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ENABLING PERSONALIZED MEDICINE THROUGH HEALTH INFORMATION TECHNOLOGY

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P R O C E E D I N G S

MR. WEST: Okay. If we could have your attention, we're going to mobilize here. Good morning. I'm Darrell West, vice president of Governance Studies and director of the Center for Technology Innovation at The Brookings Institution. And I'd like to welcome you to our forum on personalized medicine and health information technology.

This week in his State of the Union Address, President Obama highlighted the importance of innovation for long-term economic development. He made the argument that innovation is vital for job creation and building the industries of tomorrow.

Areas that offer tremendous hope in this regard are genomics, medicine, and the life sciences. Scientists have cracked the human genome and are identifying genetic markers associated with particular diseases. This has fueled efforts to personalize medicine and target treatments in a more effective manner. With these advances, we're learning how to tailor treatments based on individual's genetic structures.

Yet there remain several barriers to progress in this area. Some national policies were developed years before these recent advances in chain sequencing, electronic health records, and information technology. And so as a result, we've not taken full advantage of the opportunities that we face.

Today we are putting out a paper that makes a number of recommendations and I just want to summarize the highlights of that. I'll refer you to the actual paper for additional details. But we argue that it is vital to connect genomic and

other personalized information to electronic health records. Electronic health records and other electronic documents are moving to center stage in medical care. The administration has invested more than $40 billion in that effort.

We argue that we need to integrate data on genetics and drug effectiveness into patient's electronic records. This will give physicians the most up-to-date information and help them target drug treatments on those most likely to benefit.

We need better data sharing networks so the physicians and scientists can connect different information systems. Currently we have discrete data systems in various parts of medicine, but they are not well integrated. It's hard to determine what works and how to assess costs and benefits, so we need better knowledge management systems to help us analyze the overall contours of health care.

We argue that we need to enable rapid learning feedback mechanisms in clinical care. Right now it is difficult to integrate advances in medical research into treatment guidelines that are accessible to physicians. We need better feedback devices for physicians and patients on what works and how they can incorporate the latest research into medical care. By integrating databases, this will help them learn from the experiences of other patients.

We argue about the need to improve our reimbursement system in which we need to better align reimbursement with national goals. We need to devote more attention to preventive medicine and positive health outcomes. We know that incentives matter in terms of personal behavior, and value-based reimbursement would give physicians and hospitals more of an incentive to focus on good health.

Finally, we suggest the need to think through privacy rules. We all recognize how important privacy is and how important it is to patients. People fear

discrimination in not keeping their medical information confidential. As a result of that, in 2008, Congress passed the Genetic Information Non-Discrimination Act prohibiting the use of genomics in employment, hiring, and firing.

We need to strike the right balance, though, between privacy and innovation. There is a 2009 Institute of Medicine report that concluded that current HIPAA rules impede health research. And we suggest that we need to revise privacy rules to distinguish health research from medical practice and allow for linking data for multiple sources for research purposes in ways that protect privacy and confidentiality.

So, we suggest that the current administration is missing an opportunity to make progress on personalized medicine. We need to do more to link personalized medicine with health information technology. The President talked a lot about innovation, but the administration needs to follow up with concrete actions addressing policy barriers to personalized medicine. So if you want additional details on that argument and some of the recommendations that we make, please consult our paper.

This morning we have assembled an outstanding set of distinguished leaders discuss personalized medicine and health information technology. We are pleased to welcome Dr. David Brailer to Brookings. He is the chairman of Health Evolution Partners, a San Francisco-based investment fund that focuses on innovation and the health economy. Prior to that, many of you know he served as a national health information technology coordinator in the Department of Health and Human Services. While there, he led a bipartisan effort that moved the U.S. health care system towards greater transparency, quality, and efficiency. He has been an early leader in the use of the Internet to share health information. He founded CareScience, developed it, and brought it to market as an IPO. He clearly is a smart and talented guy and we're all

looking forward to hearing what he has to say on these important topics.

Our format is as follows. We're going to hear from Dr. Brailer and then we will have time for some questions both from me as well as from you in the audience. We will then follow his comments with an expert panel of distinguished leaders from academia and the private sector. And I will introduce them at the beginning of their panel.

So please join me in welcoming Dr. Brailer to The Brookings Institution. (Applause)

MR. BRAILER: Thanks, Darrell. It's great to be with you all. For those of you that know that I've given talks from my BlackBerry in the past, I've upgraded to an iPad now.

You might have seen something that I think draws this whole conversation into a very sharp point, which was a paper published in *The Lancet* last year that showed that a child born in the year 2000 has a greater than 50 percent chance of living beyond age 100. And I really think if there's a testament to innovation in health care, it's that. We saw life expectancy at around 67 years in 1970. So more or less we've added year-per-year about a year of life expectancy.

Not all health care innovation, for sure. We have a saner, more civil society than we have in the past. But if you just go back and think about things from penicillin all the way to dialysis and ventilators and all the great things that we believe in, they've had a great impact, although quite lagged.

And I use that as a focal point because when I think we have a conversation about the next 100 years of life expectancy, I'm doubtful that'll be things like molecules or machines. I think a lot of it will be information, whether it's information that's

gleaned through phenotypic analysis, genotypic analysis, information that is used like HIT expects it to be in terms of decision support, and things like that, which I won't detail.

My frame of reference is that's where the next 100 years comes from. And one of the things that we have to think about whenever we think about long life expectancies is that there's a downside. I learned this when I was in the administration. And as many of you know who have been in government or are now that you don't always just do your own job, you have to go do all the other jobs that you're expected to do. And one of them was to go around and to support community efforts that were doing things.

And so I was sent once -- excuse me -- to Utah to speak at a centenarian event where literally 85 centenarians were in the room celebrating the next year. And the emcee was 104, and he had been emceeing the event for some time and his wife was in the front row and she was 102 or 103, and they had been married 80 years. And so when he handed the podium to me I decided I was going to rib him a little bit and said, George, you know, let's be honest. You guys have been married 80 years, you know, is there passion? Is there love? You know, are you guys -- what's the secret of that long marriage? And he came back up to the podium and elbowed me aside and said, completely setting me up for a spike, said, well, Dr. Brailer, we haven't been in love for a long time and the passion is gone, but we are staying together until the kids die. (Laughter)

Okay. So what does health information and technology -- it's true -- health information technology and personalized medicine have in common? I would say at the 10,000-foot level let's just recognize that both of them are certain to happen on a widespread basis. You might not agree with that, you might think that there is some

chance that some of these won't happen. But I think over some period of time the use of more information in our industry is inevitable. Therefore, I think the other thing they have in common is a huge question mark over how they will be used and a much larger question mark over who uses them and to what end.

And to me, this is the issue where policy should be interested. My sense, my personal view -- I brought this to the health information technology movement -- is that we should not focus our efforts on making the inevitable faster. What we should do is steer the curve of change to make sure that it lands in a place where we want this to happen.

If you want to think about health information technology, the endpoint that doctors will use, information tools at the point of care that consumers will use, information tools to help their decision-making will be achieved by cultural, generational change. Whatever is happening outside of health care will come into health care with a lag and, therefore, to push that along, in my view, was not a good use of time.

On the other hand, to me an enormous fight over what digital medicine means and if digital medicine, health information becomes the new electronic boundary around highly monopolized health care systems, the new way to retain patients, the new way to fight a geographic turf war for prices, or if health plans or product makers or government use information asymmetrically. And I think we've certainly seen some of that addressed in health reform. Or if the information is used to advance consumer welfare.

Or one of my particular concerns -- probably because I live in San Francisco and see the Web 2.0 movement very much up close -- if health information technology will deteriorate into a product hustling arbitrage -- I'll call it a digital media

play, is the term we would use -- something that is not about the information, but about the medium that it comes through. And I think in this sense health information technology has some lessons to teach personalized medicine. Or perhaps another way, it's an earlier window.

I think, you know, technologically, politically, culturally, commercially, health information technology is ahead of personalized medicine. Physicians see an immediacy of an electronic record today that they probably don't quite feel from personalized medicine. The public certainly grasps the idea that if a physician uses a computer they give better care. We learned this very much when I was in the administration. This has continued to change. And let's be clear, we have a thriving set of multibillion-dollar commercial companies providing health information technology around the globe. There's a very robust commercial infrastructure.

So, you know, I wanted to think about for this discussion what are a few of the lessons that we learned in the health information technology effort that have some relevance to where personalized medicine is going? Particularly, again, thinking about how do we help steer. How do we help make sure that, in this case, science is used for improvement solely and not for other things?

I think first we have to recognize that the value of both health information technology and personalized medicine has not been well understood by the public. And I think when I came to the health IT scene, all of the appointed and self-appointed gurus spent all of their time talking in very coded terms and jargon, and very, very long words and were frustrated that the public and policymakers and members of Congress and governors, et cetera, didn't understand what they were talking about. And it was incredible cross-purposes.

And it was more than just rhetorical. I think this was very much about where the value judgments were about the critical issues and the critical decision points. And the public didn't understand really this idea, although there was good survey data that showed that the public certainly had some idea about their medical records and who made it available.

And our sense was that one of the clear tasks to provide, if you would, kind of the Air Force cover over the ground war was to set up the rhetorical framework so that we could communicate consistently the benefits as opposed to the technology that allowed this discussion to happen on a much more fulsome basis.

This had one catalyst that happened when I was about four months into my job and was riding the Metro and getting closed to Foggy Bottom where I got off. And I looked across the car and there was a poster that was one of these drug abuse posters, you know, like your -- this is your brain, this is your brain, you know, on drugs with the fried egg, right? But what I noticed is, down on the bottom in the fine print it said, "Sponsored by the Ad Council and the National Coordinator for Drug Abuse and Control Policy." And to talk about the apoplexy I felt having another one of the national coordinators have really cool posters on the Metro and I didn't have anything. (Laughter)

So we went and sat with the Ad Council. And candidly, after an entire day of great efforts they came back and said we don't know how to sell this health IT thing to the American public. And it took a very long time and you finally saw, you know, somebody falling off of a ladder and frozen in time and it said where's your health information? And, you know, now I think you see plans very much saying we have your health information, you can get access to it.

Health systems are doing -- this has taken a very long time. I mean, it's

recognized that we really have to describe why this is important and not just that it needs to be done.

Secondly, I think one of the real challenges in health IT -- and I think personalized medicine has this cubed or perhaps more -- it is to demonstrate that it saves money. That it is not just theoretically more efficient. Yes, we can target better treatments for people, but that it is something that is cost-effective on each step along the way.

And let me say it differently. Our arguments about the costs of personalized medicine should not be with economists, they should be with actuaries. You know the difference between an economist and an actuary -- I learned this the hard way here in Washington. You know, the -- and this was told to me by a very powerful actuary on the Hill and I won't say who it is. But he looked at me and said, you know, you're a Ph.D., trained economist, aren't you, Dr. Brailer? And I said yes. And he said, well, let me tell you something, sir. And then he went on to say this: The difference between actuaries and economists is that economists have to believe it to see it, but actuaries have to see it to believe it. And his point was very much show me the data, and it's really hard.

You know, the -- we spent a lot of time assembling, you know, the evidence that demonstrated where information technology could, in very specific areas, be very helpful as opposed to creating general efficiencies in the industry could accrue benefits to the key participants. And this is something where I think personalized medicine still has yet to confront -- I've participated in a number of conversations where I would say if I could create a capstone to date, the apologists for personalized medicine -- those people that are pushing it quite hard -- just don't quite get the importance of that.

And I think this is something that I'm glad has been brought out.

And then finally, I think we need to recognize that the rate limiting step for all of these great technologies is what a doctor can do at the point of care with the background training, education, time, support, infrastructure that they have. It's quite limited. I think it's clearly changing slowly as doctors become more and more corporatized.

I think one of the unintended consequences of the current health reform efforts is going to be a massive aggregation of doctors into hospital systems and of hospitals into hospital systems and hospital systems into big hospital systems. That's going to play very slowly and I think it's going to be enormously disruptive.

And, you know, health IT very much had to think about how to fit into those, you know, six minutes of doctor time and to deal with the workflow issues -- and I would say, candidly, we still haven't quite figured that out. And if you look at kind of the collective yawn that doctors have given, meaningful use and some of the incentives despite the incredible excitement that many of us have for it, it's because it's hard to figure out why it really matters to them still to this day. And I think personalized medicine is clearly behind that, but moving in the right direction.

So, you know, what is it that we can translate these lessons into? And I think we need to recognize that there's some really incredible driving functions here. If you think about patient care and look at the enormous number of tests we have available today that are, I'll say, genotypic or biomarker or whatever other term we want to use, but that help us shape diagnosis and help us shape treatment, we have to have some architecture at the point of care for making sense of those and making those accessible to doctors. It's more than the standard lab form. We have to have the same support for

interpreting these results.

I noticed as I've looked at the industry how rapidly the turnover of what does a certain marker mean has changed, you know, often more than once, twice per year. And I know some of the panelists are experts at this and we'll talk about this. But it's hitting landfall. And if you want any evidence that it has, I want you to go back and search through the news feeds for a Medco announcement from six months ago -- maybe longer now, eight months ago -- where they bought a company called DNA Direct. DNA Direct was the first kind of company that was selling genetic screening to patients -- the first time, a legitimate company. I think there have been a lot of fly-by-nights, but very legitimate company. Got kind of steamrolled by 23andMe and Navigenics, the Silicon Valley-funded companies, and became a company that helped health plans work with patients to figure out what their genetic tests meant.

Now, Medco bought them. Why? Well, because they're making a bet that pharmacogenetics is the next stopping point. We've got formulary compliance, we have allergies, we have indications, we have a vast amount of data that shows how to adjust the dosage of drugs -- which drugs someone should take or not, higher dose, lower dose, other common factors. And there's a massively electronic workflow around prescribing. This is probably the most automated process we have in health care today. And so they can easily plug this in. And they're making a bet that's going to become the next differentiation point to squeeze drugs and drug costs and to squeeze value from them.

So I think you pay attention to that and you recognize this idea of using personalized medicine at the point of care is not a remote idea. And it will take some time, but there's real money being bet by very, very savvy companies.

There's also synergies on the research side. Obviously, you know, we've spent a lot of time -- all of us, I'm sure, and you'll talk about this with the panel -- talking about how to take all of this wonderful genotypic information, whether it's from snips or whole genome assays or other mechanisms, and to match it to phenotypic things, whether it's imaging data, patient history, physical findings. You know, this is a key factor in many of the key studies that are going on.

And I think there's some clear work to be done, but I think we need to recognize it goes beyond that because, you know, we're really talking about reclassifying disease as it is. What a biomarker says is a disease and what a doctor says by looking at some expressions of that are very different, and today we would dismiss the markers as just being inputs. My guess is that over some period of time we'll see that change, and the disease is the marker period and we just see lots of variations in how it's expressed.

And, you know, if you wanted, again, evidence of this there have been now two major national global pharma that have announced -- more or less. They didn't quite come out and say this in a press release, but it's been said in a number of different ways that they are moving towards no more blockbusters. Every time they produce a drug they're developing concomitant diagnostics, targeting molecules that help them understand who should benefit, where it is a very interesting drug development problem. Which comes first, the marker or the molecule? Do you think about a molecule and then develop a marker for it or do you think about markers that can stratify patients into populations and target molecules? It's a whole new way to think about developing drugs. Obviously, ultimately to market those drugs. But just leaving that aside at the R&D stage, this is a huge bet that's being made on this.

This is one of the reasons I think -- just as an aside -- that the landfall for personalized medicine will be pharmacogenomics. The systemization, the -- I hate to use this term -- the enlightenment of the FDA, you know, I think this is an area where the science is quite compelling. And I think some of the regulatory apparatuses in the government do understand this, although it is a brave new world to say the least.

I'd just like to make a couple of final comments on what are some of the policy areas. And the first, I'd just like to underscore Darrell's comments about privacy and portability. You know, geno was a great breakthrough. I had the privilege of witnessing that come through and I just thought it was really remarkable. It's not enough. It sits upon a framework where HIPAA is inadequate for the digital age. It is antithetical to the digital age both in terms of how it allows control and privacy of information, but, more importantly, how it allows for the control and portability of information.

In a world where HIPAA allows information to be shared among providers with 120-day lag in whatever form the data could be stored on, i.e., paper, and given only to the patient and not to a third party or a data rep acting on behalf of that patient, we have an inadequate infrastructure.

And I think we should remember that, you know, it's one thing to have, you know, a CBC twice. But it's a whole different thing to have multiple whole genome assays. There's no reason to do that. And even though I've had two -- and, by the way, they don't agree, so the science is still evolving. But as we come to -- or maybe I'm evolving, I'm not sure which. (Laughter) But as we become more precise there is no reason.

And I think this is one of the breaches that will really demonstrate the inadequacy of the privacy paradigm we have for the age we've moved into. Classically,

technology breaks an old paradigm, regulations have to catch up.

Secondly, our standards. I know this is de rigueur. We need to talk about the need for standards. This is underway. There are efforts -- and I'm sure the panel will talk about this, because at least one of the panelists is involved in this -- to develop standards for things in at least the genotypic world and to think about them as extensions of the "medical record."

But -- and I think they could move quickly. Because unlike all the other standards that we tried to develop where there were already multiple competing standards and there were many commercial legacy overlays that created enormous friction as we tried to change the standard, this is a pretty green field. And so I think they can move forward.

But I think we should, though, be cautious about calling for point-of-service standards today, putting them into meaningful use, asking CCHIT or another entity to make these requirements. I think we need to remember the efforts there are to control the minimum set of functions that come to the market, not to set the standard for the maximum. And so I think we need to think about that regulatory schema, and if now's the time. But certainly behind the scenes and in demonstration projects where we're testing these out, this is clearly time to do this.

Finally, I just want to make the comment that we all need to make. We need to reimburse for personalize medicine. In many ways I'm not particularly optimistic that with the distractions of health reform and CMS's fears that personalized medicine will just be the next way that doctors will churn patients, the downward financial pressure. And probably biggest of all, the enormous reluctance of physicians to really betroth this. I'm not particularly optimistic that this will happen soon.

But I think there's one thing we should think about, which is to develop the reimbursement coding scheme that would flow from this is not in place. If you talk to my peers in the Silicon Valley who are financing many of health care's clinical miracles, the next technology, or the next diagnostic, they will tell you they are impelling themselves on having codes created by CPT or in other areas. And this has had a more adverse effect than any other aspect of this on the development of these technologies. And I think that does take quite a lot of time, and it's amazing how much it does drive reimbursement attention once those codes are legitimized. So, perhaps it's a battle as opposed to the war, but one that could be fought.

I will stop here. I appreciate the chance to be with you all, and I look forward to our discussion. (Applause)

MR. WEST: Thank you, David, for those opening remarks. And I was very interested in your comments that you think that both HIT and personalized medicine are certain to happen. And the key thing that we need to do now is to -- I think your words were to steer the curve of change. So, I'd like to focus a question on the policy actions that we need at this point.

And you mention meaningful use. And there certainly has been a lot of discussion about, you know, minimum standards, maximum standards, and how we should think about personalized medicine. So I'm just wondering if you could elaborate a little bit on your comments on what you think -- how you think we should handle the meaningful use comments, and to what extent should personalized medicine appear in those requirements?

MR. BRAILER: I think it's one of the key questions. And if you step back and look at the point-of-service efforts, when we started those efforts our goal was to be

able to create -- I'll put it in quotes -- "market certainty." And the idea was to give physicians a badge of trust, hospitals a badge of trust, that they knew that a certain product met certain basic standards.

That's been taken further as a tool for reimbursement assurety, so that we can be sure that we're not just paying for a piece of technology sitting on your desk, but something you're actually using or, I think in this case, something that's usable.

So, you know, that schema is not designed to take into account, for example, many of the more advanced forms of decision support that are already here in the market today, many of the things that support further detailed patient history, for example. You know, if you think of every aspect of health information, the efforts that largely have gone on -- and, you know, obviously none of us know exactly what happened behind the scenes as the thousands of comments on the draft reg were handled in meaningful use -- but most of the efforts are focused on keeping excellence from being the enemy of good.

And in this case, it's hard to think about how that schema fits with personalized medicine. I think the specific hope would be that there is a personalized medicine killer app, the one specific test that doctors think they need to have, the test that patients can get behind. And this will become a forcing function on many of the standards -- point-of-service tools, on the actual product makers themselves -- to do this. And I think today I see some candidates for being a personalized medicine killer app. I don't quite think I see it today.

The final comment I'll make is back to the comments I made on Medco. Many of the things that happen can happen in the information chain far outside the point of service. And, you know, if the doctor is getting an alert on an allergy or on drug-drug

interaction or on a genomic modification of dosing, it's all the same message payload. And so I think it's possible with many of these areas where ultimately we want to vend information to doctors, not get it from them; that there are things that we can do that stop from getting behind a very long freight train of point-of-service standards.

MR. WEST: I have one more question, then we'll open the floor to questions from you.

At the very end of your remarks you said we need to reimburse for personalized medicine. So what changes in reimbursement policies are required in order to fulfill that?

MR. BRAILER: Well, I identified one that I think is the most complex and the most politically laden, which is the presence of a coding schema that allows personalized medicine to be acknowledged as a legitimate part of the reimbursement system. I'm sure there are people today that would contradict this comment, because you actually have information and I don't. But since I don't, I can make a sweeping comment. (Laughter)

I have heard of very few companies that have come to see us -- and we have no investments in biomarker companies, although I have a personal investment in a genomic screening company where I've had the privilege of losing all of my money recently. (Laughter) But I have yet to see a company, when asked how will you handle reimbursement coding, where the answer is not we have figured out a way to piggyback on some other code that has some other purpose and to slip it through. And all of these have to do with being allowed to have -- how can I say it? It works because there's no visibility. When things become scaled, it won't work and it produces enormous confidence concerns.

And let's be, again, very candid. For reasons that are not clear to me, the governing structures that sit on top of the CPT codes -- remember, they are controlled by the House of Medicine -- have been quite reluctant to accelerate many new codes for diagnostics and other kind of therapeutics at the point of care. Whether that is something that is related to fighting a fight around protecting doctors or if it has something more to do with the integrity of the coding system itself, these are very difficult. So I think that is one of the hardest and most important battles to fight.

But again, I come back to the comments, you know, if you want to demonstrate this is valuable to payers like CMS, I think we have to demonstrate to the actuaries of CMS that this is something that is a rational, economic investment. And I think the data is not there.

Now, in some it is. If you think of some very particular examples, there's very good trade-offs between having a $400 test and avoiding a potential hospitalization. But, again, the chain of reasoning. If you get this test and it shows that the patient needs to have a warfarin dosing change, right, or they need a different schema, and if the doctor uses the information and if the patient is compliant and if other things happen, and if something else could go wrong, we could avoid a hospitalization. That is economic rationale; that is not actuarial rationale. And they need to show if patients get this drug, costs are lower or they're the same. And so I think there is economic studies -- and there are numerous of them underway. I am aware of at least 30, I think, that are quite good. But we don't have the data today.

And finally, again, I would come back to the comment I made at the prior question, which I guess is my epiphany point, that we have to have the killer app. We have to have something that forces it, because there is a public push. And today it's not

quite there. And I think when we find that test, we will use that to plow the reimbursement fields and others will come behind it. And health IT is very much the same way. Let's remember that we could stimulate health IT all we want. That's not the same as reimbursing for the value of and quality of care and efficiency that it produces. Those are not the same.

And, you know -- so I think that we have tremendous battles that ultimately will come down to a reform of our reimbursement system around a much more rational schema on quality and access to services.

MR. WEST: Okay. Why don't we open the floor to questions and comments? There is a person with a microphone coming around.

There is a question right there. If you could give us your name and your affiliation, please.

MS. POPLIN: Sure. I'm Dr. Caroline Poplin. I'm a primary care physician. I am the point-of-service person. And I think if you help us do what we think is necessary to take care of the patient, you'll get a lot more buy-in than if you try to police us with so-called decision support and assume that we're stupid and we don't know that a diabetic needs to have a hemoglobin A1c under 7. My question is, the whole thrust of health IT at where we are seems to be standardization. And the whole point of personalized medicine is not standardization, it's just the opposite. And how do you work that out?

MR. BRAILER: To your first comment, I agree with you, by the way. I think decision support has come from the lab almost to the commercial point without really thinking through the sociology of care.

I saw a very interesting innovation, actually, in Boston in one of the

research labs, that rather than showing doctors here's how you care for this patient and here's the next step and the next step, or here's the order set is, the doctor entered information about the patient. There was a window that showed how many patients in their database was like that patient by age, by patient, by sex, by disease, by finding. And it came down to saying there were 62 patients like this that we've treated, and the doctor could click on that if they were interested to find out what happened to them.

And embedded in that were -- I don't know if anybody is a gamer, you know, an online gamer, you know, PS3 types, but all the gaming companies create NPCs. Does anybody know about this? They're fake people that are playing, but they teach you how to play the game and you can't friend them. So, some of those were NPCs. They were not real kind of pathways, but they were ones that were built by evidence. And I thought it was one of the most clever things I had ever seen because it really was something you could use if you didn't want to or you could use if you wanted to, but not if you didn't.

Look, I think the standards are part of this. Let me give you a metaphor -- and I'll give you two quick metaphors. In manufacturing, before we had the just-in-time flexible manufacturing miracle, when things used to go down factory lines as opposed to be routed around factory floors, and we had years' worth of inventory on hand as opposed to things showing up that we needed that day. We now have a world that is highly customized to the manufacturing environment and the order sets that come through for a car or whatever. But it was predicated upon a standardization of the factory floor process that had every information step automated and every information step collected and aggregated and that standardization was the fulcrum around which the customization happened. I think it's true in our banking system today. The kinds of much

more complex transactions that people can do, very personalized movements of cash and transfers of things that are more than just taking money out of an ATM are predicated on an infrastructure that is completely standardized.

So I think the issue is not that we have to standardize. I think the issue is that doctors have largely stood alone without any institutional or system support. And my view over 20 years, we've hung physicians out to dry on the front line. And we're paying the price for it now with really significant challenges that people like you are dealing with. And I think you're a heroine, and I appreciate it. But in the end, I don't see someone coming to help you in the next couple of years. So, I would say, take your lumps, keep pushing your health IT. And if you get out ahead of this it's going to be a very, very powerful pull for you.

MR. WEST: Okay, right there's a question.

MR. McNAMEE: My name is Jim McNamee University of Maryland School of Medicine.

So much about what we hear in terms of personalized medicine seems to take the person out of the picture. That is, the patient or the subject out of the picture. But if you think about personalized computing, it puts the subject and the consumer right in the center of it.

Who owns and controls medical information? The presumption is, I think, that it's the institution: the laboratory, the physician, the organization, the insurance company. How do we put the patient back in the center of this equation to get the buy-in that you were talking about earlier to occur and that blockbuster support?

MR. BRAILER: Yeah, it's a great question about who owns the information. I think ownership is not a term that one could use to describe the

constellation of rules and laws that influence control over health information.

For example, if I said you owned it just like if you owned a building or some other property -- software, other data -- you should be able to delete it. And, you know, I think the social conviction that we all have is you should be able to delete information from your health record. You should be able to stop people from seeing it, perhaps. But you can't change, you know, an illness from yes to no or something like that.

So I think there's not a social accord on what that ownership means. But let's cut to the core policy issue, which is, HIPAA largely and perhaps unintentionally said that the people that produce the data own it. And I'll put "ownership" in quotes here, because I don't think it says that, per se. And it does, though, in the way that English common law largely said who owned the property. If you're squatting on it and you're sitting on it and you have a gun, you largely can keep someone from coming on your property.

And in this case, if I'm a hospital I can make it really hard for you to get your data or I can make it really easy for you to get your data. It doesn't say, for example -- and I'll go back to my comment before that you as a patient shall direct me as the data holder to give to your data manager or to another entity the data that they need, in real time, in a form that's usable. That would constitute something closer to personal ownership over your information. In fact, I think that would create an enormous marketplace for agents and intermediaries that would assimilate information much faster than our current personal health records efforts do.

So, I think we will see that one of the key steps in our health information and personalized medicine journey is a refresh of the concepts of portability and

ownership that are currently locked, largely, in HIPAA. And I hope that we can make a declarative statement that says a person owns their health information, almost period, although I do think there will be some caveats. But they think that would be an enormous step forward for us, as a society and as a health care industry.

MR. WEST: Okay, there's a question right up front.

MR. BOND: My name is Robert Bond, I'm with a company called Washington Consulting. And one thing we're doing is helping organizations think about how to use changes in health care and health IT to impact their practice.

One thing I'm interested in is comparative effectiveness research and how do you get the evidence of what works out there to the point of care. And I just wanted to hear your thoughts on that.

MR. BRAILER: Yeah, it's certainly hard, to say the least, because, you know, let's start with the obvious probability. If I think of any test or treatment that I'd like to perform on a patient, chances are there's not a lot of evidence about that test that is -- we would consider meeting any scientific adequacy. But where it does exist, we don't have a mechanism for knowing that. I think they get embodied, as the prior question was, into something called evidence or pathways or guidelines, which have become a very politicized process as opposed to a scientific process.

I don't think comparative effectiveness as defined is going to focus its attention on supporting that point-of-care doctor. I think it's more about reimbursement policy, about coverage policy, and it certainly needs to be done. But there are some efforts. I've seen some private companies that basically scan the literature every week and update instructions or guidance to doctors that they can use. There are, you know, some efforts that are quite far along and some that aren't.

But, you know, this mechanism of how to get information and knowledge to the doctor, to the patient, and do so in a collaborative way is clearly the next frontier. But to the comment that I made earlier, it is one of the trains that moves down the railroad tracks once we've laid the tracks.

There are so many things that we can do if we get the basic infrastructure in place. And if you look at the IT automation wave in nearly every other industry, it's a generational phenomenon. You lay out one set of information capabilities -- in the case of manufacturing, keeping track of machine times -- then the next step of being able to control and adjust those, and then another step. So it's a matter of time, but I don't see it happening immediately.

MR. BOND: So, I heard you say --

MR. WEST: Excuse me, we just have a couple more questions. There's someone back here, right there is a question.

MR. DuBOIS: Jason DuBois with the American Clinical Laboratory Association. Good morning, Dr. Brailer.

MR. BRAILER: Hey, Jason.

MR. DuBOIS: My question really revolves around cloud computing. I had the opportunity to ask Dr. Blumenthal last year in kind of the adoption curve of technology, we haven't really kind of tipped to the heavier side of adoption yet and what will really get us there. And he said addressing privacy concerns by patients everywhere. And he thought that once we can get over that hump, he really saw kind of patient medical records moving to the cloud. And I wonder what your take on -- and really the migration, is that going to happen? And what impact that might have on both health care and personalized medicine, since we are talking about it today.

MR. BRAILER: Well, it's an easy answer. Whatever David said, I agree with. (Laughter) And I both agree -- never contradict your successor who is carrying your legacy forward is a simple rule of thumb you should follow.

I do agree that cloud computing is -- you know, again, I think an easy mechanism for understanding where health care may end up is looking at other industries that are further along the information curve. And if you look at financial services and investment areas, you know, where -- just a more sophisticated information infrastructure, about half of the enterprises at steady state are doing cloud solutions versus enterprise solutions. And I don't know if that's a weighing point on an ongoing trajectory to everything in the cloud or if it's stratifying around some kind of size or organizational preference, but clearly it's way further ahead than health care.

I see no institutional reason that health care won't follow that. I think the economics of cloud computing are enormously powerful. I think the benefits and portability and of movement are clearly there. I also see incredible reluctance in the industry. So if I had to say, I think it would have about the same contour of a significant chunk of doctors' offices, smaller hospitals, labs, some pharmacies being in the cloud or in the implied cloud. I mean, you know, some of your members are very, very large organizations. And perhaps they won't be in the cloud in the virtual sense, but they will in the sense that they're going to maintain central trunk lines for repositories of data that are shared together.

So I think it's an inevitable change. But, you know, in the end the one thing that the cloud does is that it brings a new way of interacting with information. It's more than just the economics and the data storage, it's a different experience with information because it has different assumptions. And I don't think those assumptions

are quite right for health care yet. And what I'm talking about particularly is the economic model is often one of secondary data monetization, other uses of data that make the cloud solution very cost-effective, and I just don't think we're ready for that. But putting that aside, I think it's a contour that we'll clearly see happen.

MR. WEST: Okay. I think we have time for one more question. And we'll take it right here. And there's a microphone coming over to you.

MR. PANTOS: Thank you. My name is George Pantos. I am executive director of the Health Performance Management Institute, which is looking into use of innovative technology to cut costs in the health care field as well as to improve outcomes of individuals and without sacrificing quality.

I quite appreciate the comment that you can use technology for treatment and diagnosis as part of the whole process of medicine. I was wondering how you feel and what your view would be on the use of data -- the use of significant data that could be used for prevention. In other words, the other side of that coin is to avoid expenses and costs before they incur with prevention.

We have a new emphasis on the accountable care act for wellness, increasing incentives for personalized behavior. This sort of hitchhikes on the question that was asked by the gentleman from the University of Maryland. And that is, is it also in the equation here for the use of data to prevent illness rather than just simply focus on treatment and diagnosis, which of course are important?

MR. BRAILER: I think you've put your finger on a really key issue. And let me just sharpen it just a little bit.

The value proposition of nearly all biomarkers that I've seen comes down to the patient shall be motivated to be more compliant with a known set of preventative

behaviors. Not all are like that, but some in pharmacogenomics. Certainly many in, if you would, disease screening have the premise that we're not motivated enough to engage in the preventative behaviors that we know we should. But if I know I have a genomic risk that would give me a 10X or 20X the population risk of a certain disease, I'll be more motivated.

I consider that rationale specious. I have not seen real evidence. I have seen a couple of examples of evidence where I think there is a marginal behavioral benefit that is sustained over a period of time. And one of the challenges I've thrown out to these companies -- and I'll just say it here -- is, find a more closed form framework by which information can drive the behaviors we want without relying upon ongoing stimulated remembrance, which is, I think, kind of what motivation is about.

So, you know, how do we take that data and when we find out that someone is at risk for Alzheimer's or diabetes and say here is what you should do and we will help you do it in a way that is different than you just being a little bit more careful? And this is one of the cusp issues that we just have not breeched yet. But when we do, I think you'll see an enormously forward -- and the commercial viability of diagnostics marker companies because the clinical utility is quite apparent, but the behavioral component is questionable. And I hope we get there, because it's really a very promising area.

Thank you all very much. It's really been great being with you.

(Applause)

MR. WEST: Okay. I want to thank Dr. Brailer and now would like to invite our other experts to come up on stage and we will get them set up.

What we wanted to do in this session after hearing from Dr. Brailer was

to assemble some academics and private sector leaders of people who were on the front lines of personalized medicine and health information technology and give them a chance to share their views on what they're seeing in their areas of inquiry and what policy actions need to be addressed. So, we're going to get into some of the issues that Dr. Brailer suggested in terms of privacy, reimbursement rates, meaningful use policies, and so on.

And we're fortunate to have a distinguished set of people participate on this panel. Mark Boguski is an associate professor at the Center for Biomedical Informatics at Harvard Medical School. He has written extensively on personalized medicine and he also has worked to train pathology residents in genomics. He has a long list of over 100 publications covering informatics, genomics, and sequence databases.

Donald Rucker is vice president and chief medical officer at Siemens Medical Solutions. In that position he leads Siemens sales and marketing groups and provides clinical direction for the company's Med-Meets-IT Initiative. He has worked hard to meld medical equipment with information technology in an effort to create greater efficiencies across health care and supporting decision-making at the point of care for physicians.

Emad Rizk is president of McKesson Health Solutions. He works to bring transformational strategies and operational execution to health care through information technology. Previously he served as global director for Deloitte and led its medical cost and quality management practices. He's published a number of books and articles, including *The New Era of Healthcare: Practical Strategies for Providers and Payers*.

Pat Billings is chief medical officer of Life Technologies. He works to improve patient care by expanding the use of medically relevant genomic technologies in clinical settings. Prior to that position he was director and chief scientific officer of the Genomic Medicine Institute at El Camino Hospital in Silicon Valley. He has been a founder or chief executive officer at a number of companies and is the author of more than 200 different articles.

I think what I'd like to do is start with Mark. And we talked a little bit in our first session about consumer-driven medicine and the role of patients and how technology enables patients to play a more prominent role in their medical care than previously was the case. So, based on your experience, what is it that patients care about? What is it they want, and particularly in the areas of personalized medicine and health information technology?

MR. BOGUSKI: Let me start off by saying that I believe that personalized medicine is participatory medicine and what that means is that the patients themselves have to take an active role in managing their health over their lifetime in addition to responses to individual clinical encounters.

Over the last few years there's been a growing movement of so-called e-patients who are empowered, enabled, engaged patients -- it doesn't stand for electronic -- and right now it's a fairly small but very vocal group. There's the Society for Participatory Medicine, which has a manifesto, if you will, on how patients interacting with professional health care providers will be co-managers of their care and not just passive recipients of whatever the medical health care system wants to deliver.

So, another point I'd like to raise, and I guess an actuary wouldn't have a way of measuring this, but what we've heard from patients involved in genomic testing is

that there's clinical utility which is subject to evidence basis and things like that, and there's also personal utility. That personal utility may not be an evidence-based reimbursable phenomenon, but it can be tremendously important to them in terms of managing their lifetime risk, buying certain kinds of insurance and so on and so forth, and so I think there is an important role to play for patients. They won't all participate to the same degree, but it could be that a small number of very super consumers of health care could drive a lot of the trends in personalized medicine.

What -- I'd like to talk about the role of the medical profession in this now and I think there's an old saying, at least among medical specialists, that the pathologist doesn't meet the patient until the autopsy. And it's true that pathologists often operate in the background, but insofar as 70 percent of the clinical decisions that the 650,000 physicians in the U.S. make, 70 percent of those clinical decisions are based on laboratory analysis. And there's a tremendous role for pathologists to play in terms of quality assurance, quality control, outcome measurements, predictive medicine, modeling, learning in real time, that they're just beginning to engage in.

In terms of genomic medicine we -- Darrell alluded to this, but we started the first genomic and personalized medicine training program at Beth Israel Deaconess, which is a teaching hospital at Harvard Medical School. We subsequently worked very closely with the College of American Pathologists to nationalize the training of pathology residents and current practitioners to be a credible workforce to engage in this new area and one of our goals is really to demystify genomics. At the end of the day it's just another laboratory test and it can't be fully interpreted outside the context of everything else we know about that patient -- their medical record, their other laboratory values -- and the extent to which pathologists do not currently have access to the complete

medical record, I think, is a detriment to the whole health care system.

I'll make one more provocative comment, that perhaps contrary to what Dr. Brailer said, I think that whole genome analysis will be part of routine medical care in the next five years. That will be in the area of cancer diagnosis and lifetime management. And I think in the next 10 to 15 years, every newborn will have a complete genome analysis done and that data will be used to manage their risk of disease throughout their lifetime. The medical profession -- or the medical specialty that will be helping patients manage the risks are the pathologists who will periodically report back to the primary care doctors what the revolving interpretation and actionability of that genomic information is. Thank you.

MR. WEST: Thank you. I like that line about pathologists not meeting the patient until the autopsy and it kind of reminds me of that Woody Allen line about death. He said he was not worried about death, he just didn't want to be there when it happened.

But Don, Dr. Brailer mentioned the need for reimbursement reform, and I know that's an issue you've thought about. What is your view about current reimbursement policies and what changes, if any, do you think are necessary?

MR. RUCKER: Yeah, I think from a personalized medicine point of view, we have a very problematic reimbursement. You know, some of it, I think, everybody absolutely knows. As Dr. Brailer mentioned, when you actually do some of these high information content -- so we have a lot of challenges with reimbursement. I think when you get into these very high information density tests, it's something that I think historically CMS hasn't really had a mechanism to deal with. We see this. We're a large manufacturer both of lab tests and radiologic tests, and there are a lot of challenges in

getting reimbursed. The structure on lab testing really sort of goes back to the 1980s, so I think that's a fundamental challenge.

One of the things that has been talked about to address that is coverage with evidence development, sort of as an ongoing science incorporation. I think the challenge there that we face as a country is doing those types of clinical trials takes three or four years realistically. In a Moore's Law world, right, everything you're hearing about today is on Moore's Law, information doubling every 18 months or in the genomic space, arguably, a lot faster, so that type of science acquisition doesn't work. So, I think we need a sort of a more plastic reimbursement scheme.

If you're in the primary care business a lot of what we reimburse for is non-information, right? I mean, I think everybody who's sort of ginned up a review of systems or a 8 organ or a 10 organ or a 12 organ physical exam for somebody with a one organ complaint, knows that we have a lot of sort of funky information that we're paying for and maybe we should just think about paying for some simple collections of electronic information like continuity of care documentation as a straight up, unvarnished thing that would potentially get us out of some of the complexity that I worry we're getting into with meaningful use.

MR. WEST: Okay. Paul, privacy issues continue to be controversial and with genomic information getting incorporated in medical care, that continues to be an issue because almost by definition genetic information is highly personal, if not unique, to the individual. So, I'm just curious your thoughts on privacy policies and how we should think about that as we move into this area of integrating personalized medicine and health information technology.

MR. BILLINGS: Well, first let me thank Darrell and Brookings for inviting

me. I come to Washington frequently for oversight of genomic medicine at the VA and now -- previously, and now Sunset Secretary's Advisory Committee on genetics, health, and society, and they've considered some of these issues and it's now good that the Brookings and the Personalized Medicine Coalition and others are taking some of these issues like privacy and how we create these databases and the standards for interoperability and so forth up.

I would also, by the way, echo many of the comments of my fellow panelists about the current system that we live with and that I have practiced in. The -- you know, I've dealt with innumerable illegible paper medical records and scrips of, you know, silo data that I couldn't get a hold of in an emergency situation or when a patient comes to visit me. How much time have I spent in the basement of hospitals looking of X-rays? It's just unbelievable that that's the legacy of the biomedical system that we're currently dealing with and that's still generally in effect.

And, you know, layered on this we have now the growing database and the growing methods to entirely redo the textbooks as well, from the bottom up. You know, we're going to reclassify disease, how we treat it, and we're going to reclassify risk as well, and thus enable preventive medicine. So, we're going to create a bottom up system of disease information, which is going to completely make our current textbooks, the current way we train our physicians, obsolete very quickly.

And so we're in a very important time of change and this is substantially driven by the fact that life technologies and other individual and institutional and corporate and governmental innovators have created the -- they have taken the Human Genome Project and have now made it possible and conceivable that in my professional career, when you come to visit me I'll ask you why you've come to visit me. What's your

complaint? I might check your vital signs and I will actually then, on specific visits or maybe on a general visit, look at your genome and use your genome in an active way to care for you.

Now, how do we get -- I think that would be a better model. It's a more reliable model, it's a more quantifiable model. I think that would be a better way to practice medicine. How are we going to get there? The methods, the cost of generating the data dropping dramatically; we've already heard Moore's Law evoked here.

The second thing we need is research participation. We need to create large databases, both of people's genomes and of their health -- their phenotypes, their health outcomes, and that requires protections for research subjects, protections that are begun by GINA. I worked on GINA for 20 years beginning in California in the early '90s, and I can tell you that GINA is the beginning, but we really need to stand up and say that we need to enforce the principles of GINA of non-discrimination and increase research participation in this country, because in the absence of research participation much of the benefit of the technology advances will be lost.

And then the final thing that we need to make the reality of real genomic medicine, real personalized medicine, is the financing for it. And I think in particular that the interested parties, like the payers and the providers as well as the enablers, like my company and others, should work together, create the large standardized, interoperable databases and repositories in maybe a Phase IV-like research construct that will provide the data that I'm quite certain will show the benefit of genomic medicine, will entirely redefine what we call normalcy in this country, will most importantly provide immediate assistance to people with advanced cancers, to families who are motivated but are struggling with a congenital disorder, a genetic disorder in their families, which -- and

these people just bounce around our system and, you know, get very little help. And finally, we'll enable individuals to get personalized medicine, and for us who want to help those individuals to assist them.

MR. WEST: Emad, we need infrastructure and data sharing networks to manage personalized medicine. What should that infrastructure look like and how do we address the interoperability concerns that are strong in the current system?

MR. RIZK: Well, the worst part of going last is you have nothing more to say, so I could just say ditto. But it's a privilege to be here on this panel with so many distinguished folks.

I'd like to concentrate a little bit on the operationalization and the infrastructure of what's going to happen over the next two to three years, that's sort of my strength. We all know the importance of personalized medicine, we understand the privacy, we understand the technology, but, you know, in my mind you could actually apply a lot of what was said to the current health care system. Interoperability, you know, whether or not you have a genetic predisposition to a disease, whether or not you have a chronic disease right now doesn't necessarily get shared across the entire continuum of care.

At the point of care that physicians are taking -- I think one of the physicians mentioned at the point of care you don't have actually all the data right now. You don't have the demographic data, you don't have the labs, you don't have anything. So in my mind I actually do believe that from a practical perspective, what personalized medicine is going to do, it's going to stress our current disconnected system. So all the principles that we are trying to do right now are actually going to get even more stressed as more and more genetic information becomes available.

So, that being said, some of my comments around infrastructure and technology -- except I'm going to mention three just for everyone to kind of think about as you formulate your questions for the panel. The first two are very specific and the last one is actually very specific to the genetic personalized medicine.

The first one is the point-of-care data. I think at this point in time, the point of care, the point of service, we do not, as physicians, have that data. And I think as we move into personalized medicine, how do we make that information available to the caring physician? Eligibility, financials, information around the lab, information around what the genetic predisposition is, at the point of care we are lacking in terms of clinical data to the physician or to the caring physician. That's the first one.

Second, that data actually is connected in silos across the health care system, so I believe that there is a new level of investment that needs to occur in terms of connectivity and infrastructure. How do we -- keeping in mind the privacy, of course, but we really do not have a connected health care system. And I know we've been saying this for 10 years, but this is going to become even more and more relevant as we move forward.

And I think David mentioned the fact, the third point is coding. You know, when we speak to payers, whether it's government or whether it's industry, and you talk to them about how much they're spending on genetic testing, do you know how many of them are aware of it? Hardly any, because there's no coding. They're bundled in a great deal of CPT codes. So I really do think that this is an opportunity for us to be able to develop the codes with government and industry, and I think this is something that we really have to push because a lot of industry -- we're spending a great deal of money in trying to understand all these codes and documenting them and creating a registry.

We need these codes not just for reimbursement -- reimbursement is just one of the pieces -- but we need it for outcomes, for tracking, to understand exactly the correlation and the causality of many of these tests.

So, those are the three things. The first two are very health care fundamental, point of care, and I think that could be applied across health care, the connectivity, and we really do need to get on top of spending and investment on the coding mechanism.

MR. WEST: Okay. I'd like to ask a question and just throw it out to anyone who wants to answer. What policy changes do you think are necessary to enable personalized medicine through health information technology? This could be infrastructure issues, reimbursement reform, changing privacy rules, the coding issues that have been raised. You know, if you were in a position to really make some concrete policy changes, what would they be?

SPEAKER: Can I respond to that? One of the dichotomies here is that the cost of diagnostic testing, actually just running the test in the lab, decreases. You know, they talk about the $,1000 genome where the first one cost $3 billion. I think payers are focused on what it costs just to run the test, and that's a vastly different proposition from how to interpret the test. And I think what we're reimbursed for now is just running the test and the prices are falling there, but we're not really reimbursed for the full professional services that we put into interpreting the results in an actionable way.

SPEAKER: Yeah, I think that most of this is going to end up as bundle payments. I mean, if you sort of look at what's economically stable out there in a sort of market economy -- because really we're talking about information. In our health care economy we don't use price, fundamentally, as the communication tool, right? In every

other sector of the economy it's price equals marginal cost equals marginal utility, right? So, we're sort of in Econ 1 microeconomics term, somebody has to do the price equals marginal cost equals marginal utility calculation.

If it's coding at the CPT board, which is largely influenced by CMS, that's a really poor place to do it. I think if you have a private pricing mechanism, which happens within large accountable care organizations -- to use the de jour buzzword you could call it managed care, you could call it integrated delivery systems -- I think those people are going to be in the best position to do it. Much of what we are talking about is very long term, right? If you've identified a cardiac risk factor, do you want to manage it after they've had cardiac heart failure and either by ventricular resynchronization, or do you want to manage it with just a little bit more statin 5 or 10 years earlier? So, I think we also need to reform that has people longitudinally enrolled in the system so that people can get the downstream return of their upstream investment. All of those things speak to more integrated payment systems and I think that's going to probably be the most practical way of getting in what are often very subtle technological issues throughout the portfolio of potential products.

SPEAKER: So, as I said, I think one key is research participation. So, you know, we see integrated health care systems, the VA doing their million veteran program. We need to figure out a way to make research safer for individuals even if it's just perceived safer, since most research, I think, is probably safe now, and we need to incent participation.

The second thing I suggested was finance reform. I'd love to see CMS, for instance, do pilot projects that would use advanced molecular testing, whole genome data or some variant of whole genome data, because the payers, whether they be a

governmental payer or private payers, are the ones who are really going to benefit from the improvements that genomic information and from the dropping cost of molecular testing.

And then finally, obviously, some regulatory clarity about how we're going to -- with this incredible avalanche of new molecular information, basically assessing, testing every base in your 3 million base pairs that exist in most every one of your cells, how are we going to assess the quality of that and regulate it in a practical and efficient manner?

MR. RIZK: Well, I'm glad the ACO issue was raised. This is where I see, again, where the rubber meets the road. If you look at this year and next year there will be a great deal of integrated delivery systems that take on some level of risk with ACOs. Here's the issue: the payers do not know how much they're spending on molecular testing at this point in time. We estimate that it's about maybe a billion and a half to $2 billion, which is going to double every single year. But when we go in and we try to figure out how much they're spending, they're usually pretty -- it's a big aha moment to them and say, oh, my god, we're spending that much? We didn't even know.

So, now you have a sophisticated payer that collects all this data and now you're going to shift some of this global risk to an ACO and that ACO is not -- does not even understand the risk associated with the molecular testing, so they're going to take an associated payment with -- for heart disease. And what's going to happen is when they get that population of patients, that cost on a molecular testing piece is going to just continue to grow. And, you know, that further emphasizes the fact that we need clarity and we need some way to identify all of these tests because I think right now a lot of the changes that are happening in health care is going to create even more of a void,

because providers are not spending significant amounts of money on data, they're just not, because, you know, most of them are operating at 1 to 2 percent margins or 3 percent margins.

So, we really do -- back to your point, Darrell -- we need some level of investment to create clarity now between government and industry to start tracking on creating that level of an infrastructure to understand what even the size of the situation is. We all know that the tests are moving up, we don't know it's cost -- how much -- you know, costs between labs are completely from $150 to $2m000 for the same test, and like David said, you come up with different data. There's no level of control on it.

MR. WEST: I'm curious how each of you would grade the current administration's efforts in regard to personalized medicine and health information technology. What is the administration doing well? And where do they need to undertake some other actions?

MR. RIZK: This is hard. Is this recorded? (Laughter)

All right. Let me say the politically correct answer. I do believe that the current administration is focusing on the appropriate things in terms of technology. I honestly do not believe that molecular diagnostics is on their radar screen, so -- not that I am aware of. Maybe other panel members are aware of that. So, I do believe that there is a little bit around health care reform and giving some economic incentive for providers to adopt technology. That's a good thing. So, I would give them a C+ to B there, although we haven't seen real adoption. But in terms of personalized medicine and making sure that we get that information into the technology, I would probably -- that's an F.

SPEAKER: Well, I will point out that Francis Collins is the NIH director

and he's probably arguably one of the fathers of personalized medicine. So, I think in that respect this administration has done the right thing by suggesting that genomic medicine, which he certainly is one of the fathers of, is essential to the health agenda and the biomedical agenda, biomedical research agenda, of the country. And I also think that the regulatory agencies where I said previously that we need more clarity, the regulatory agencies have considered some of the aspects of personalized medicine and are struggling with it, and it isn't an easy question.

So, from those two points of view I would commend this administration. They've also published the enforcement rules under GINA and those are, in my view, a bit of a mixed bag. But there are rules, so those are all three good things.

SPEAKER: Yeah, I would say, I think in no small part due to the efforts of Ed Abrahams and the Personalized Medicine Coalition, we're seeing certainly in the FDA where a lot of this stuff sort of lands first in terms of technology, I think we're seeing a real willingness in the last little bit to rethink a lot of these root processes, the 5-, 10K process, some of these things, you know, in this brave new world. So, I think that's very admirable.

I think on the IT side the administration and everybody in the field sort of runs into there's some deep challenges when we really get into how we're going to manage reducing data from 3 million base payers to something that sits in my electronic order entry system, you know, how are we going to manage, you know, these data flows over time? There's definitely been an effort there, the Presidential -- the PCAST Commission, the advisors that is mentioned, that Darrell has in the report, are looking at this. When you get into the nitty-gritty, you get into some deep computational issues on things like semantics and syntax and meaning that are typically, I would say,

misinterpreted. So you really -- you know, you're deep in the weeds of the swamp there when you're getting into that, but they're at least looking into it and I think that's admirable.

SPEAKER: So, my take on it is that if personalized medicine is participatory medicine, the participants or potential participants don't have the degree of health literacy and medical knowledge that they need to be fully effective as co-managers of their health care, and I've seen no realization of that fact at all. Increasing health literacy has traditionally meant public service announcements and printed materials. And I think of all the government agencies I'm familiar with, only the CDC has realized that people are going to get their health information through Twitter and Facebook and blogs, and only the CDC is really making efforts to utilize those new modes of communication to get health messages out. It's not about public service announcements on the radio anymore. It's really about these new means of social media to communicate reliable and authoritative information and I think more emphasis and effort needs to be put in that direction.

MR. WEST: One more question, then I'll open the floor to questions from the audience. Peter Neupert of Microsoft says that, "Personalized medicine provides a promising path forward in cancer care, but accelerating this research requires lots of relevant, annotated, real time data." And then he points out, "Today we are missing the lots of data pieces." So, what should we do in terms of collecting and integrating data into medical care, and are there changes in privacy rules that inhibit the collection of data that need to be changed so that we can actually get the information on what works and what doesn't work?

SPEAKER: Well, let me take a gander at that. I look at information -- I

look at this clinical information basically as sitting in two absolutely separate camps. One is the camp that's entered from a machine, and I think we actually do some relatively good things there, and then the other is the camp that's entered by human beings. And so when you look at interoperability, when you look at all of these, those two sets of data have absolutely different things.

I think when you look at the machine data, we don't, I think, really have the best handle yet on what we're going to do with all of the genomic data, but it's certainly sitting there electronically. I'd like to make the point that we have tremendous information electronically available on many networks now with phenotypic data. We think of personalized medicine as purely as sort of a Genes-R-Us kind of thing. But I would just point out the Moore's Law revolution has also attached itself to every computer that you don't know is a computer in the hospital, like the lab -- the automated lab analyzers, every CT, every MR. So, we spend a lot of time arguing about, you know, is 9P21 what kind of risk factor for heart disease or KIV6 or something. It's worth noting that we can unambiguously with 1 millisievert now tell you whether you have coronary artery disease in one single heartbeat on a CT scan, right, at a level of a third of a millimeter grain size. So, we can, you know, map out the plaque.

If you're worried about, let's say, cancer in terms of the response to chemotherapy, for some cancers now you can do a PET-CT and see within one day whether over every genome in that cancer it's responding by FTG take up. So, I think if we look at the data and we put it in the pool of coming from machine, pretty good; coming from doctor/nurse/clinician, not so good.

SPEAKER: We are conducting at least three studies on the role of genomic information in advanced cancer, one that's already been published, one that's

underway using -- on women with triple negative breast cancer, and one which is in the protocol writing phase on all advanced cancers -- on a group of advanced cancers. There is no shortage of clinical information to do those studies within the research environment. Where there is a deficit is in the ability to blend those research databases across institutions, across different research protocols so that we can build these extremely large data sets which will increase the power of our detection of these new methods.

So, it's not that the data isn't there -- I think I would agree with Don, it's not that the data isn't there, it's the ability to link them up and increase the power.

SPEAKER: I'd just like to remind everyone of the distinction that everyone already knows is there's a difference between data and information, and knowledge and wisdom, right? And a focus on data alone is -- can be counterproductive.

One of the sources of information that is most valuable is data from the patients themselves. There's an association called the Association of Cancer Online Resources. ACOR.org has about 65,000 members. It's been around for about 15 years, and particularly for rare cancers it's probably the best online source of information ever because it aggregates the personal experiences of patients who've actually had these tumors, who've done their homework online, who've sought out the best care and exchanged information in this social networking environment.

So, I think, again, we've overlooked the patient in all of this and what they have to contribute to their own health care and they're self-organizing. I mean, you know, they're not going to let all these other kinds of deliberations slow them down and I think we should pay more attention to that.

MR. WEST: Okay. Why don't we open the floor to questions and

comments from you? And again, if you can give us your name and your affiliation. There's a question right over there on the side. There's a microphone coming over for you.

MS. GIFFIN: Good morning. My name is Mary Giffin. I'm from the U.S. Government Accountability Office, and I have a -- sort of a very specific question for Dr. Boguski -- did I get that right? -- which relates to something Dr. Brailer raised early on having to do with the public not really understanding personalized medicine. And I wonder whether -- of course part of that may be that they may not understand all of the science and the evidence base that's being developed. But I wonder if it isn't also possibly because, depending on their providers, depending on whether they have health coverage, depending on who they're covered by, they may anticipate that they wouldn't have the benefit of the kinds of tests or they wouldn't be covered for -- you mentioned that you thought within, I think it was 10 years, that every delivery would be accompanied by a genetic test, and I'm wondering -- the question is -- would you recommend to Deaconess that the cost of that test would be part of the regular delivery fee? Would Deaconess feel that there is value in that? I mean, how do you see access to those tests being related to coverage and reimbursement?

MR. BOGUSKI: Right. So if a genome sequence is part of a new preventive or preemptive medicine regime, it's cost has to be amortized over that patient's lifetime. And if you hop from one health care reimbursement system to another, it's going to be hard to get any one of them to compensate for that test when they may not be covering the patient at the time they got the test.

So, that being said, however, the costs of a complete genome scan are decreasing so precipitously that I think a lot of the assertive patients, the e-patients, the

participatory medicine types, will pay for it out-of-pocket. Even at current costs, it's only -- to get your genome done is only about 20 to 40 percent of total labor and delivery costs now. You can get your genome done for about -- I don't want to get into the technical distinctions here, but $6,000 or $7,000 for a genome and a rudimentary interpretation. And if you compare that with what a labor and delivery cost is, that's maybe 40, 50 percent. And as that cost gets driven down to $1,000 or $2,000, I think, you know, patients who get, you know, core blood stem cells, you know, frozen in case one of their kids gets a tumor or needs an organ grown in the future, they're going to be opting to do that out-of-pocket. And I think that there's a consumer aspect here that -- I mean, consumers now spend about $17 billion out of pocket on supplements and other kinds of questionable things that you see on late-night infomercials and all that stuff, you know. You don't think they're going to spend $500,000 for a genetic test if it can help them manage their health risks over their lifetime or at least purports to --

MR. BILLINGS: So, could I just also add that, of course, you know that virtually every child in the country is given the Guthrie test financed by the state public health systems and that that screens for -- it varies from state to state -- a few to tens of mostly genetic disorders now. The cost of that test is sort of in the tens of dollars and as the cost of more comprehensive and more accurate molecular testing comes, we're going to see just an expansion of the quality and the amount of information generated by, let's say, a Guthrie heel stick-like test.

SPEAKER: Yeah, I think that's really important, Paul, and let just underscore that. Every newborn now is genetically tested for 30 to 50 conditions, and it varies by state law because it's regulated at the state level, but every newborn is already genetically tested and, you know, it's just part of routine health care.

Once complete genomics becomes in the same sort of ballpark price range, you're going to get a lot more data and a lot more information about that patient than you do out of current, existing --

MR. BILLINGS: Right.

MR. WEST: Back there.

MR. NAEGELE: Hi, my name is Doug Naegele. I'm from Infield Health. We're a technology firm here in D.C. in health IT.

I want to talk about privacy for a second and patients and this idea that as health IT continues to reach out of the hospital payer world and down into the patient world, that ideas about HIPAA and privacy, really, clearly they're going to have to change in some way. It's unclear what the timeline is for that, but if you -- to some degree it depends on, as a patient, where you are in the medical stream, right? If you're a well patient, you're probably very concerned about HIPAA and privacy, but if you're ill or you're facing end-of-life issues, privacy isn't your biggest problem right then, right? And so to the degree that we have this new conversation about HIPAA going forward where health IT meets patient empowerment and participatory medicine, it's going to be interesting to see how HIPAA changes and if we can get to the point where a patient could actually sort of set a HIPAA dial based on their preferences or their life situation, that might be an interesting scenario. So, I just wanted to make that comment.

SPEAKER: I think part of the challenge with privacy is also that I don't think we've defined a good payload to share. So we have the continuity of care document, which I think is probably the closest that we have on sort of a general thing, but we don't really know what to share. On one hand, we sort of do, right? So if you get a knee MRI, that can be taken to your orthopedist, right, they'll give you the DVD or

whatever, and so there we have a pretty good payload. And if you're at a place like MGH or MD Anderson, they're getting hundreds of thousands a year of, you know, maybe pathology slide or an imaging study, we don't know what your payload should be to share if you spent a month in the ICU and have, you know, blood pressures and telemetry and wave forms, you know, every second. So, I think part of the -- since -- if we don't know what to share, we can't share it, and so we can't put any of our classic, you know, public key/private key encryption kind of technologies on to it. So I think part of the HIPAA problem is that we haven't figured out what to share. Again, maybe the complete genome sequencing will actually be the kernel that drives all of this, but I think that's as much a challenge as anything around HIPAA.

SPEAKER: Could I make a comment about that? I'm going to resurrect an old term from Al Gore, "lockbox," right, and -- but not applied to Social Security funds, but your genome. Suppose that all newborns get a whole genome sequence just because it's the most cost-effective thing to do. That doesn't mean we have to unlock all the information. Perhaps we only unlock the 30 or 40 or 50 genes that are tested for now, and that patient would control who gets to look at the rest of the box over their lifetime. And the medical profession, the role they would play is to inform the patient about what that genome meant at that particular stage in their lifecycle or environment, and they could get -- they could decide to change that payload over time as it becomes developmentally and environmentally relevant to them during the course of their lives. And so when you would come in for a well information check, you know, the doctor -- primary care doctor in the back, you know, he'd take your blood pressure, height, weight, temperature, you draw blood for serum cholesterol and other established biomarkers, but you would also write an order, in our view, to the pathologist to reinterpret the genome

based on all the other information that's accrued and been validated since your last encounter with the medical -- with the health care system.

The genome is large but finite, and we don't know everything about it yet, but that doesn't mean we can't act on what we do understand, and I think it will be continuously reinterpreted throughout your lifetime based on a revolving knowledge of it.

MR. BOND: Robert Bond with Washington Consulting. My question is around bringing this information to the point of care. What is on the top of the mind of providers around, what are they going to do in terms of how do I get this at the point of care, this information?

MR. BILLINGS: Well, in my previous experience before I joined Life, as was mentioned, I ran a genomic medicine institute at Community Hospital, and the things that are on their mind at the point of care or elsewhere in the organization were, what the heck is this stuff? They wanted to be educated. And interestingly, we found that they didn't want to be educated online, they wanted CMEs and, you know, lunchtime with lunch or dinners and traditional education about what's known and not known about this stuff.

The second thing they wanted was ease in access to it, in other words, ease in ordering the test. There are -- currently we have kind of a fragmented menu of providers of what is now the tests that are the backbone of personalized medicine. They want a portal, they want it made easy to access it, and then they want more research.

MR. RIZK: There are -- I think there's a spectrum of what providers want. There are some providers that probably will say I'm going to get the information, I'm going to decipher through it, and I'm the physician and I know what I'm supposed to do, so just give me the data. There are others, probably of a younger generation, that

are saying I cannot possibly synthesize that much data in an ongoing basis. It takes about 7 to 10 years to take evidence into medical practice, right? So, as these things are evolving very quickly, on a yearly basis, they would like some decision support tools and as the newer generation of providers are becoming more technology-enabled and they're using smart phones and all of this, they really want decision support -- what's covered, what's not, what's the appropriate test for this patient, you know, they don't know. And so the fact -- the point that we can give them that -- the other thing is, is if we move into this ACO world or the shifting of risk back to a practicality perspective, these providers are starting to take risk and so they would like to understand not just decision support, what's covered, what's not covered, how much is out-of-pocket for the patient? I really cannot emphasize enough that we have to build this infrastructure at this point in time for the point of care information.

I've spoken -- you know, we happen to be lucky because we have both the payers and a lot of the providers, you know, in our organization, so we have a tendency to be able to speak across the spectrum. But I will tell you that right now I would say a greater percentage of providers want decision support tools either through a portal, either through a tree mechanism that gets them to the right test and to understand the financials that are involved with that. The financials are becoming huge for them.

MR. WEST: Yeah. Okay, there's a question right here.

SPEAKER: Hi, my name is Preveen. I'm a cancer researcher at UCSF and a health policy fellow at the Center for the Study of the Presidency.

So, one of the main problems in personalized medicine is that the rate at which new clinically validated genetic tests are submitted and approved by the FDA hasn't kept up with the pace of discovery in biomarker research. So my question is, what

policy measures can be put in place to fix this gap? It's largely an evidence problem and, like, how can health information technology be used to collect more evidence to support the clinical utility and validity of genetic tests and biomarkers?

SPEAKER: I'll take that on. If you look at the time and money it costs to validate the genetic tests for warfarin dosing, 5 years, tens of millions of dollars to validate a test based on 3 genes, it simply doesn't scale to the whole genome where there's 21,000 genes. And so the regulatory pipeline and framework and apparatus, it's going to break when you start looking at these multidimensional molecular tests. And that being said, even the randomized clinical trial is something that needs to be rethought as well because you just can't possibly do it one gene at a time, it's just not practically or economically feasible.

So, I think we're going to have to really take a hard look at what validity means, what evidence basis means, what personal utility versus clinical utility is. And it's a brave new world because -- I don't have the answers. I can just point out that the way we're doing things now is just not going to scale, it's going to break very soon. It's kind of broken already.

SPEAKER: I think that a lot of these things are going to be sort of self-documenting in a funny kind of way. I think as you do these things I think there's going to be so much electronic information out there that, you know, the answers are going to pop out.

I think the other thing to remember that I think sometimes is a challenge on the regulatory side is old technology gets replaced by new technology. I know there's a big belief in a lot of sectors that, you know, the new technology is piled on the old technology, but I think when you actually really look at these things, there's a

replacement effect on this.

So, I think the things that work are going to stick around and the things that don't actually are going to get moved out all the more rapidly now because we have so many tools to actually figure out whether they work. And you're seeing this -- I know we're seeing this in the imaging business on an almost a day-by-day basis as old technologies are just moved out -- nobody buys them, nobody uses them -- new ones come in.

MR. WEST: Yes? Right there.

MS. NADLER: Hi, Jessica Nadler with Deloitte. Do you have a wish list for what perhaps the New Translational Medicine Institute at NIH could do to advance health IT and personalized medicine that might have been their traditional purview?

SPEAKER: Well, that's a good one.

SPEAKER: So, we get to advise Francis, right now. Who's going to do that first?

MR. RIZK: Well, we're working with the NIH right now and Palmetto to try to create some knowledge around the codes. And we've put something called -- I think, Doug, it's called the Z-codes, and we have about, what, 300, 400 of them?

SPEAKER: It's more like 2,000.

MR. RIZK: Two thousand? Okay, so they've been moving much faster than I thought. But we're literally spending millions, if not tens of millions, of dollars in these -- in this area of trying to get the codes, building a registry, and understanding -- getting the evidence around those codes. Because back to your point that there's just not enough to keep up with the evidence, I mean, it's really hard getting all the evidence, and then creating sort of some technology infrastructure.

What I would -- I applaud these small steps that I think the NIH is taking and Palmetto in a lot of other areas, but I really do think that it's just a drop in the bucket in terms of spending and investment that need to happen in this area. This is just a -- if you have a 1- to $2 billion spend on an annual basis, and you're spending $100 million against that, I mean, from a business perspective that's not enough, you need to spend a lot more, and that's going to double and triple over the next couple of years.

MR. BILLINGS: I mean, I guess I would say that the translational medicine activity at the NIH should be a provings place that the different stakeholders within the government can, in that focused area, come together and work out a system that actually rapidly translates findings into medical practice so that they're working with the FDA, they're working with the health IT folks in the Executive Branch, that all that could sort of come together in that hothouse and get activated more quickly, and then also that the community, the interested corporations and research institutions, could be invited in as well and lend their own expertise to moving that along, sort of a new model for openness at the NIH and in those federal systems.

SPEAKER: What I've seen so far is that they're going to set up, you know, molecule screening libraries and do all the same kind of stuff that the pharmaceutical industry has been doing for 30 years and I don't see that really -- I don't see the value of that. I can tell you one thing that, again, I think the government in general is ignoring, is the input of patients. Let me give you an example.

Despite decades of investment and billions -- untold billions of dollars in basic research and technology development and experimentation with different management and organizational structures, it still takes 10 to 15 years and a billion and a half dollars to develop a new drug to address a single unmet medical need. The pharma

industry has figured out that the best way to discover a new drug is to discover a new use for an existing drug. It's called repurposing or repositioning, and there's a lot of effort in that now. But I think they're missing a huge opportunity to get input from people who are taking the drugs in a new kind of post-marketing surveillance.

Right now there's post-marketing surveillance for adverse effects, but there's no concept of post-marketing surveillance for new uses that may come out of millions of people taking a drug and coming up with rare -- not adverse effects, but unpredicted beneficial effects that weren't even sought in a clinical trial.

So, I think, again, it's a form of sort of crowd-sourcing new uses for existing compounds. It could be tremendously cost-effective, but there's all sorts of regulatory and intellectual property challenges that would have to be addressed there because -- yeah.

MR. RIZK: That's an interesting concept if we could create a post-marketing surveillance for all the molecular diagnostics and track it over time, these Phase III D-4s, that would be -- I never thought about that. That's a great idea.

MR. WEST: Well, I'm glad we could be helpful here. In the very back.

MR. LOUIE: Hello, Ryan Louie. I'm a medical student at Stanford. With a lot of social technologies right now linking peer-to-peer networks and where people are getting information from their peers, what do you think needs to be done to build a sense of trust in network with expertise while still maintaining the engagement of the public for sharing this type of medical information? Thank you.

SPEAKER: I think some of this is going to be relatively simple and it's going to be, you know, personal reputation and brand reputation. I mean, you know, the tools obviously have changed quite a bit, but I think people still rely on those and there's

a lot of information signaling and brand. You know, that's probably why you're at Stanford, I'm guessing.

Sorry about the attempt at humor.

MR. McNAMEE: Thank you. Jim McNamee, University of Maryland School of Medicine. That last question raises an interesting point. We probably have in this room three different generations of patients who are represented and at some point in their lives need different kinds of health care. If we're going to personally engage patients, how do we do it so that each one of the generations feels comfortable and is able to exchange the necessary information at the appropriate time in their life? My parents, for example, never learned how to e-mail and, frankly, didn't care. I don't text and I probably never will, but there are other people who are looking at texting now saying how passé, why don't you move on to something else?

How do we accommodate this vast array of comfort and capability when it comes to the technology or when it comes to the policy and the expectations?

MR. RIZK: That's a great question. That's left up to the individual practitioner in my mind. I think we can give the practitioner the data, but that relationship between me and my patients, I know them. I know exactly -- you know, for me to get my mom to do a colonoscopy is -- I might as well just send her to surgery or something. She will not have it done. So, you know, there's no policy and there's no group that could decide what is going to happen to Generation A, B, and C. I think the only thing we can do is give the data to the physician and that physician has to interact with the patient and it's -- that's where science meets art. That is exactly where science meets art, and we cannot automate the interaction between the physician and the patient. I think that's where we fall short. We can bring all the information to the physician, educate the

physician on how to make the appropriate decisions, update the physician on an ongoing basis, and then leave that interaction back to the physician and the patients.

MR. BILLINGS: I will point out that in *Star Trek*, the tricorder that Spock used, he interpreted and personalized that data for the various people on the *USS Enterprise*, and that will always be true. There will always be someone who needs to talk, personalize, deliver the information in a palatable and digestible way.

SPEAKER: It was McCoy, not Spock.

MR. BILLINGS: Oh, you're right. I'm sorry. (Laughter)

SPEAKER: I'm a Trekkie.

MR. BILLINGS: My kids would hate me for making that mistake. I'm so sorry.

MR. WEST: Now we're getting serious into the *Star Trek* part of the panel.

MR. BILLINGS: Gene Rodenberry would kill me, too, God Almighty.

MR. WEST: Over there is a question.

MR. BILLINGS: Unbelievable. Thank you.

MS. McCOLLISTER-SLIPP: Hi, I'm Anna McCollister-Slipp, a co-founder of Galileo Analytics. We're a clinical data analytics company based on Washington. And my question kind of gets back to what we were talking about just a little bit ago in terms of not just looking for -- doing post-marketing surveillance for pharmaceutical tests or other types of public health, you know, large-scale studies like, you know, the Nurses' Health Study or whatever. I'm wondering how much effort is going on currently to collect the genetic information even though we may not know exactly what kind of data we're going to have or what kind of ability we're going to have to make sense of it?

So, for instance, you know, looking -- if you do a broad-scale study on a new statin, you know, collecting the genetic information and looking in the groups of responders versus non-responders, are there any genetic correlations or significance in terms of the ability to respond to that? Because I have, you know, talked to my mother about this stuff and said, you know, they're looking at ways to be able to do this and then be able to say rather -- you know, we can try this statin and maybe that statin -- she had very dramatic problems with one particular statin -- you know, we'd be able to say, based on your genetic makeup, you're going to respond to this one, but this one's going to cause you problems and have to, you know, not go through several months of hell of trial and error. What kind of effort is being made on the part of either private sector or public sector researchers to be able to collect that information?

And I know, I mean, there are people who are actually already working on some of that stuff. We've had conversations with some people in the Scandinavian countries who are working with the same kind of technology we're using to put together those kinds of surveillance studies, but to my knowledge there's nothing that's being done yet in the United States. But I'd be happy to chat with you afterwards if you're interested.

SPEAKER: My impression is, is that in the U.S., the organization that's farthest along in that is the military. In the private sectors and academic sectors it's being done in a very preliminary, piecemeal, and patchwork fashion.

MR. RIZK: I agree. Piecemeal, sporadic, different organizations. We're collecting a whole lot of data and generally it's because a lot of payers or government ask us to come in and we have to kind of go through their entire claims data and peel back the onion to understand exactly what they're spend is and then we start to collect it and

we start to put together some sort of registry. But, you know, I think we're doing something, others are doing others, but there's no collective -- I don't know, Ed, is there a collective sharing of information? Does anybody -- everybody know Ed? I don't believe there is. Is there? Nothing.

SPEAKER: But I think a lot of trials are getting tissue specimens, though, so I think that, you know, the option of doing that is going to be available because I think, you know, tissue baking of various sorts is really out there. So I know it -- you know, the I2B2 projects at Partners now, and a lot of the clinical translational science centers, are putting a fair amount of software into matching up the symptoms and, you know, the phenotype with the genotype, so I think you're going to see a lot of that even on things like statins.

SPEAKER: I'm just wondering if that's something that would be relatively easy to dictate from a policy perspective. I mean, the FDA is already very active in determining specific protocols for pharmaceutical companies and their clinical trials. It seems like that would be a relatively -- I'm sure there's a lot more expense there than I can possibly imagine, but it would be, you know, one additional thing that they might be able to require or government research grants to be able to collect this information so that you might be able to do some, you know --

MR. BILLINGS: Well, to the extent that the payers will benefit from more selectivity of who uses drugs or who shouldn't use drugs, the FDA and the payers are aligned on that issue, aren't they?

SPEAKER: Let me answer that question by sort of speaking to the issue of making -- providing guidance and regulations too early in the technology cycle. I mean, it could be that -- actually if you look at the cost curves of generating the sequence

data and storing it, pretty soon it's going to be cheaper to regenerate it at will rather than to store the data long term. So I've seen some technology projections where you could do a genome in 15 minutes for $100 on a handheld device, and when we get to that point it's actually cheaper just to reproduce the genomic information rather than store it in a databank. So, at that point it's like, you know, an instant strep test. I mean, you'd just do it in real time every time.

SPEAKER: We're a ways from that.

MR. WEST: Okay. Any other questions?

Okay, if not, I think the take-home message that I have gotten out of this panel is we have great opportunities in terms of personalized medicine and health information technology, but we do need to make progress in several areas in terms of building the infrastructure and the data sharing networks, making some changes in reimbursement policies, especially as it relates to new codes that provide more nuance and more information, thinking about how to balance privacy on the one hand versus innovation on the other, and data sharing and connectivity, ways to incorporate rapid learning feedback mechanisms so the physicians have the most up-to-date information and then some predictive modeling decision tree help that will help physicians manage the flow of information that is coming their way.

So, I want to thank Mark, Don, Paul, and Emad for sharing their views with us, and thank you very much for coming out to Brookings. (Applause)

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I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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