SYMPOSIUM COMMENTARY

BUILDING A HIGH-TECH, 21ST CENTURY ECONOMY*

Panel 2 – Biotech and Healthcare

REMARKS OF DR. JACOB REIDER**

Thank you Kevin and thank you Albany Law School. You know, I started there twenty-six years ago I think; I started my career at Albany Miracle Centers as we lovingly call it and started with some entrepreneurism and really wanted to change the world, and as Kevin was talking, I was thinking, "Wow, maybe if you were there twenty years ago, I wouldn't have had to leave to have all the fun that I've had." So, my career started

here, but I really had to go elsewhere to do things that would impact the delivery of health care nationally and even globally. So when I left this place, where I ran from a physician's perspective the implementation of information technology, the reason that I went in to health IT[1] was because I knew that this was how we could change the way we delivered care.

In case you didn't know, physicians don't know everything and physicians sometimes make mistakes and physicians don't remember everything about all of our patients and I know that's impossible for you to believe too. What I recognized early in my career was that computers could actually help us do things that we physicians don't do all that well and would free up our time to do things like actually listen to our patients and actually pay attention to what's important to them and not what's on our clipboards or what's in front of us. So, I recognized early that we needed to do that.

I can vividly remember when I started here at Albany Med, people would shake their heads in the hallway and one of my jobs was to help docs adjust. Back then it was just "get." So we think of information technology and the technical perspective of "gets" and "puts." So we "put", we "get" and back then it was only "get" and even then they were shaking their heads and I was saying, "You know, someday, we'll actually use these systems to store our thoughts and our plans about our patients. We'll use these tools to communicate with each other." People shook their head, "No way that's ever going to happen" and of course now today, as you'll hear me talk about, most physicians in the nation use information technology to record our thoughts and our plans and most hospitals have implemented information technology.

So I'm going to try and talk very briefly about what I'm guessing is very interesting to this audience, but if you start falling asleep, I'll try and be agile and change the paths. So sometimes people at Price Chopper ask me, "What were you doing in Washington for those three years when you were there and abandoned your wife and your dog?" So, this is the slide that I try and spit out over the broccoli and try and express what I

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[1] The term "IT" refers to "information technology," which includes "computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources." 40 U.S.C. § 1101(B) (2012).

was doing. At the end of my career at HHS,[2] I was the deputy national coordinator in the office of the national coordinator for health information technology. For about four months in there, I was actually the national coordinator because our one political appointee left and the next hadn't come so I ran the organization. So we had about a $100 million budget and about 180 people. I chaired the standards committee for health information technology. What that committee does is it defines the standards by which the health information systems in various organizations will talk with each other because of course…the reasons that I'll be the next person to waive one of these things in the air and probably not the last today. The reasons that these things talk to each other is that they're standards and in this case it's telecommunications standards.

In health care, you may have heard that it's not easy for health information systems to communicate with each other. Well, one of the reasons for that is that these are actually much simpler and the banks of course are actually much simpler. Banks communicate information and the information is always a fraction of a penny or a multiple of a penny and that's the depth of the semantics that has to be conveyed. But there are about a 150 different ways to describe a heart attack and therefore there are 150 different codes that we can use to express a heart attack in various levels of granularity from "It was some kind of heart attack" to "It was some kind of heart attack that was a byproduct of a certain artery being occluded a certain percentage."[3] So, when we have differing levels of granularity and differing semantics, it makes it very difficult to create and maintain the standards for communications. So this is just a snapshot of stuff I

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[2] The U.S. Department of Health & Human Services (HHS) is a department of the federal government whose mission is "to enhance and protect the well-being of all Americans." *About HHS*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://www.hhs.gov/about/index.html (last visited Aug. 28, 2015).

[3] *See, e.g.*, *ICD-9 Codes included in Range 410.00 - 410.92*, CMS.GOV, https://www.cms.gov/medicare-coverage-database/staticpages/icd9-code-range.aspx?DocType=LCD&DocID=29217&ver=8&Group=1&RangeStart =410.00&RangeEnd=410.92 (last visited Aug. 28, 2015)(noting that ICD-10 will replace ICD-9 and take effect Oct. 1, 2015); *ICD-10, Medicare,* CMS.GOV, https://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/ICD10) (last updated Aug. 28, 2015). See also *International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)-2015- WHO Version for ;2015, Chapter IX Diseases of the Circulatory System (I00-I99), Ischaemic Heart Diseases I21–I23.8*, CMS.GOV, http://apps.who.int/ classifications/icd10/browse/2015/en#/I23 (last visited Aug. 28, 2015), for the new diagnosis codes under ICD-10.

was doing back when I was in D.C.

Raise your hand if you've heard of the meaningful use incentive program. All right, you're way ahead. So what I like to think about is information technology that's meaningful. We don't use it for the sake of using IT. It's not the coolest thing. If its not improving the quality of care that we're proving to ourselves and our parents and our children and our communities, then its not meaningful so I like to focus on meaningful IT as a way we do this. The HITECH Act, which was a part of the American Reinvestment and Recovery Act,[4] otherwise known as ARRA, specified that twenty-two (more like thirty) billion dollars be allocated in various ways so that we can simulate this market segment because the hypothesis was that if we electronify (sic) health care then we can use the byproducts of the electronification (sic) of health care to improve both the efficiency of care, the cost of care, and most importantly the quality and safety of care. So, that was the hypothesis. What the law said was that "hospitals and eligible providers" (and I put it in quotes because there's a long paragraph that describes them that Jim's going to be able to tell us and I have memorized it but won't burden you with my version) "who make meaningful use of certified electronic health records."[5] I underlined certified, and the reason I underlined it was because you have to have a definition of certified and you can't just make up a program, use Microsoft Word or Word Perfect or some other thing. It has to meet a set of criteria and that was what our office was responsible for was defining that set of criteria that would reflect certification of these systems.[6]

After Albany Miracle Center, I went to industry and I worked in industry for seven years. The reason that I went to government was because I was actually a victim of the first

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[4] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

[5] *See Federal Health Information Technology Strategic Plan (2011-2015)*, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO., 4, *available at* https://www.healthit.gov/sites/default/files/utility/final-federal-health-it-strategic-plan-0911.pdf (last visited Aug. 28, 2015) (stating that the HITECH Act created programs to incentivize payments "to encourage eligible professionals and hospitals to adopt and meaningfully use certified EHR technology.").

[6] *Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark*, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO., 3 (Feb. 2014), *available at* http://healthit.gov/sites/default/files/hit_certificationterms_of_use _final.pdf.

iteration of the certification program so this is my . . . remember, my wife, for those who don't know, is a lawyer and so I was the doctor and then I was coming home complaining about these you know "fill in the blank expletive deleted" regulations that the government was imposing on us, and so then I started going to Washington and talking to these (I called them idiots then but) visionaries who created this program and what I learned was that they were actually really well intentioned, really smart people who knew nothing about our industry. So, I think one of the messages here is for either regulators or future regulators or those who critique regulators: You need to really understand an industry in order to regulate it.

When I went there and interacted with these folks, I learned that none of them had worked in this industry and in fact very few of them had even been practicing clinicians and therefore didn't know either end: the industry that made the tools for the domain or the industry that was using the tools. I had done both and so eventually I got talked into (as they said to me, "Half the money, twice the fun" and) becoming a federal servant. So this is what I did, and this is the byproduct of the high tech act, and this is my dumbed down version. But use of "health care version technology," and notice that I use that term instead of "electronic health record," and the reasons for that, you can bug me about during the next break, but the use of health information technology went from: 2008-2009 (the high tech act was 2009) up to now from a minority to a vast majority. There are some specialties that still haven't adopted health IT, but most have. And in my specialty, family medicine, now over eighty percent of family doctors in the country use certified EHR technology and are so called "meaningful users."[7] Over eighty percent of hospitals have also adopted it, so hospitals are actually more . . . a greater percentage of hospitals than doctors now use health IT.[8]

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[7] Office of the Nat'l Coordinator for Health Info. Tech., *Percent of REC Enrolled Physicians by Specialty Live on an EHR and Demonstrating Meaningful Use*, *Regional Extension Centers (REC) Enrolled Physicians Adoption of Electronic Health Records*, HEALTHIT.GOV (June 2015), http://dashboard.healthit.gov/quickstats/pages/FIG-REC-Physicians-Live-MU-Speciality.php.

[8] Office of the Nat'l Coordinator for Health Info. Tech., *Hospitals Participating in the CMS EHR Programs*, *Health IT Quick-Stat #45*, HEALTHIT.GOV (July 2015), http://dashboard.healthit.gov/quickstats/pages/FIG-Hospitals-EHR-Incentive-Programs.php; Office of the Nat'l Coordinator for

Raise your hand if you've been to a doctor and have watched your doctor fart around with a computer. Now, since we're doing audience participation, raise your hand if you know that you have a right to access that information electronically.[9] Excellent. Raise your hand if you've actually accessed your information electronically. Very few. So this is your homework assignment, go home tonight and download your record. See if you can get your record, and you can email me if you couldn't because if they are meaningful users, if they have attested to participation in the meaningful use incentive program, they have to provide that to you.[10] And I know the people to call if you have trouble.

Meaningful use, this was a funny joke last October, you can't just get it. So the metaphor I use when I'm talking to my mom is that the meaningful use incentive program is about meaningfully using the product. You can't just buy a BMW and put it in the driveway. The state defines a set of criteria for what a meaningful user of a car is; we call that a driver's license and this is my attempt to characterize that. You have to do it properly, you have to do a three-point turn, and you have to turn on your turn signals when you go left. If you're using it for health information technology, you have to be able to use it properly, you have make a problem list for your patient, you have to e-prescribe so that you're sending the prescriptions to the pharmacy directly which reduces the likelihood that the pharmacist can't read your writing and so on and so forth. You need to use clinical decisions support. So, if your patient's allergic to something, you won't write them a prescription to the thing they're allergic to. In addition to that, as I mentioned, there is a certification program.[11] And so we also make sure that the products can do the things that the meaningful users are meant to do.

So using my car metaphor, it has turn signals so you can use

Health Info. Tech., *Office-based Health Care Professional Participation in the CMS EHR Incentive Programs, Health IT Quick-Stat #44*, HEALTHIT.GOV (July 2015), http://dashboard.healthit.gov/quickstats/pages/FIG-Health-Care-Professionals-EHR-Incentive-Programs.php.

[9] 45 C.F.R. § 164.524(a)(1) (2015).

[10] *See Step 5: Achieving Meaningful Use Stage 1, Patient Electronic Access*, HEALTHIT.GOV, http://www.healthit.gov/providers-professionals/achieve-meaningful-use/menu-measures/patient-electronic-access (last updated Feb. 27, 2014) (inferring that patients have a right to timely electronic access to their health information when physicians participate in meaningful use programs).

[11] 45 C.F.R. § 170.314(a) (2015).

them, it has tire treads of a certain depth, it has things that make things safer like seat belts. And so one of the things that we did was we made sure that the developers of these products . . . because remember, I had seen the inside of these sausage factories. The developers of these products made them in a manner that was safe so that we protected the public's interest and this caused a lot of complaints from my former colleagues in the industry.

So the systems have to be able to exchange, and again this is my dumbed down version of information exchange. It has to go from one place to another if you use the wrong protocols, if you use the wrong concepts, or the wrong terms, the receiving system won't be able to understand what you're talking about. So, we define standards for how systems need to exchange with each other. We needed to make them safe. This is so that you always remember that I talked about safety because safety is really important. And attached to safety, of course, is privacy and security. I'm guessing Jim might mention something that was the health information portability and accountability act,[12] which was also modified,[13] and we called them high tech mods last year. And so they define how it is that businesses and covered entities maintained the privacy and security of the information that are in these systems.[14] I would argue that with information technology, your records are safer than they were and or are in paper form. The cleaning lady can never get to your electronic records; she absolutely could get to your paper records.

So, summary so far: there was ARRA, which begat high tech, which created the meaningful use incentive program; what to do certification, the tools standards information exchange safety privacy and security (just in case you are worried about the test). So, you hear about all of these regulations, and there are these things that you had to do. And as a federal regulator, I would

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[12] Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, 110 Stat 1936 (1996) (codified as amended at 42 U.S.C. § 201 (2012)).

[13] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5565 (Jan. 25, 2013) (to be codified at 45 C.F.R. §§ 160, 164).

[14] *See generally* 45 C.F.R. § 164.306 (2015) (requiring businesses and covered entities to "ensure the confidentiality, integrity, and availability of all electronic protected health information" that the businesses and covered entities create, receive, maintain or transmit).

think very carefully about how it was that somebody would be reading the regulations that I was writing. It was really important for me to put myself back in my industry hat and say, "Well how is it that this might be read?" And this is actually how federal regulations . . . instead of saying, "Do it this way," use nine paragraphs to describe sort of how it might be done but are never prescriptive of how it must be done unless they made mistakes.

And here's an example that I learned towards the end of my time there. You don't need to read this. This is from the Department of Transportation, and it defines the things that you use that are on the sides of your car that allow you to see behind yourself.[15] What do you call those things? Mirrors! And in fact the Department of Transportation mandates that there be mirrors on the sides of cars and they be a certain size and a certain in fact level of concavity and there are pages and pages that go on about what the mirrors should do.[16] I would call this a very prescriptive regulation. I tried very hard not to be prescriptive, and I can tell you I edited out a lot of well-intentioned prescriptiveness from my colleagues who had not been in the industry.

Then this company came along. Who has heard of this company? The company is called Tesla, and Elon Musk, who was already mentioned once today, in addition to building solar panel factories in Buffalo,[17] Elon Musk created a car company when everybody said, "You're crazy, you cant make a car company." Car companies as the time where General Motors was coming down,[18] Elon Musk said, "We're going to make a thing that its going to be a car company." Then the engineers at this car company that was doing things differently came up with this idea of using these things called cameras. Has anybody heard of those? It turned out that you could use cameras on the sides of your cars. You would never have a blind spot, you could actually project inside the car in a manner that was much better and gave you a much better view than those archaic things called mirrors. And guess what? No dice. Department of Transportation says you

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[15] Federal Motor Vehicle Safety Standards, 49 C.F.R § 571.111 (2015).

[16] *Id.*

[17] Nick Bunkley, *G.M.'s 4.3 Billion Loss Makes Progress*, N.Y. TIMES, Apr. 7, 2010, http://www.nytimes.com /2010/04/08/business/08motors.html.

[18] Diane Cardwell, *SolarCity is Acquiring a Start-Up, Silevo, To Build Panels*, N.Y. TIMES, June 17, 2014, *available at* http://www.nytimes.com/2014/06/18/business/energy-environment/solarcity-acquiring-a-start-up-to-build-panels.html?_r=0.

need mirrors.[19] It was going to save electrons because the mirrors are microscopic practically and the mirrors stick out.

So, these guys started a campaign last spring they are continuing it.[20] Maybe they need to . . . and other folks. I think because . . . then I called my colleagues at DOT . . . because this is one of the great things about being a Fed is that you're all part of the same family. So, I called my new friends at DOT and I said, "What's going on here?" and they were like, "Yep, we know about it." You can't change federal regulations on the turn of a dime but they get it and we will see at some point, I have no idea when, new regulations from the Department of Transportation that say those things that help you see behind yourself instead of those things called mirrors.

So, this is how federal regulation stopped an innovation and we need to be very thoughtful about how we perceive the federal regulations and how we interact with them and that means state regulators too who are in the room. So, we need to see what's next. And when I say "we," it's those of us who are back in the private sector, but also those of us in the public sector. You need to really stay aware of what's there. This is my favorite author, Clay Christensen talking about what's next. This is how I see the role of information technology in how we manage care in the future.

So this is the so-called "triple aim" from Don Berwick, who lost the primary race of governor in Massachusetts,[21] but he's still a great guy. He came up with the triple aim at IHI[22] and he went to CMS[23] for a while. So, if you have better health, our goal is better health,   and   better   care,   remember   those   two   are different . . . better health is a byproduct of lots of things, social

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[19] *See* Federal Motor Vehicle Safety Standards, *supra* note 14.

[20] *See generally* Letter from James C. Chen, Vice President of Regulatory Affairs & Assoc. Gen. Counsel, Tesla Motors, Inc., to David Friedman, Acting Adm'r, Nat'l Highway Traffic Safety Admin. (Mar. 28, 2014) (petitioning the National Highway Traffic Safety "to update Federal Motor Vehicle Safety Standards (FMVSS) No. 111, 'Rearview mirrors' with a compliance option that reflects new and emerging technology.").

[21] Kyle Cheney, *Coakley Survives Mass. Dem Primary*, POLITICO (Sept. 9, 2014, 10:36 PM), http://www.politico.com/story/2014/09/2014-primary-election-martha-coakley-massachusetts-110793.

[22] Dr. Kathleen Tschantz Unroe & Dr. Diane E. Meier, *Palliative Care and Hospice: Opportunities to Improve Care for the Sickest Patients*, 25 NOTRE DAME J.L. ETHICS & PUB. POL'Y 413, 414 (2011).

[23] Ruth F. Maron, *Who Has a Will to Live?: Why State Requirements for Advance Directives Should be Uniform(ly Revised)*, 24 REGENT U. L. REV. 169, 181 (2011).

determinants not to be ignored.[24] Better care is an important part of better health for a population but better care is Better efficiency, so we don't wait in a waiting room more than we should because that's stupid. Why do we go to a doctor's office and tolerate that kind of garbage? We shouldn't! We don't tolerate standing on street corners anymore. Whose used Uber?[25] Right? We just don't! We don't tolerate these sorts of things.

And what's improved? Information technology has helped us understand. So if I were to use my phone to understand what's the wait time in the gastroenterology clinic at Albany Med., I guess this is a challenge right? Why can't I do that? Because they know what the wait time is. They know it because they are sitting there and they can see nine patients ahead of me, and yet still somebody's going to get in their car in Latham and drive to wait. Couldn't we use information technology to provide better care that would also result in better health and of course lower costs? Roughly thirty percent of health care cost is wasted in this country.[26] My argument is that it's a byproduct of our fee for service care delivery model, which ideally will be changing.

We've heard the secretary announce about two weeks ago that her goal is by 2018, thirty percent of Medicare payments will go towards fee for value payment models rather than fee for service payment models.[27] I think that makes perfect sense. We are currently paid in order to render more care which of course then causes more care to be rendered which of course is not necessarily better care. This is reference to the delivery system reform initiatives of the Department.

An important piece that I always want to make sure we think about is design. We've all used well-designed products, and this

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[24] *See IHI Triple Aim Initiative*, INST. FOR HEALTHCARE IMPROVEMENT, http://www.aaos.org/news/aaosnow/aug10/ advocacy6.asp (last visited Aug. 27, 2015) (discussing the importance of the IHI Triple Aim framework to optimize healthcare and better health).

[25] *See* Brian Solomon, *The Numbers Behind Uber's Exploding Driver Force*, FORBES (May 1, 2015, 12:27PM), http://www.forbes.com/sites/briansolomon/ 2015/05/01/the-numbers-behind-ubers-exploding-driver-force/ (discussing the explosive market and popular use of Uber over the last two years).

[26] INST. OF MED. OF THE NAT'L ACADEMIES, THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 586 (Pierre L. Yong et al. eds., 2010).

[27] U.S. Dep't of Health & Human Servs., *Better, Smarter, Healthier: in Historic Announcement, HHS Sets Clear Goals and Timeline For Shifting Medicare Reimbursements From Volume to Value* (Jan. 26, 2015), http://www.hhs.gov/news/press/2015pres/01/20150126a.html.

is from Don Norman, one of the original developers at Apple. And I think when we think about innovation, and we think about information technology, we also need to think about usability. So when we think bout usability, and making great products self-evident and how to use them, we shouldn't forget that that's a component of the safety of those products. So, well-designed products are safer to use. Poorly designed products, especially in health care and airplane cockpits, are very unsafe. And so a lot of my work both at HHS,[28] and before HHS, and likely after HHS, will be focused on usability, user experience, and how really you need to understand a culture in order to design innovative products for it.

In my last slide: who's this guy? He's already been mentioned once today in the supply chain component. It's Henry Ford, who said, "If I built my customers what they had asked for, it would have been a faster horse."[29] We have to think about what the customers' needs are and those go beyond what they ask for. And sometimes when I interact with physicians, I remind them that if they gave all their patients all the antibiotics they had asked for, we'd have multi drug resistant everything. Physicians ask for things a lot and this is maybe my anecdote for those trying to develop tools for health information technology tools for physicians. Physicians who are used to ordering things: giving orders, making orders, telling patients what to do and when they don't do what we do, we call them non-complaint. So, when we interact with technicians, we expect them to do what we say they should do, which of course is the opposite of what should happen. We should define the problem and let the technology designers solve the problem for us. That's all for me. Thank you.

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[28] *Dr. Jacob Reider, FAAFP,* AM. HEALTH INFO. MGMT. ASS'N, www.ahima.org/speakers/jareider (last visited Aug. 28, 2015).

[29] Patrick Vlaskovits, *Henry Ford, Innovation, and That "Faster Horse" Quote,* HARV. BUS. REV. (Aug. 29, 2011), https://hbr.org/2011/08/henry-ford-never-said-the-fast/.