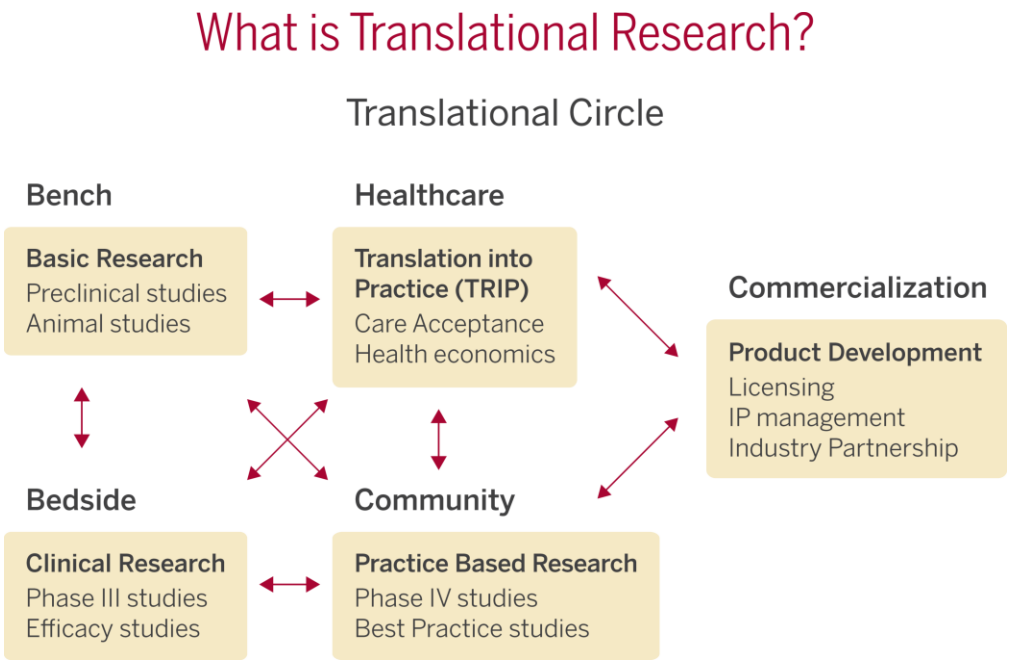

Figure 2. The cycle of translational research from basic research, to translation into practice, to product development.

Two characteristics distinguish the approach Indiana University is leading within the state of Indiana (these partnerships are shown below in **Error! Reference source not found.**):

- The level of collaboration across academic, private, and governmental sectors
- The use of leading edge cyberinfrastructure and advanced networks to enable collaboration and accelerate the translation of innovations into practice and products improving health in the state and our nation

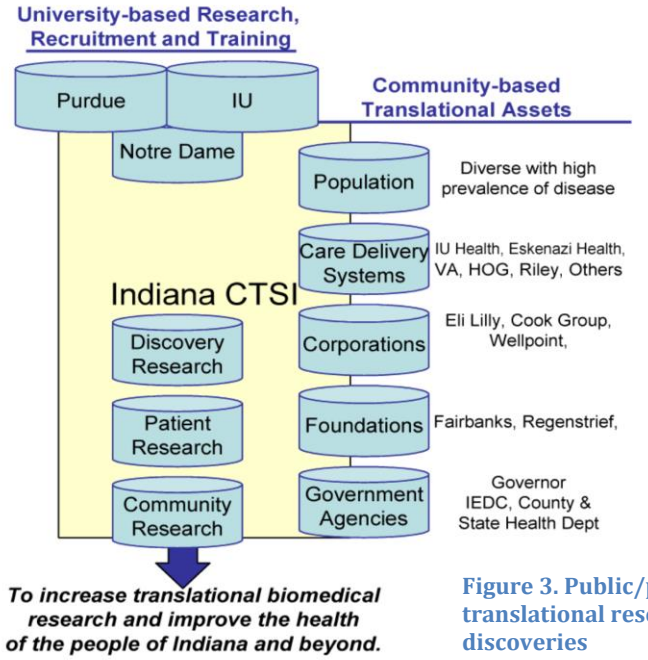

Figure 3. Public/private partnerships enable translational research collaborations and new discoveries

Establishing a model for others

Critical factors that have enabled the state of Indiana to effectively bridge public and private sectors to accelerate medical and health research include:

- **A shared commitment** to improving health across many organizations and many sectors of the Indiana economy

- **A statewide research network** (I-Light) that creates a secure and high-speed backbone for collaboration and exchanging data (See **Error! Reference source not found.**)

- **An advanced cyberinfrastructure** at Indiana University consisting of supercomputers, sophisticated databases, massive high-speed data storage systems, and archival tape storage systems, *all HIPAA-aligned and suitable for storage and analysis of protected health information*

- **A robust private-public partnership** in which the Regenstrief Institute, affiliated with IU, and the Indiana Health Information Exchange (IHIE) maintain a data warehouse with data from 103 of approximately 120 Indiana hospital systems, and almost all Indiana labs, X-ray facilities, and governmental databases (See Figure 5)

- **An online collaboratory** – also secured and suitable for transmission and analysis of protected health information (See Figure 6)

- **IU Health, an 18-hospital public/private partnership** led by IU providing excellent healthcare throughout the state of Indiana and also serving as a venue for clinical, translational, and population research

- **Two new accredited schools of public health** – the IU Fairbanks School of Public Health, located in Indianapolis, and the IU

Figure 4. The statewide I-Light network, supporting research and development throughout the state of Indiana.

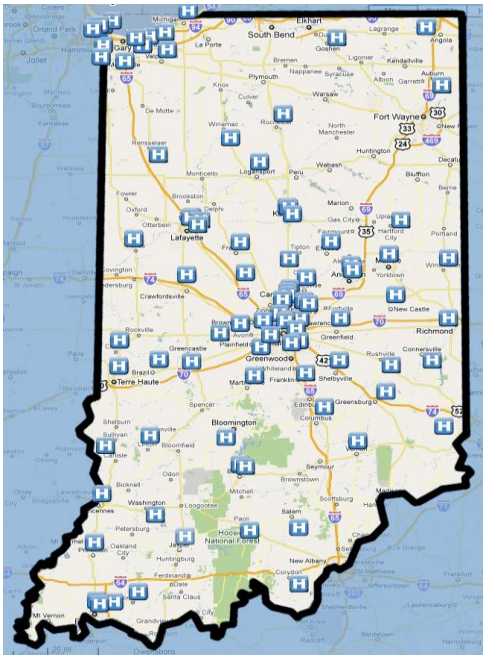

Figure 5. The IHIE contains more than 5 billion observations for over 12M patients. It is the oldest, largest, and most comprehensive health information exchange in the US. Map from ihie.org.

Bloomington School of Public Health – that focus on urban and rural health and are expanding the reach of medical research efforts focused on curing disease into community-based medical research to improve the quality of lives of Indiana's citizens.

Figure 6. The Indiana CTSI (Clinical and Translational Studies Institute) online collaborator enables secure, real time collaboration across public and private to advance medical and health research.

Indiana University embraces and supports the goals set out in the House Energy and Commerce Committee white paper "21st Century Cures: A Call to Action."

We believe that the state of Indiana, through collaborative efforts led by Indiana University, provides a model that can be adopted throughout the US. The combination of willingness to collaborate across public/private boundaries, a high performance network, and a cyberinfrastructure suitable for research using private and protected health records, is enabling the state of Indiana to accelerate new discoveries and their rapid translation into everyday medical practice and improved quality of life. Similar collaborations in other states and between states across the country would accelerate the delivery of medical breakthroughs and improve healthcare delivery and lower costs across the country.

To: U.S. House of Representatives, Energy and Commerce Committee, 21st Century Cures Initiative, Chairman, Congressman Fred Upton and Congresswoman Diana DeGette.

From: Medidata Solutions **Data:** August 15, 2014

Re: Response to White Paper: Leveraging Technology to Accelerate the Path to Cures

Author: Steve Smith Director of Patient Value, Medidata Solutions.
[redacted] n collaboration with Mike Cestone, VP Product Management

We are responding to the 21st Century Cures call for responses as stated in the white paper, Leveraging Technology to Accelerate the #Path to Cures.

http://energycommerce.house.gov/press-release/21st-century-cures-leveraging-technology-accelerate-path2cures

Author's Note

My son has a rare, genetic disorder for which there is no cure, but for which clinical trials have been planned since the 90s. A first treatment was approved in 2014, but this is not a cure. As I watched the progressive damage done by my son's unchecked disease, I have also carefully watched in detail the clinical trials process working very slowly since the 90s. Over these years, I have met with FDA officials, pharmaceutical companies, members of Congress, and many patient advocacy groups to discuss the clinical trials process, and the, then pending, PDUFA V legislation. I am pleased to see recent changes via FDASIA, and the 21st Century Cures Initiative. I know my colleague Mike Cestone is also a rare disease advocate, and believe there are others among us here at Medidata Solutions. From this perspective, we feel privileged to be able to work everyday on a key part of the solution to the problems that 21st Century Cures seeks to address.

Summary

We agree there is a gap between the advances made by science, and the current regulatory process for drug development. New software systems for clinical trials data collection help close this gap and can greatly enhance the chances for success of clinical trials.

We see three fundamental components of U.S. leadership in drug development that have recently advanced, but are only just beginning *to work together* to drive development of new medicines for unmet medical needs. Attention by legislators, the FDA, and industry

is needed to accelerate the benefits of these advancements by ensuring that all three components work *together.*

These three advancements are:

1. **Science:** scientific advancement has progressed ahead of the clinical trials process
2. **The Clinical Trials Process:** recent improvements in PDUFA V/FDASIA may be a good start to help the trials process yield more successful clinical trials.
3. **Software and devices** for collection and organization of clinical trials data are essential means to realize the value of advances in science and the clinical trials process.

Drug developers are using increasingly comprehensive clinical trials data collection systems. Recent testimony by FDA Director Janet Woodcock (May 2014) indicates they are also utilizing the new Breakthrough Therapy Designation pathway in encouraging numbers. We believe each of these separate developments are synergistic.

Quote from Janet Woodcock, FDA, Director CDER. Capitol Hill, May 19, 2014

We have been inundated with requests for the breakthrough therapy designation, said Janet Woodcock, MD, Director of FDA's Center for Drug Evaluation and Research. She said the new designation is working well. … "It's very inspiring to work on something that's really going to make a difference to lives," Woodcock said. "The pace of this designation is much faster than we had expected."

If there is a downside to the new breakthrough therapy designation, it is the burst of high-pressure work required for shortened review under this new regulatory pathway. "It is a lot of work," Woodcock said, noting that the compressed review process is very demanding for both the FDA and the drug sponsor.
http://www.focr.org/5-19-2014-oncology-times-fda%E2%80%99s-breakthrough-therapy-designation-update-janet-woodcock

The challenge Dr. Woodcock mentions is also clear to us. She cites (above) a "burst of high-pressure work required for shortened review under this new regulatory pathway." That hard work will be accomplished, increasingly, through use of software and data collection systems. FDA data, and statements issued by pharmaceutical companies reveal that sponsors are using the new accelerated approval pathway since it was passed in 2012. Separately, in their annual reports and industry presentations, pharmaceutical companies also indicate their intent to scale up and attain more drug approvals going forward. The new, more intense, interaction with the FDA, utilizing the new accelerated approval pathway, *and* a scaling up to attain even more drug approvals requires companies to leverage sophisticated software and devices to manage data collection and preparation for submission.

To derive the value of improvements to these three critical components (science, regulatory process, software technology), the three components must work *together*.

Congress and the FDA are in a position to remove some obstacles to adoption of technology. To meet the challenge of the 21st Century Cures Initiative, there needs to be more commitment and clarity that these three items work hand in hand. Within existing mandates, Congress should encourage the FDA to proactively promote the use of electronic data collection and accelerated approvals. Doubt still exists about how the FDA will regard data collected remotely, electronically, and in other modern ways. We urge more proactivity on the agency's part and clear guidance. Drug developers have concerns about liability related to data collection. These concerns hold back adoption of wireless technology, remote data collection, and other new technology. They load their clinical trials data collection with extraneous data because of concerns about FDA acceptance of data. Consistency from the Congress, the FDA, and the NIH are also a concern. This concern is most dramatically expressed in discussions of budget reductions. Additionally, Congress can also play a role by encouraging a more proactive FDA in pursuing its mandates.

We see a promising collaboration between FDA, Congress, Industry, and Patients. In this context, we encourage an awareness of the role of technology in accelerating the common cause of all these stakeholders.

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Who We Are

We are Medidata Solutions, Inc., a publicly traded, cloud-based software company with global headquarters in New York, New York, USA. Our systems, and the projects we do with our customers, are focused on speeding up throughput of life-saving treatments from the research lab to patients.

Medidata develops software used to transform clinical development, from study design and planning through execution, management and reporting.

Our software is used by pharmaceutical companies from all over the world who run thousands of trials using our software. Our customers include over 90% of the top 25 pharmaceutical companies, and hundreds of emerging small and mid-sized pharmaceutical companies. Since 2009 we have invested over half a billion U.S. dollars to develop these systems. At any given time, data from thousands of clinical trial data collection efforts is being collected using our system. We accumulate operational data that shows us, and our customers, where the efficiencies and the waste are in their data collection processes. This helps them streamline operations and gather data that is meaningful and relevant, in shorter periods of time, and for a lower cost.

As a result, Medidata has *experience and metrics* that highlight opportunities for reducing the *cost and time* of a clinical trial and reducing the *risk* that a trial will fail.
Due to advances in clinical trials software, stakeholders have the means to *measure and prove* like no time in history.

Reducing the Cost, Time, and Risk of Clinical Trials

The role of such software systems and the companies that make them, as stakeholders in the 21st Century Cures initiative, relates to this excerpt from The President's Council of Advisors on Science and Technology report (PCAST). We have added red italics below to emphasize our point.

> From: PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, EXECUTIVE OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT ON PROPELLING INNOVATION IN DRUG DISCOVERY, DEVELOPMENT, AND EVALUATION:
>
> "Double the current annual output of innovative new medicines for patients with important unmet medical needs, while increasing drug efficacy and safety, through industry, academia, and government working together to double the

efficiency of drug development, by decreasing clinical failure, clinical trial costs, time to market, and regulatory uncertainty.[2] "

"such a goal is attainable over the next 10-15 years, "… but that it "will require advances in: the science of drug development; the execution of clinical trials; the development pathways used for innovative medicines; the mechanisms for drug approval, surveillance and communication of risk; and management at the FDA."

2. Footnote: The report clarifies that such a goal means "the time and cost of projects that begin in the 2020s will be two-fold lower than costs and development times for current projects."

http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/21stCenturyCures/20140512PCASTWhitePaper.pdf

Use of Software for Trial Design, Planning, Setup, Data Collection & Analysis

It is no longer enough to have software for just part of the trials data collection process. Using a platform *across* the trials planning and execution process is necessary to tap the potential of any new, accelerated regulatory pathway and new science. Movement of data from diverse data collection devices and systems into clinical trials data collection systems holds much promise for advancing drug discovery and development. Patients, widely scattered, can now see data consolidated without having to travel to far away trial sites. Natural history and epidemiological data collection will become more common, even in cases of very rare disorders. Reduction of extraneous data can not only reduce cost, but provide a clearer view of the meaningful data that regulators need to see.

We foresee that wider adoption of such systems will enable these benefits:

- More promising science will make it out of the labs and into trials.
- FDA's accelerated approval pathway will be used more successfully.
- Improved use of Risk vs. Benefit analysis in cases of serious disorders.
- More clinical trials will succeed: reduced risk of failure
- Patient burden during trials will be significantly reduced.
- Cost of trials will be reduced.
- Time for a trial will be reduced.
- Reduced need for the use of placebo during trials.
- Increase in effective use of intermediate clinical endpoints and surrogate markers
- Improved communication between the FDA and pharmaceutical trial sponsors
- Reduction in costs of drug development in the Billions of dollars per company

2

Accelerated Approvals

It is too early to consider implementation of FDASIA successful. We have seen our clients access this new pathway and benefit from faster drug approvals, so we agree that FDASIA holds promise. But we have seen many sponsors who are still figuring out how to meet the opportunity that this new fast path represents, just as the FDA still has work to do to more proactively enable its use.

We agree with the testimony regarding breakthrough therapies, by Hyman, Phelps, and McNamara's Frank Sasinowski in his testimony to PCAST.

> *Congress should use its influence to compel the FDA to use existing powers to expand adoption of accelerated approval pathways, including those defined in PDUFA V, FDASIA.*

Systems such as ours *are a critical component* for pharmaceutical companies, research institutes, and the agency (FDA) to get this joint work done together. It is the way to gather, analyze, and *communicate* regarding the data that is the critical proof for a trial. The new accelerated pathway mandates more frequent interaction and transparent *communication* by the agency with sponsors to facilitate approvals sooner in the trials process. Effective use of modern software systems is the way to have data ready for such meetings about protocol and findings.

It is the only way to effectively manage the ramp up of activity in this regard for the FDA, the sponsors, and investors. Proper use of such systems is a net savings because it reduces the cost of a clinical trial. In some cases, we estimate annual savings for a large pharmaceutical company could exceed $1B per year from optimized use of computer systems and intelligent data analytics in clinical trials. Removing wasteful cost from the clinical development process is of value to all stakeholders.

Recommendations

For the desired ramp up of successful drug approvals, we need a wider, faster adoption of systems, *and* proactive development, promotion, and use of effective accelerated pathways through clinical trials, to keep up with, and promote, advancements in science.

A more proactive push by the FDA to gain adoption the accelerated approval pathways can help change the landscape. Pharmaceutical sponsors are more likely to adopt modern systems when they see a consistent, proactive, and transparent effort to gain adoption of the accelerated approval pathway. We have better software systems today than ever before to support such activity.

All INDs should be considered for Breakthrough Therapy Designation

Risk vs. Benefit consideration should be much more proactively applied by the FDA to allow patients with serious and life threatening disorders to access treatments after safety (and minimal, reasonable efficacy) is shown. Data collection and analytics provided by modern systems make this much more feasible.

Post marketing surveillance should be more frequently utilized instead of lengthy Phase III double-blind placebo trials. Modern systems can be used to collect the supporting data for early market release of new drugs and for tracking via post market surveillance.

Fears about how the FDA will regard the use of data collected remotely using portable devices should be alleviated by clear guidance from the FDA encouraging use of portable devices to collect data directly from patients, and perhaps by pressure from congress to remove unwarranted liability concerns.

Congress should pass new incentives for pharmaceutical companies to re-purpose successful drugs for rare diseases, by removing fears of liability, and giving more exclusivity and tax incentive. Many approved drugs, including blockbuster drugs, could be re-purposed for orphan diseases. But sponsors worry about losing their blockbuster rights if serious adverse events occur during an orphan drug trial.

Congress and the FDA should each consider incentives, within their respective mandates, to encourage the use of software systems for clinical trial planning and execution, whereby such systems encompass a wider range of applications *used together*. A precedent for this has been tried in hospital systems under the "meaningful use" incentives in which hospitals get financial breaks for using three or more separate applications (software programs) in an integrated way. Lessons learned from this experience may be carefully applied to speed up the

process of drug development. Never should such government intervention slow down or impede development of safe, effective drugs for patients in need.

Clear guidance, and consistent, proactive promotion is needed from the FDA for orphan drug developers on the use of intermediate clinical endpoints, surrogate markers, and trial designs that don't require placebo.

We need to find a practical way to repurpose trial data and other clinical data across disease groups, and patient populations, without harm to the business models and intellectual property that keeps industry healthy, and to the very substantial benefit of patients who need treatments. So new legislation that removes barriers to such data gathering should be considered. Unintended consequences of such legislation that may slow or impede drug development should be avoided.

New software, smart phones, and other remote devices in general enable a much-improved clinical trials data collection capability. This includes, but is not limited to, an improved "Patient Reported Outcomes" capability. Computer systems and devices enhance our ability to collect data from scattered patient populations who cannot travel to trials. A broad spectrum of data collection technology, used properly, can remove obstacles to drug development. Pharmaceutical companies are hesitating to deploy such technology, in some cases, due to concerns about whether the FDA will allow data collected in such ways. We urge congress to mandate the establishment of clear guidance and promote modernization of clinical trials data collection using remote data collection through electronic devices, including widely used smart phones and other patient owned devices.

Questions or Comments:

Steve Smith
Director, Patient Value
Medidata Solutions
[redacted]

Reference: http://energycommerce.house.gov/cures

Patient Command, Inc.
McLean, Virginia 22101

July 15, 2015

Via Electronic Mail: cures@mail.house.gov
The Honorable Fred Upton
Chairman, Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Re: 21st Century Cures Initiative (Comments of Patient Command, Inc.)

Dear Chairman Upton:

The federal government remains stymied in developing interoperable health records because the Department of Health and Human Services continues to push the wrong architecture for health information exchange (HIE). However, hope abounds.

During two Administrations (Presidents George W. Bush and Obama), HHS policy has pushed health data exchange systems designed to blast a flurry of electronic requests to vast, multiple databases – locally, regionally, nationally – asking that a patient's records be sent immediately to the requesting doctor or hospital (the point of care). In theory, if everything worked, the records from previous providers would be assembled instantly into a current compilation to support care.

Over decades, HHS's and the health industry's invariable experience proves conclusively that this "shotgun query-immediate response" architecture cannot be made to work. For example, the Departments of Defense and Veterans Affairs have failed repeatedly to develop a way for military members who become veterans to enjoy interoperable patient records. Many millions have been wasted, decades lost; the silos persist. Why? Over and over, DOD and VA keep trying to build HIE systems using "shotgun query-immediate response" architectures, failing every time. They do not learn from experience. You can offer, and should demand, a different path.

Your committee and your counterparts in the Senate working on the *Reboot* initiative can benefit from experience. Please cooperate to require HHS (and DOD-VA) to support health information exchange that, logically and efficiently, is integrated around the patient. Secure, patient-controlled repository accounts can store electronic records obtained from all a patient's doctors, hospitals, pharmacies, and other providers. Even records from many otherwise-incompatible health record systems can be formatted using existing technology, and sent to a patient's health record banking account to form a cumulative, patient-controlled, privacy-protected record.

The attached *Reboot* comments of Patient Command, and supporting comments from the Health Record Banking Alliance, explain in detail how HIE salvation is possible now.

Respectfully,
/s/ Richard D. Marks
President, Patient Command, Inc.
[redacted]

Attachments:
Reboot Comments of Patient Command, Inc. (May 13, 2013)
Reboot Comments of the Health Record Banking Alliance (May 13, 2013, with two attached articles)

Comments of Patient Command, Inc.
In response to
Reboot:
Re-Examining the Strategies Needed to
Successfully Adopt Health IT
April 16, 2013
Senators Lamar Alexander, Richard Burr, Tom Coburn
Mike Enzi, Pat Roberts, John Thune

Submitted May 13, 2013

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Executive Summary

The federal government has failed to develop a technically feasible network design for nationwide exchange of health records and other health data among patients, doctors, hospitals, pharmacies, insurance companies and other payors, and others who would participate in routine exchange of health data. *Reboot* accurately, and with some restraint, recites the inability of the Office of the National Coordinator for Health Information Technology (ONC) to carry out its mandate under the HITECH Act, part of the American Recovery and Reinvestment Act of 2009.

This document responds to *Reboot*'s invitation to participate in a dialog about ONC's inability to make progress under HITECH. We believe ONC under two administrations has pursued the wrong architecture for nationwide health information exchange.

Were ONC to concentrate instead on integrating health records around patients, society would realize great benefits. If patients had easy, affordable access to compilations of their own aggregated records, they would make more informed, better decisions in the marketplace. The healthcare services market would become more efficient; societal costs for healthcare would decrease. This is essential to reining in health system costs, and key to better health outcomes.

ONC has long tried to achieve interoperability among institutional Electronic Health Record (EHR) systems operated by physicians, hospitals, and other providers. The EHR systems would use a network allowing, for example, a given doctor to request all other EHR systems on the network to identify whether they held records for a particular patient and, if so, to transmit those records to the requesting doctor. There the various providers' records would be assembled by the treating physician's EHR system and used to diagnose or treat the patient.

We explain why that systems design, "provider-query," has proved technically unattainable. It cannot be successfully engineered using currently available technology.

We also analyze how ONC has failed to develop interoperability standards, which are the essential foundation for accomplishing all subsequent tasks under HITECH. ONC has failed to follow HITECH's structure because it is pursuing "Meaningful Use" of interoperable technology before the protocols for interoperability are developed and promulgated. This mistake has doomed ONC's efforts under the statute. ONC's serial failures, now more widely apparent, have prompted *Reboot.*

Yet there is reason for optimism, because an alternative network design is readily attainable. It is based on interconnecting patient records compiled from various providers and stored securely in repository (health record bank) accounts that patients own, and access to which they control. Integrating health records around patients using an existing format (the "Continuity of Care Document," or CCD) and connecting them via a network message standard protocol already acceptable to ONC, "Direct," is within reach now.

We also offer a brief introduction to how identity management and authentication issues can be addressed in the network design framework we propose. We conclude by suggesting criteria Congress can use in bipartisan planning of how best to achieve the goal of nationwide health data exchange.

1. Introduction – Achieving Health Data Exchange Through a Workable IT Architecture

Since 2001 Patient Command, Inc. of McLean, Virginia, has been developing a system for patients to collect, compile, control access to, exchange, and otherwise use their health information to help manage their health and health care. We are pleased to offer these observations in response to the invitation from the senators who authored "*Reboot.*"

We agree with *Reboot's* authors that policies and programs adopted by the Office of the National Coordinator for Health Information Technology (ONC) have failed to meet the promise envisioned in HITECH.[1] That vision is of a secure nationwide system for sharing health records in digital form. We offer a brief analysis of how ONC, almost from the start, chose an unworkable system architecture to implement HITECH. ONC remains on that wrong course today.

ONC's choice for health data exchange is what we will call a "*provider-query-based network architecture.*"[2] Experience during the administrations of President George W. Bush and President Barack Obama repeatedly proves this architecture will not work at scale.[3] Available technology cannot support it, as we explain below.

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[1] Title XIII of The American Recovery and Reinvestment Act of 2009, Pub. L. 111-5 (the "HITECH Act").

[2] ONC acknowledges that its choice of provider-query-based network architecture cannot succeed in achieving nationwide health data exchange. Department of Health and Human Services, Office of the Secretary, Centers for Medicare & Medicaid Services, *Advancing Interoperability and Health Information Exchange*, 78 Fed. Reg.14793, 94 (Notice and Request for Information, March 7, 2013) :

> The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs and Office of the National Coordinator (ONC) for Health IT (HIT) Certification Program are increasing standards based health information exchange (HIE) across health care providers and settings of care to support greater coordination of health care services. *However, this alone will not be enough to achieve the widespread interoperability and electronic exchange of information necessary for delivery reform where information will routinely follow the patient regardless of where they receive care.*

Id. (emphasis supplied).

[3] *See generally,* W. Rishel, et al. (Gartner, Inc.), *Summary of the NHIN Prototype Architecture Contracts*, Report for the Office of the National Coordinator for Health IT, May 31, 2007, available at http://www.healthit.gov/sites/default/files/summary-report-on-nhin-prototype-architectures-1.pdf. This pre-HITECH report should be read, not so much for its analysis and laudatory conclusions, but for what it missed. The report summarizes four substantial projects exploring architecture for the proposed national health record exchange network. The four contractors were Accenture, CSC, IBM, and Northrop Grumman. The report praises the four projects for exploring complexity in health data exchange and for drawing conclusions about what a national "network of networks" would look like. Those networks would use variations of what we are calling here a provider-query-based architecture. Six years later, readers will observe that the four prototype projects have not served as the basis for ONC's (or anyone else's) engineering a successful health data exchange network, whether on a local, regional, or national

An architecture that is scalable nationwide[4] is within reach, however, and we propose that Congress evaluate it.[5] This architecture offers a pragmatic approach, using available technology, for achieving HITECH's goals and other objectives such as routinely, affordably, and securely exchanging the health records of military members and veterans.

The architecture is based on using secure repositories offering consumer-controlled data accounts. There patients can accumulate, compile, review, analyze, send, and grant access to their health records to providers, family members, advisors, researchers, and others. The repositories, called "health record banks," would be connected by a secure backbone. The

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scale. With hindsight and six years' experience, we know these four projects demonstrate instead the insurmountable technical complexity of scaling up any system based on provider-query architecture, and hence the engineering infeasibility, of any health data exchange based on a provider-query template and constrained, as are all health network designs, by the limitations of currently available technology.

[4] V. Lapsia, K. Lamb, W. Yasnoff, *Where should electronic records for patients be stored?*, 81 Int'l. J. Medical Informatics 821 (2012) (simulation studies show that the "distributed" (provider-query) architecture – where each patient's records are likely to be spread over multiple nodes – is greatly inferior to the "patient-centric" (patient record repository account or health record bank) model in terms of transaction efficiency (it requires exponentially more transactions); scalability; data retrieval integrity, accuracy, and completeness (it inevitably produces substantially more errors); usability; and timely availability of access):

> In the distributed model multiple queries are needed to retrieve the fragmented patient data from the source nodes, whereas only a single query is required to obtain a patient's file in the centralized model. By design, large distributed systems with heterogeneous data sources incur a query performance penalty. Various methodologies and techniques that optimize the query performance and improve scalability and workload adaptability have been proposed and validated. An example of such optimization is the use of a 'Record Locator Service' (RLS) or similar index to identify and track the file locations of each patient's records. In the distributed model, a patient's record would be retrieved via queries to the various sites of care documented in the RLS at the time of previous encounters. Query search optimization using a solution such as an RLS dramatically reduces the cost of locating nodes with relevant data in a distributed model. *However, unlike the centralized model, the distributed model will still incur the cost of multiple queries to assemble the patient's record, in direct proportion to the extent of fragmentation.* Essentially, the total number of queries required to retrieve a single patient's complete record in the distributed model will at the very least equal the number of nodes across which the record is fragmented.

Id. at 822 (footnotes omitted, emphasis in original). This article explains why the provider-query model cannot be scaled up for a nationwide health information architecture.

[5] *See* W. Yasnoff, L. Sweeney, E.H. Shortliffe, *Putting Health IT on the Path to Success*, Vol. 309, No.10 *J. Am. Med. Assn.* 989 (March 2013)(recounting ONC's failing programs to support the provider-query model as essentially seeking "to replicate existing manual processes for contacting other clinicians or health care organizations to get patient records," listing the deficiencies of that approach, and pointing to health record banks as a better architectural foundation that is "simpler, scalable, less expensive and more secure," *id.* at 990).

backbone, or hub, would enable a "publish and subscribe" protocol using a variant of an interconnection protocol, "Direct," already under development and known to ONC.[6]

The virtues of this architecture are considerable. It is feasible and affordable. It also would introduce new market mechanisms for controlling health care costs by giving consumers information they need to make informed decisions when purchasing health care products and services. It would enable, but not require, consumers to "engage" by giving them easy, inexpensive, routine Internet access to their own health data, which they could study, analyze, and use for more efficient management of their health and health care. It would help patients invest in wellness in addition to spending to control or cure illness.

We turn to the centrality of patient engagement as a prime criterion in selecting a health data exchange architecture that can be scaled for a nationwide infrastructure.[7]

2. Refocusing Objectives of Digital Health Information Exchange – Integrating the Network Patients' Access to and Control Over Their Compiled Data to Alter Healthcare Market Behavior, Lower Costs, and Improve Care

Our starting point is with healthcare costs. Hopes for reducing the rapid escalation of healthcare costs are as important a goal of health IT as are improved patient care and better outcomes. Yet discussion of runaway costs often omits analyzing how our present system hinders patients in making rational decisions when purchasing care in the U.S. healthcare market. We hinder patients by largely excluding them, the consumers of care, from access to information (their own records) essential to their purchasing choices. Meanwhile, we make health records routinely available to many others, such as providers, insurers, vendors, and regulators.

One could hardly devise a more inefficient, essentially anti-market, mechanism. Is it any wonder that costs in the U.S. healthcare market increase rapidly and continually?

Reboot itself falls into this trap, no doubt because we as a society are in the habit of forgetting about the centrality of patients when discussing health IT. We focus on doctors and hospitals. Here is an example:

> 'Health information technology,' as referred to in federal law and in this white paper, broadly refers to electronic storage of records, electronic billing, electronic ordering of tests and procedures, and even a shared, interoperable network to allow *providers* to communicate with each other.[8]

The picture of health IT as an exchange mechanism primarily for providers, rather than as a system integrated around healthcare consumers (patients) and designed to help patients make

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[6] For discussion of Direct, see *infra* notes 17 & 20 and accompanying text starting on p.12.

[7] The Appendix to these comments is a graphical comparison of "provider-query" architecture to the "patient-centered repository" or health record bank architecture. It illustrates why the provider-query model cannot be scaled to support a nationwide health information infrastructure.

[8] *Reboot* at 6 (emphasis added). Here is another example: "If *providers* are not able to achieve meaningful use of their new technologies, they will not be in a position to share electronic records with other *providers* at the interoperability stage." *Id.* at 13 (emphasis supplied).

sensible choices in cooperation with providers and other advisors, appears throughout *Reboot*. It is an ingrained assumption in analyses of U.S. healthcare.

Thus we have a market in which under-informed consumers are incented to buy health services, most often because they are sick and sometimes because they want to stay healthy. They usually have means to purchase almost unlimited expensive services because they are insured. Meanwhile, the sellers – doctors, hospitals, and other providers – are primed to sell more and more expensive services because most care is reimbursed under a business model from the 1960s (based on Medicaid and Medicare). This is a system primed to produce rising costs.

The practice of keeping important health information (the contents of their own medical records) from consumers helps to perpetuate this fundamentally inefficient health care market. Its underlying premise is that medical information is too arcane for untrained consumers to use when making healthcare choices, and hence when selecting healthcare services to purchase.

Today in the U.S. this premise is wrong. We have both technology to make people's medical records available to them privately and securely, and a range of advisors and advisory services to help them use that information in making sensible healthcare purchasing decisions. We could therefore create a far more efficient market for health services and products.

We can use this realization to reorient public policy for health information exchange by redefining our basic goal thus: *The purpose of health IT is to compile health information from various providers and other sources, and place that information in a secure repository under the patient's control so that the patient can make it available in whole or part at various points of care or for other purposes such as research in which the patient wants to participate.*

The re-orientation to a patient-centric model for health care information exchange leads directly to a corollary: The most efficient way to implement health information exchange is to establish secure repository accounts so that patients can deposit their health records in compilations they control, and to which they can grant access to providers, medical researchers, family and trusted advisors, insurers and others as appropriate. Access and information exchange is accomplished through secure networks. We deal below with some authentication and other privacy and security features that can be used for these networks.

The "engaged patient" is a goal of much writing about health IT policy. Patients who lack routine access to their own health records have difficulty maintaining the level of engagement necessary to manage their health effectively long term. Conversely, giving patients routine, easy, inexpensive, secure Internet access to their own health information is probably the best approach to engage them for the long run in helping to manage their health and healthcare.

Integrating health information around the patient-consumer to whom they pertain is inherently efficient. It can be the basis for a redesign of health information exchange under HITECH. It is a practical network architecture in contrast to the principal architecture that has been ONC's focus under HITECH, and to which we now turn.

3. Understanding ONC's Selection of an Unworkable Network Architecture for Health Information Exchange

When ONC first sought to implement HITECH, it set a course that disregarded both law and logic. ONC did so (prodded by the Policy Committee established under HITECH) because it sought to define "Meaningful Use" of "Certified EHR Technology" prematurely. ONC attempted to define "Meaningful Use" before establishing the interoperability standards that HITECH specifically requires as a prerequisite to any such definition.[9] The consequences of this mistake bedevil U.S. health IT programs to this day. This is the root cause of the deficiencies outlined in *Reboot.*

Subtitle A of HITECH, Section 3000, dense and prolix, is fundamental. Under subsection 3000(13)(B)(iv), a "Qualified Electronic Health Record" must include the capacity for what we understand colloquially as interoperability. Here is that subsection:

> [Qualified Electronic Health Record. – The term 'qualified electronic health record' means an electronic record of health-related information on [*sic*] an individual that –
>
> (B) has the capacity–
>
> (iv) to exchange electronic health information with, and integrate such information from [*sic*] other sources.

Earlier in Section 3000, in subsection (1), the term "qualified electronic health record" is used to define "Certified EHR Technology":

> The term "certified EHR technology" means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved . . . .

ONC is charged in Sections 3001-3009 with overseeing the standards development process for Certified EHR Technology. Adopting these standards is crucial, because what is to be "used meaningfully" under HITECH is Certified EHR Technology. If the standards used to define how an EHR will "exchange electronic health information with, and integrate such information from other sources" (subsection 3000(13)(B)(iv)) are not established first, then any discussion of Meaningful Use becomes meaningless. How is any doctor or hospital to know how to use Certified EHR Technology meaningfully when the standards underlying the secure exchange of health data are left to some later time?

The quandaries summarized in *Reboot* are consequences of this fundamental mistake at ONC. For example, *Reboot* notes the proliferation of entities with overlapping, and perhaps conflicting, health IT roles:

> [H]ealth IT policy is governed by a complicated patchwork of overlapping federal legislation and standards. Federal laws and standards are implemented through CMS, the

[9] The areas for which the standards are required are listed in Section 3002(b)(2)(B) of HITECH. They include security, privacy, a nationwide technology infrastructure for the electronic use and accurate exchange of health information, and use of a certified EHR for each person in the United States by 2014.

> Office of the National Coordinator for Health IT, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the National Institute of Standards and Technology, among others. Additional entities working on standards include the Health Information Security and Privacy Collaboration, which is developing a national privacy and security framework, the Health Information Technology Standards Panel, a public-private effort to develop standards for the certification of health IT products, and the National eHealth Collaborative, a public-private advisory body to make recommendations on health IT adoption and usability. The multiplicity of actors and entities has created a confusing, complicated system of requirements that providers must navigate in order to avoid mandated penalties for noncompliance. These compliance burdens are largely not in sync and create a tangle of requirements that may be well intentioned, but will likely be opaque and confusing to stakeholders.[10]

These organizations and others in the private sector are foundering because they are, essentially, attempting to compensate for the basic, fatal structural weakness in ONC's Meaningful Use criteria. That structural flaw is the absence of data exchange standards for information to be sent back and forth among the vast array of disparate EHR systems already installed throughout the U.S. These disparate health record systems use different, proprietary code structures, operating systems, and communications protocols that make them incompatible and non-interoperable with most other installed EHRs bought from other vendors.

Omitting the essential first step of defining standards for a specified initial (and presumably rudimentary) level of health information exchange, ONC concentrated instead on trying to define Meaningful Use. Because Meaningful Use of interoperable data exchange cannot have real meaning until the initial specifications for the data exchange are defined in a government-adopted standard, ONC's approach has proved infeasible. (ONC did not perceive this infeasibility, nor did the ONC Policy Committee.) However, some in the health IT industry knew soon after HITECH's enactment, and after the first few meetings of the Policy Committee, that ONC's chosen course would fail.

Reboot correctly concludes that ONC's federal subsidies continue to make the problem worse week-by-week. ONC's programs encourage doctors and hospitals to install more of these incompatible systems, that is, systems that are non-interoperable under the criteria demanded in HITECH subsection 3000(13)(B)(iv). Of course, they are not interoperable because ONC did not publish interoperability (data exchange) specifications. ONC instead concentrated on fleshing out Meaningful Use, despite the obvious proposition that "Use" cannot be "Meaningful" until everyone knows how and the extent to which a federal government exchange standard will control health data exchange nationwide.

Here is the fundamental logical, engineering, and legal precept that Congress, HHS, and ONC should adopt in rebooting efforts to create a systems design that will actually work for nationwide health data exchange: *both in law and systems design logic, HITECH's core – and by far most difficult – task is developing standards for secure data exchange in health IT.* That task must come first. It is the foundation for everything else in HITECH. ONC unfortunately bypassed it.

[10] *Reboot* at 25.

Until Congress corrects that mistake and mandates adoption of that systems design approach, the foundation for further progress under HITECH does not exist. Congress must, through oversight or legislation, require ONC to develop and publish mandatory initial data exchange standards.

At present, therefore, it is idle to speculate about what doctors and hospitals should be required to do under Meaningful Use (though ONC's Policy Committee continues to do so in exquisite detail). It also is ultimately useless (and vulnerable to successful legal challenge) to incorporate the Policy Committee's Meaningful Use wish list into HHS regulations.

Any federal judge who reviews those regulations under the Administrative Procedure Act (which applies to ONC's implementation of HITECH) would readily see violations of law. Meaningful Use regulations that are not based on published federal interoperability standards, are by definition under HITECH, arbitrary and capricious.[11] That is an inevitable, unavoidable conclusion. Put another way, and incorporating systems engineering logic into the HITECH legal analysis: If no one knows what data must be exchanged because they do not know how it will be exchanged, and do not know what format or other requirements the data will have to meet in order to be exchanged, the HHS regulations makes no sense.

This tautology extends beyond the courtroom to the real world. ONC's current approach creates an insurmountable engineering barrier to meaningful progress. It is why ONC-sponsored health data exchange projects are and will continue to be unsustainable, and have and will fail over the course of 2013.[12]

The absence of data exchange standards has an impact beyond HITECH implementation. It is also, for example, the fundamental obstacle to efforts of the Department of Defense and the Veterans Administration to enable their respective health record systems to exchange medical record data for the benefit of service members and veterans.[13] The continuing costs of this interoperability barrier in outcomes and dollars are well known. They are the target of oft-renewed efforts by the secretaries of both departments. Yet DOD-VA efforts, like a raft of health information exchange projects in the civilian sector, are unlikely to succeed until ONC

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[11] For an example from the field of securities regulation of the intersection of an agency's substantive statute with the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, resulting in the invalidation of agency action, see *Business Roundtable v. SEC*, 647 F.3d 1144 (D.C. Cir. 2011). (SEC's 2010 proxy access rule vacated because of deficiencies in the SEC's rulemaking process, due to inadequate cost-benefit analysis).

[12] *Cf.* Hon. Lamar Alexander, et al., *Letter to Hon. Kathleen Sebelius*, Apr. 16, 2013, available at www.thune.senate.gov/public/index.cfm/files/serve?File_id=04df (requesting, *inter alia*, information on progress under $250,000,000 in cooperative agreements with "Beacon Communities"). The site for the Beacon Community Cooperative Agreement program is http://www.healthit.gov/policy-researchers-implementers/beacon-community-program .

[13] *See generally, Statement of Valerie C. Melvin, Director, Information Management and Technology Resource Issues,* United States Government Accountability Office, Testimony Before the Committee on Veterans Affairs, U.S. House of Representatives, GAO-13-413T (February 27, 2013) (analysis of the failure of the Department of Defense and the Department of Veterans Affairs to develop an interoperable health record system despite being required to do so by Act of Congress).

takes a different approach to the architecture of health information exchange. We need an architecture we can actually build, and so turn next to that task.

4. Planning Successful Health Information Exchange Through a Simplified, Achievable Network Architecture

We refer to ONC's technological approach as a *provider-query-based network architecture*. The theory of this architecture is well known. A patient presents (appears) at a doctor's office or hospital (the point of care). The doctor sends a computer query to all EHR (Electronic Health Record) data bases locally, regionally, or nationally. The query asks all the data bases whether they contain information about the patient in question. All EHRs that can identify the patient and that hold such information are asked to send it securely to the point of care. There it is assembled immediately so the treating physician can use it for treatment.

Alternatively, a *provider-query-based network architecture* can in theory be built using an additional, intermediate component – a master index database. In this theoretical structure, every provider locally, regionally, or nationally must send every entry in every EHR for every patient to an index kept by a computer. Each entry specifies that the provider's medical record database contains an entry for each given patient. Every time a provider sees a patient and makes an entry, a message reflecting that entry is sent automatically to the local, regional, or national index.

The index is itself a huge database that grows constantly and rapidly. It is always available to doctors, hospitals, and other providers. When a patient presents at a point of care, the doctor, hospital, or other provider sends a query message to the index database. The index database sends queries to every physician's or hospital's database which has listed an entry for the patient in question in its EHR. The EHRs each send all the data for that patient to the index, which then transmits all those entries to the point of care. The computer system at the point of care then assembles all the messages it receives through the index into a comprehensive record for the patient. The treating physician or hospital in theory then has a current, compiled medical record in its own EHR to use to treat the patient.

The provider-query-based blueprint is elegant in outline. The problem is that we lack the technology to make it work.

This lack has been demonstrated repeatedly. It is the lesson of the well-known Santa Barbara demonstration project[14], for example, though many who analyzed that debacle failed to understand how the selection of a provider-query-based network architecture made success unattainable. Among other things, the architecture created substantial privacy, security, and safety problems that proved insoluble. It was also a lesson taught repeatedly in projects sponsored by ONC during the eight years of George W. Bush's administration (though ONC did not recognize that lesson in its projects). It is a lesson that will be taught again this summer as ONC-sponsored Health Information Exchange (HIE) projects, including the "Beacon" projects, continue to fail across the country. We believe that almost none of those projects will prove

[14] *See* Robert H. Miller and Bradley S. Miller, *The Santa Barbara County Care Data Exchange: What Happened?*, *Health Affairs* 26, no.5 (2007):w568-w580, available online at http://content.healthaffairs.org/content/26/5/w568.full.html .

workable, sustainable, or scalable. This is a harsh reality and bespeaks a huge waste of federal and matching money.

ONC and the nation need an alternate system architecture that uses existing technology to facilitate the interchange of health information among the hundreds of thousands of existing EHR computer systems installed in doctors' offices and hospitals around the country. The exchange system must specify a data format protocol to enable the vast existing EHR base to send patient data back and forth in a form usable by physicians, nurses, and others. The data format protocol must be technically feasible in the short term, such as within a year.

There is a temptation at this point to wish that any system ONC specifies must be able to exchange data with a high level of semantic interoperability. (Semantic interoperability is the ability of two or more computer systems to exchange information and have the meaning of that information accurately and automatically interpreted for use by the receiving systems.)[15] In a future health IT network with very highly developed semantic interoperability, computers could exchange health data reliably and interpret the data as well. That would require, in colloquial terms, compatibility among the computers' transmitting and receiving methods (protocols) and a pervasive use of common ontologies (structured vocabularies) covering all or most of the health data exchanged, plus the capability to exchange free (unstructured) text. This is an ideal vision of health data exchange that may be developed years in the future.

Technology available in the short term is not that capable, however. Useful and more realistic – but still robust – data exchange goals are therefore a practical necessity. That must become a guiding principle if Congress expects ONC to start down the path toward a workable health exchange architecture. That shift to the pragmatic is essential to getting widespread health data information networks up and running in the near future, however that time frame is defined. In this important sense, technological limitations control the policy options that Congress can mandate with a realistic expectation that the mandates will actually be carried out.[16]

In systems design, the key to connecting patients' health record bank accounts and providers' various EHR systems is, from the outset, to restrain the societal urge to try to do too much – to require what available technology cannot support. The federal government's systems design choice must respect the limits of interconnection technology. It must seek the achievable. So far ONC and its Policy Committee have not done that. Reboot *catalogs the dismal consequences.*

Thus, until ONC is convinced or otherwise forced to change its choice of network architecture based on the criterion of technical feasibility, its policies will continue wasting time, effort, and money. Moreover, its programs' failures will continue impairing the ability of

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[15] Explanations of semantic interoperability and its prerequisite, syntactic interoperability, are available from many sources. *See, e.g.,* EN 1306 Association, *Semantic interoperability of health information*, available at http://www.en13606.org/the-ceniso-en13606-standard/semantic-interoperability .

[16] *See Statement of Valerie C. Melvin, supra* n.13, at 7: "[T]he National Defense Authorization Act (NDAA) for Fiscal Year 2008 included provisions directing VA and DOD to jointly develop and implement, by September 30, 2009, fully interoperable electronic health record systems or capabilities." In 2013, no such system exists and the two departments remain stymied in their efforts to fulfill this mandate. *Id.* at 17.

patients, providers, insurers, and others to exchange health information in digital form efficiently and affordably.

Fortunately, a technically achievable architecture exists for nationwide exchange of digital health information. The most efficient way to organize digital health records for nationwide exchange is to integrate them around the patients to whom they pertain. Each patient's records can be stored in secure repositories ("health record banks") in accounts where access is controlled by the patients themselves. This solves myriad privacy and security issues that are insurmountable using provider-query architecture.

Doctors, hospitals, and other providers would still maintain their own office or institutional records to document their internal clinical processes and the care they give to each patient. Vendors of current Electronic Health Record (EHR) systems would continue selling and improving their products. Providers and hospitals would be able to continue using the vast base of clinical record systems already bought and installed. That is true even though, today, those systems cannot routinely exchange digital records because they are operationally incompatible and thus not "interoperable."

As we explain below, the more practical, achievable systems design respects the proven limits of interconnection technology. That means making policy decisions to design a system that initially will achieve a very modest, rather than a high, level of interoperability. However, even the modest level of interoperability we suggest will be a signal improvement over the status quo, a quantum jump; and it will get the interoperability process out of the present quagmire.

The architecture we suggest therefore uses a variant of "Direct"[17] an interconnection methodology suggested to ONC as a stopgap and then developed with ONC's encouragement and assistance. Direct is capable of using a health record exchange format, the Continuity of Care Document (CCD). CCD is based on Extensible Markup Language (XML), which is well known and widely used. The CCD already has robust data exchange capabilities; it embodies significant progress towards creating semantically interoperable, essential clinical data.[18]

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[17] Information about the Direct Project is available at http://www.healthit.gov/policy-researchers-implementers/direct-project .

[18] *See, e.g.*, National Institute of Standards and Technology (NIST), *Meaningful Use Test Method*, available at http://healthcare.nist.gov/use_testing/finalized_requirements.html, and listing, *inter alia*, under Certification Criteria at §170.306(f), *Exchange clinical information and patient summary record* (pdf), Aug. 13, 2010). That document, *Test Procedure for §170.306.f Exchange Clinical Information and Summary Record* (Approved Version 1.0, August 13, 2010), specifies:

> Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).

Id. at 4. Thus, HITSP C32 is the version of the CCD in use. Version C32 offers substantial semantic interoperability by virtue of extensive accommodation of standard vocabularies, specified in detail in the test procedure that follows, *id.* at 10-18. *See also*, HITSP, *C 32 –*

Because CCD is an exchange format that works today, its selection for current systems design purposes is the essence of practicality.

In the systems design we propose, health record banks and EHRs in doctors' office and hospitals would be required by federal rule to have the capacity to write to and read from a central communications backbone that would be available nationwide. This is called a "publish-subscribe" backbone (or hub). Messages written to or downloaded from the backbone would be addressable (akin to electronic mail).

The common standard for exchanging data over the Direct or Direct-like backbone would be the XML-based Continuity of Care Document (CCD). This is an industry standard format.[19] CCD is constantly being improved yet is of great utility in its current iteration.

Using the CCD would enable significant interchange of appropriately formatted medical record data and other health information in digital form. It would not enable digital encoding of all information that physicians and hospitals will record in their institutional EHRs, but it would enable a level of interoperability that is both far beyond the status quo and of significant help to patients and providers who participate in the exchange.[20]

One objection to this patient-account-health-data-repository architecture is that physicians and other providers will distrust any health records that they do not control, and especially will distrust health records compiled in patient-controlled repository accounts. This

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HITSP Summary Documents Using HL7 Continuity of Care Document (CCD), available at http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32:

> The Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. This Component defines content in order to promote interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others.

[19] Background about the Continuity of Care Document is available at, e.g., http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6 and http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32 , among many sources.

[20] Patient Command has long been in favor of this approach to health network exchange architecture, even before Direct was first suggested to ONC. *See* B. Strom, R. Marks, W. Knaus, *Letter to Hon. Kathleen Sebelius*, (May 6, 2009). The later proposes that HHS and ONC implement HITECH using a national health data architecture based on integrating data around patients. The patient-focused integration would be accomplished via patient-controlled health record bank accounts. The letter proposes interconnecting the patient-owned and controlled accounts to institutional EHRs through an XML backbone and using the CCD. The letter is available on the website of the Health Record Banking Alliance at http://www.healthbanking.org/docs/PComm%20ARRA%20RuleM%20Ltr%20SecHHS%20050609.pdf . The letter illustrates that the fundamental task under HITECH – first developing and publishing federal interoperability standards – has not changed since the day HITECH was signed into law.

objection is overcome because health record banks can label each data input to a patient's record with the provenance (source of and transmission path for) the particular data entry. That way, physicians and others can make a clinical evaluation of each data element they consider in evaluating and treating a patient. Moreover, the health record bank's software can help identify conflicts or other anomalies in the compiled data.[21]

Providers will readily become accustomed to using data they receive, or are authorized to import, from patient-controlled health record bank accounts. Further, physicians and providers will always be able to conduct their own up-to-date evaluations, repeat tests if that appears warranted, and rely on their own institutional records about a given patient. The societal advantages of having patient-controlled medical data compilations is so compelling that we believe providers will quickly adjust to using them, with appropriate cautions. Enabling patients to be part of their own care team will bring myriad benefits.

We believe that a pivot to this architecture can reboot the federal government's health IT initiative. It can make HITECH work. A patient-account-health-data-repository architecture using a publish-subscribe backbone and the Continuity of Care Document as the principal content protocol sounds complicated. It is, however, attainable using available technology.

This pivot would suddenly make development of sustainable health record banks achievable. Consumers, acting directly or through their health record banks, would have an automated way to extract medical record data from their providers' EHRs and move it easily, without any transcription, into their health record bank accounts. They could also with ease send extracts from the data compiled in their health record bank accounts to various providers, family members, and other advisors. The data would be stored and exchanged securely. The architecture would ameliorate many of the daunting security problems ONC has failed to overcome, because patients would be able to exercise dynamic access control, i.e., they would make privacy decisions access-by-access as circumstances dictated.[22]

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[21] *See* W. Knaus, *Health Records for Safer Care – Faith, Hope, and Reality (How Consumers Now Can Control their Medical Information and Help Physicians Provide Better Care)*at 5-6, 14-15 (Sidebar - Characteristics of a Personal Health Record that Will Make It Useful to Clinicians as an Accepted Supplement to Their Institutional Medical Record) (White Paper, Feb. 25, 2008), available on the Health Record Banking Alliance site at http://www.healthbanking.org/docs/White%20Paper%20Faith%20022508.pdf. For additional analysis about overcoming physicians' reluctance to use compiled medical records stored in health record banks, *see* R. Marks, *Regulating Personal Health Records – Why HIPAA Won't Work*, at 4-5 (eHI Policy Paper, 2008) (discussing in detail issues of clinical credibility and utility for compiled medical records in Personal Health Records (PHRs)),available on the Health Record Banking Alliance site at http://www.healthbanking.org/docs/eHI%20Policy%20Paper%20v1pdf%20090108.pdf.

[22] Background about health record banks (including a short introductory video) is available at the site of the Health Recording Banking Alliance, http://www.healthbanking.org/ . A December 12, 2012 white paper on health record bank business models, *Health Record Banking: A Foundation for Myriad Health Information Sharing Models*, and a January 4, 2012 white paper, *A Proposed National Infrastructure for HIE Using Personally Controlled Records*, are available at the site. (For disclosure purposes, Richard D. Marks is Vice President of the Health Record Banking Alliance.)

Vendors of existing EHR systems would need to add the publish-subscribe (write-read) capability mandated by the federal standard. Then their EHR systems' records could be output into the Continuity of Care Document format (including XML-based free text for narratives in patient's digital records). They could also receive CCD input through the backbone for input into their systems' EHRs.[23]

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[23] The recent announcement from a group of prominent industry vendors of The CommonWell Health Alliance illustrates how the lack of a HITECH-mandated data system interoperability standard continues to slow vendors' progress in developing capacities to communicate among various brands of institutional EHRs. CommonWell is a consortium of some, but not all, major vendors of institutional EHR systems. Its website is http://www.commonwellalliance.org/ . CommonWell's announced purpose is to promote development of health industry data exchange standards – the very requirement mandated for ONC in Section 3000(13) of HITECH. CommonWell is thus a telling industry response to ONC's failure to adhere to the statutory requirement to develop a data exchange interoperability standard. We note again for emphasis that such a standard is the prescribed statutory foundation necessary to achieve all subsequent HITECH goals.

In any case, CommonWell announced that membership in its consortium was open to other health IT industry vendors. CommonWell became controversial, however, almost as soon as it was announced. Epic, one of the largest and most successful health IT system vendors, charged that it was excluded from the consortium. As one article reported:

> Epic Chief Operating Officer Carl Dvorak had more harsh words for CommonWell, calling it a 'marketing opportunity,' according to *Forbes*. Dvorak added that he doesn't think Epic would join the alliance, and *said the company, instead, would prefer for a national standard to be set.*

D. Bowman, Epic *CEO: CommonWell being used as a 'competitive weapon,'* FierceEMR, March 7, 2013 (emphasis supplied), available at http://www.fierceemr.com/story/epic-ceo-commonwell-being-used-competitive-weapon/2013-03-07. Thus CommonWell's formation raises competition questions that remain open and may presage the possibility of litigation.

In addition, and more significant for near-term progress, CommonWell's likelihood of success in developing comprehensive data exchange standards acceptable to the entire health industry is open to substantial question. This is apparent from reported comments of CEOs of two CommonWell consortium members:

> Healthcare's going through significant change, all of us know it. We're living through it,' McKesson CEO John Hammergren said. 'We believe that one of the key challenges we face is not just automated healthcare, but connecting it together. Over time, we've done a good job as an industry automating our silos, but we've not done a very good job of collaborating across the silos and developing the connectivity … the data liquidity necessary to make that happen.
>
> '*This interoperability mission is really an imperative for us. We know that it's going to take significant work.*'

Engineering these system capabilities will be straightforward for some system vendors, expensive and time-consuming for others, and attainable by all. It is a practical first step because Direct as far enough along in its development. We will address in the next section how use of Direct can be simplified by modifying the current approach to authentication issues under Direct.

5. Adopting Authentication Measures in Health IT Compatible with Incremental Societal Developments

In *Reboot*, the authors note:

> No system is completely invulnerable to criminals or reckless actors who do not follow protocols. As systems become more secure, they may be less useful to providers and patients. Therefore, concerns about the security of patient information need to be balanced against the burdens placed on entities that are responsible for the safekeeping and disclosure of the data. It is unclear if HHS has properly considered the safety and security issues, much less the burden, to date.[24]

These considerations come into play regarding the identity management and authentication system for Direct. This is a technically complicated security subject. The question is whether ONC should allow Direct to adopt a special set of authentication standards for Direct called DirectTrust[25], or mandate instead that Direct use authentication technology that is likely to be gradually adopted more widely.

> Cerner CEO Neal Patterson *called the collaboration a beginning, saying that the government has not and is not going to deal with the problem of interoperability.*

D. Bowman, *Cerner, McKesson and other EMR rivals form interoperability partnership,* FierceEMR, March 5, 2013 (emphasis supplied), available at http://www.fierceemr.com/story/cerner-mckesson-and-other-emr-rivals-form-interoperability-partnership/2013-03-05.

The CommonWell Consortium is but the latest of many industry initiatives. They all respond in one way or another to the same deficiency. It is a recognition that engineering a nationwide health IT data exchange *requires* ONC to develop the interoperability standards demanded in HITECH, and an acknowledgement that ONC remains mired in its own misconceived processes and is unlikely to develop those standards any time soon.

CommonWell – in its early stages, unproven, and saddled from the start with charges of anti-competitive conduct – is no substitute for ONC's changing course and fulfilling its duty to develop interoperability standards as the essential initial step in HITECH implementation.

[24] *Reboot* at 22.

[25] The site for DirectTrust, "an independent non-profit trade association created by and for participants in the Direct community," is http://www.directtrust.org/.

One such authentication option is the identity management trust framework set up under a federal government committee infrastructure.[26] So-called approved trust framework solutions exist under this approach consistent with OMB and NIST guidelines.

The General Services Administration manages the Identity, Credential and Access Management (ICAM) program that uses credentials (e.g., tokens such as smart cards) that enable various levels of security authentication (or levels of assurance).[27] These tokens are already available for purchase outside the federal government. In time ICAM could become a widespread, relatively inexpensive means for individuals inside and outside government to establish identity credentials for a governmental, commercial, and social uses. Another option for health care is to adopt the identity standards developed by the NIST-sponsored Identity Ecosystem Consortium based on the National Strategy for Trusted Identities in Cyberspace (NSTIC).[28]

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[26] The Identity, Credential and Access Management (ICAM) Subcommittee was established in 2008 by the Federal CIO Council's Information Security and Identity Management Committee (ISIMC) is http://www.idmanagement.gov/pages.cfm/page/ICAM .

[27] From the GSA website at http://www.gsa.gov/portal/category/26757 :

> Identity, Credential and Access Management (ICAM) is the intersection of digital identities and associated attributes, credentials and access controls into one comprehensive approach.
>
> The OCIO ICAM Division is responsible for coordinating ICAM activities across GSA by:
>
> - Supporting GSA Access Card issuance, usage and lifecycle maintenance for GSA personnel
> - Developing GSA-wide identity, credential and access management solutions
>
> The ICAM Division was originally established to help GSA comply with the Homeland Security Presidential Directive - 12 (HSPD-12). This directive requires that all federal agencies adopt common, reliable and interoperable identification standards for employees and contractors. The ICAM Division safeguards GSA assets by ensuring that all GSA personnel obtain Personal Identity Verification (PIV) credentials, and by developing enterprisewide, compliant, identity solutions. GSA branded the PIV credential it issues to its employees and contractors as the 'GSA Access Card.'

[28] The NSTIC website is http://www.nist.gov/nstic/. NIST Special Publication 800-63-1, *Electronic Authentication Guideline*, available at www.nist.gov/itl/csd/sp80063-121311.cfm, states in the Executive Summary at vi:

> These technical guidelines supplement OMB guidance, *E-Authentication Guidance for Federal Agencies* [OMB M-04-04] . . . . OMB M-04-04 defines four levels of assurance, Levels 1 to 4, in terms of the consequences of authentication errors and misuse of credentials. Level 1 is the lowest assurance level, and Level 4 is the highest. The OMB guidance defines the required level of authentication assurance in terms of the likely consequences of an authentication error. As the consequences of an authentication error become more serious, the required level of assurance increases. The OMB guidance provides agencies with the criteria

For purposes here, we suggest only that oversight activities resulting from *Reboot* consider whether directing ONC to mandate a standard, widely used authentication methodology for Direct is a better approach than the customized methodology being pursued by DirectTrust.

In all events, Congressional oversight should recognize that identity management and authentication are security problems confronting society at large. Adopting a network architecture for health information exchange can benefit from identity management systems developed for government or industry generally, but creating unique or specialized authentication frameworks under HITECH is unnecessary. For ONC to develop or even support specialized healthcare authentication strategies would add unnecessary complication to an already formidable task.

6. Conclusion – Navigating the Bipartisan Politics of Successful Nationwide Health Information Exchange

As Congress performs oversight and considers the virtues of ONC's pivoting to successful new health IT exchange architecture, we suggest keeping in mind these factors to help assess interoperability standards:

- Patient engagement through control of access to their compiled health information from all their providers.
- Dynamic (ongoing) patient privacy control to give consumers confidence in their control of access to their compiled health data, an important privacy concern.
- Technical feasibility in the short term, as reflected in a simplified network architecture that uses technology available today.
- Connecting disparate legacy EHR systems using a "publish and subscribe backbone" (a hub or bus) using the current iteration of the XML-based Continuity of Care Document (CCD) as the initial vocabulary exchange standard which is proven, available, and amenable to evolution.
- Affordability and cost-effectiveness, both system-wide and for small providers.
- Ability to facilitate patients' access control over their own health data for participation in research under informed consent and the Common Rule by making available both identified and de-identified information as patients may elect through dynamic access control.

Health IT is complex enough. Adding unnecessary complexity by continuing to chase the wrong network architecture will only further frustrate ONC's progress and the industry's.

Congressional oversight can succeed by basing health IT policy on unambiguous experience under the George W. Bush and Obama administrations: nationwide health information will not succeed until and unless HHS adopts a network architecture that integrates data around each patient. The inherent efficiencies of that design are in undeniable contrast to the insurmountable inefficiencies, privacy and security concerns, and unaffordable costs of a "provider-query" network design.

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for determining the level of e-authentication assurance required for specific applications and transactions, based on the risks and their likelihood of occurrence of each application or transaction.

Successful oversight will succeed only if Republicans and Democrats join in these conclusions. The incentive is there for political collaboration on health IT policy, because delay and unnecessary cost in ONC's performance span the stewardship of both parties.

Bipartisan cooperation on interoperability standards offers the potential for structural change in the market for healthcare. Easy, affordable health data exchange can alter the market behavior of patients and the providers who must respond to them.

When consumers have access to the information in their own medical records, they will make smarter choices in purchasing health care and managing their health. That means systemic health care costs are very likely to go down while outcomes improve. That great prize is at stake in the *Reboot* oversight initiative.

Respectfully submitted,
PATIENT COMMAND, INC.

By: *Richard D. Marks*

Richard D. Marks
President

Contact Information:
[redacted]

Comments of Patient Command, Inc.

Appendix
Schematic Comparison of Health Information Infrastructure Architectures

Provider-Query Architecture *versus* Patient-Centered Repository (Health Record Bank) Architecture

Provider-Query Architecture

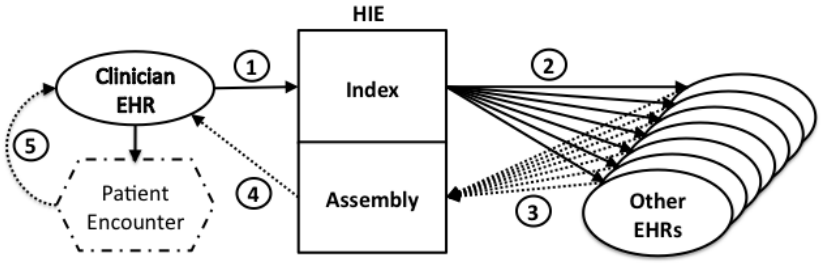

Figure 1. Institution-centric Community HII Architecture.

1. The clinician EHR requests prior patient records from the HIE; this clinician's EHR is added to the index for future queries for this patient (if not already present)
2. Queries are sent to EHRs at all sites of prior care recorded in the HIE Index; patient consent is verified at each "other" EHR prior to release of information
3. EHRs at each prior site of care return records for that patient to the HIE; the HIE must wait for all responses
4. The returned records are assembled and sent to the clinician EHR; any inconsistencies or incompatibilities between records must be resolved in real time
5. After the care episode, the new information is stored in the clinician EHR only

Patient-Centered Repository (Health Record Bank) Architecture

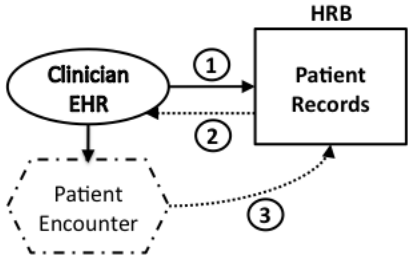

Figure 2. Patient-centric Community HII Architecture.

1. The clinician EHR requests prior patient records from the HRB
2. The prior patient records are immediately sent to the clinician EHR
3. After the care episode, the new information is stored in the clinician EHR and sent to the HRB; any inconsistencies or incompatibilities with prior records in the HRB need to be resolved before that patient's records are requested again (but not in real time)

(Note: This process is repeated whenever care is provided, resulting in the accumulation of each patient's records from all sources in the HRB)

HEALTH RECORD BANKING ALLIANCE

May 13, 2013

To: Senators Alexander, Burr, Coburn, Enzi, Roberts, and Thune

Re: Response to "Reboot: Re-Examining the Strategies Needed to Successfully Adopt Health IT"

The Health Record Banking Alliance (HRBA) is pleased to respond to your thoughtful "Reboot" white paper. HRBA is a non-profit 501(c)(6) membership organization that promotes the availability of accurate, secure, and comprehensive electronic health records that can be accessed by both patients and their health care providers under the control of the individual patient.

We advocate for legislation and regulation consistent with community repositories of electronic health records (health record banks or HRBs) as an effective and sustainable health information infrastructure solution and programs that provide assistance to communities building HRBs (see http://www.healthbanking.org for more information). HRBA members include national, state and community health information exchange organizations, health information providers, physicians, and vendors interested in health information technology, exchange, and services.

In lieu of our own separate detailed comments, we are writing to endorse and support the comprehensive response submitted for Patient Command, Inc., by Richard Marks (Vice President of HRBA). As he clearly describes, the underlying obstacle to our nation's progress towards an effective health information infrastructure is the federal government's pursuit of a misguided architecture that attempts to retrieve patient information in real time from all existing sources again and again each time it is needed. This architecture is impossibly inefficient,

expensive, and prone to error as demonstrated clearly in the attached simulation study.[1] The evidence is now overwhelming that this approach has and will continue to fail (as detailed in the attached article[2] from the *Journal of the American Medical Association*).

It is time for the nation to redirect its health information infrastructure efforts to an architecture that is feasible and effective: patient-centric, patient-controlled HRBs. With this approach, when patients seek care, they give permission for their health care provider to access some or all of their up-to-date health records that have already been compiled and stored in their HRB account. When care is complete, the new records from that visit or hospitalization are securely deposited into the HRB and are immediately available for future care.

This solves the problems of privacy (with patient control), stakeholder cooperation (because the patients request their own records, the HIPAA regulations require every stakeholder to provide them electronically if available in that form), and financial sustainability (with revenue generated from optional applications for patients and research use of the data with permission) that have stymied prior efforts.

HRBA appreciates your interest in this issue and welcomes the opportunity to be of assistance. If we as a nation are to have any hope of controlling the costs of health care in an informed manner, we must have an effective and comprehensive health information infrastructure.

Sincerely,

William A. Yasnoff, MD, PhD

President

enclosures (2)

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[1] Lapsia V, Lamb K, and Yasnoff WA. [2012] Where should electronic records for patients be stored? *Int J Med Informatics* 81(12):821-7.

[2] Yasnoff W, Sweeney L, and Shortliffe EH. [2013] Putting Health IT on the Path to Success. *J Am Med Assoc* 309(10):989-90.