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Session III: Sentinel as a National Resource for Evidence Development:

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P R O C E E D I N G S

DR. McCLELLAN: All right, so, I'd like to ask everyone to take their seats. We're going to get started right away.

We have a lot to discuss. And I especially want to thank all of our panelists for this panel, and everyone has a busy schedule, but these people really do, and for our last session today on Sentinel as a Natural Resource and Sentinel fitting into a broader set of approaches to develop better evidence in the United States. We're going to look beyond medical product safety surveillance to think about ways to coordinate what Sentinel is doing and what FDA's post-market safety activities are undertaking with other ongoing evidence development initiatives.

And I know earlier in our previous discussions, we identified a number of significant issues and challenges: methodologic, resource related, infrastructure related, communication related, and so forth. So, certainly, there are some real challenges here, but I think something that's very important to recognize is that a lot of other issues and a lot of other areas where we are trying to develop better evidence, whether it's on quality of care or comparative effectiveness or other topics are facing some of the same challenges. So, thinking about all of these issues in a broader context is very important and we've got a number of people here on this panel that can provide a range of those perspectives.

We'll be hearing first from Janet Woodcock, the director for the Center for Drug Evaluation and Research at FDA.

And then Sherry Glied, the assistant secretary for Planning and Evaluation at the U.S. Department of Health and Human Services, and there, ASPE is very much involved in some of the strategic thinking at HHS on developing better evidence and the range of different data resources available and methodologic resources to bring to bear on that challenge.

And then my friend, David Blumenthal, the national coordinator for Health Information Technology at HHS. ONC has been very much involved in leading some of these major steps to support better information systems for evidence on safety and many of these other areas, as well.

And then we're going to hear from a couple of private sector leaders. Sam Nussbaum is the executive vice president for Clinical Health Policy and the chief medical officer at Wellpoint. You've heard from Sam briefly earlier, and, as you know, they are one of the major participants in the Sentinel Initiative.

And Reed Tuckson, the executive vice president and chief of Medical Affairs for United Health Group, oversees many of United's strategic leadership initiatives related to improving quality of care, improving evidence, and other related areas, as well.

So, it's a terrific panel, and, once again, I have the same format with some initial opening comments from each of our speakers, and then you all should be ready for comments and questions to continue that dialogue.

So, let me get started with turning to Janet.

DR. WOODCOCK: All right, so, I'm going to make a few brief remarks about where we are now and how this might fit into a broader scope of evidence development from electronic health records.

So, what we've been talking about in Sentinel is, of course, medical product safety surveillance through the Food and Drug Administration, through our coordinating center at Harvard Pilgrim, and there is a circle in the center of this diagram. And I think this circle is important because really the data partners have to be central to this whole enterprise because they are not only the folks who have the patients, they're the folks who need the information to deliver the best care.

And, so, while the Food and Drug Administration and other folks who might use these data are important, the real key should be driven by those who have the data and those who have the patients and those who represent patient and provider communities. So, they're in this center of this, and, of course, there are also payers who have data and other groups that have data, and there are registries out there, and within this circle, it shows that from the analytic perspective, we're trying to unite this in some way using a common data model. And I think that's been talked about this morning; that's how you can do queries.

Now, of course this isn't the only use of these data, and what we've heard and

we can maybe hear a little bit from some of the folks representing health care systems is that they are viewed as the repository by everyone of the data. So, this data might be used for medical product safety surveillance, it might be used for quality, it might be used for many other things, and, so, they have many people coming at them asking for the use of this data.

And another area related to medical product safety surveillance is that there are many sponsors and other researchers and private parties who are interested in medical product safety who are not going through the Sentinel, not through the Food and Drug Administration arrangement, but also want to do the same kind of queries and get the results for their purposes, but from the same data sources, the people in the center of this diagram. All right, so, one thought that we've had is can we have more a public-private partnership that would also enable this type of activity utilizing the same infrastructure because don't forget the people in the center of this diagram, do they want to have 7 common data models and 12 different infrastructures to offer these data for different sources?

So, that raises the question, if we move on, what's the potential future scope of using secondary electronic health information generally? All right, and it isn't just medical product safety. How about on the other side of the diagram, quality of care? The data that would be accessed from these data partners, registries, payers, is the same kind of data, and should they have another several sets of common data models for that use of the data?

And then public health surveillance, there are many, many issues that people want to look at this type of data for public health purposes that is separate from medical product safety, and, again, the same group of people may be asked to contribute data to that use.

And, finally, there's great interest in biomedical research, identifying and accessing patients with particular conditions or whatever based on this electronic health data, which is a lot more efficient probably than trying to recruit them in one or two medical centers in the United States to find these people to identify them and recruit them into studies or what have you. Again, it's really the same type of data that we're talking about, probably not just the claims data, but the extended health record data put into some type of query-able form that would be used here.

So, and then at the very bottom, a lot of people are initiating comparative effectiveness research on electronic data that, again, the source of those data would be to providers, the registries, the payers, and so forth. And, so, we are hoping that we're building Sentinel, but if you see the larger circle around this, which it says "distributed network governance," we're hoping that whoever comes together for whatever purposes of use of electronic data, we could build a common infrastructure. I think the Office of the National Coordinator is building the existence of that electronic data, which doesn't exist to the extent that it needs to exist now. They're also building some of the interfaces and interchanges so that the data is easily exchangeable, but these uses of data are analytic uses, secondary uses where you have to do analyses.

So, they're extremely common, and I would be very interested to hear from the folks on the panel who, in fact, represent a health care systems or payers and so forth about how all this could come together. I think this is one way that it could come together that those who have the data, the data partners, could actually represent a distributed network that could have governance, could have common data standards, and would kind of be the interface between all this data that's out there and all these different analytical needs that exist for secondary electronic health information and the use of it.

And we feel that in Sentinel, we're moving ahead on our part of this, which is simply the medical product safety, but we're certainly more than willing to only be a node on this larger network that we would foresee existing in the future for analysis and advancing public health in general.

Thank you. (Applause)

DR. GLIED: I can stand because I don't have any slides. So, what I want to talk about today is an initiative at ASPE in my office that is kind of complimentary to the Sentinel Initiative, which is ASPE's Multi Payer Claims Database, MPCD. And also to talk about how Sentinel and the Multi Payer Claims Database fit into the overall HHS data strategy, which we're continuing to develop.

I want to start off by talking a little bit about this ASPE project, the Multi Payer

Claims Database, and to talk about some technical aspects of that database, which I think complement a lot of the discussion around Sentinel, and then conclude by talking more broadly.

So, our Multi Payer Claims Database was established as part of the Recovery Act, and was intended as part of its investment in the infrastructure around comparative effectiveness research. That kind of research is going to require the development and expansion and use of many different kinds of data sources and methods, and this Multi Payer Claims Database is intended really as a pilot project to think about where we can go with that kind of infrastructure development.

The project began just now in January. It's supposed to run for 33 months. And we're working to build the database that incorporates data from many different types of health insurance plans, and includes as many people as possible so we can conduct comparative effectiveness style research on multiple priority populations, on multiple interventions, and many kinds of conditions.

The MPCD is going to be implemented as a hybrid architecture, so, it's going to incorporate both a central warehouse and the kind of distributed data network that you see in Sentinel. There will be like in Sentinel a central coordinating center that will perform the function of taking requests from researchers, querying different data partners, consolidating results, and delivering them back to researchers. The central warehouse is going to include from CMS. We are still working out exactly what data that will be, and private plan data, which are contractors, are going to de-identify so that they can be put into the central warehouse. That warehouse is going to be supplemented with a distributed data network. The network will include several private sector health insurance plans and possibly also some providers who voluntarily choose to participate, and as in the Sentinel Project, they would allow their data to be accessed from behind firewalls so that they can retain control of their data and privacy concerns can be addressed.

We're also collaborating very closely with ongoing state efforts to maintain and develop state all payer claims databases and the distributing network is intended to also include data from those systems.

As in Sentinel, the coordinating center is going to query the distributed network

with one set of programming code, get the results from multiple partners, pull them together, and send them to requesting researchers.

There are a couple of innovative features in this design that I think I want to emphasize. I think one important feature is that it's going to incorporate analytic tools that allows researchers to perform preliminary analyses before they actually have to make full data requests, and the hope is that that will allow us to really tailor the data that people need and make the request happen quicker, so, on a faster timeline.

Another key feature is that we intend to lay the foundation to incorporate clinical data in the database into the future. That should make the database much more useful for doing clinical types of comparative effectiveness research.

Very clearly, there are some important design and methodological overlaps between the Sentinel Project and this project. But their missions are different in intention. So, the Sentinel Project's mission will concede for the primary application of drug and device safety surveillance, really resonates with the comparative effectiveness theme, and we can imagine that there are comparative effectiveness research questions especially around drug and device choices, but which the Sentinel Network would be ideally suited.

In parallel, the Multi Payer Claims Database, which was built to contribute to data infrastructure development for comparative effectiveness research, will also likely be valuable for additional applications, including safety surveillance, delivery system research, and so forth.

So, we're actively exploring synergies between the two projects, particularly by way of the Mini Sentinel Pilot Project. We're looking into ways that we could utilize the same data network infrastructure, including overall design, design platform, the way communication occurs, the format for data so that requests will be coordinated and we don't have to bother our data partners unnecessarily.

We also hope to coordinate outreach to new data partners to minimize the cost they face in participating. Based on feedback, we are really designing this network to be very cognizant of what our partners need in order to participate.

Going forward, we also see that future investments would be made in the context

of both initiatives. For example, both initiatives are aiming to capture clinical data as they evolve, and, so, we are going to be working together to make sure that we can facilitate the process for doing that.

One idea that we've been developing is at the Multi Payer Claims Database, and Mini Sentinel could each be a node on each other's distributed network. That would mean that they would overlap, we'd get the full richness of both efforts, and they could serve as a portal to access of complementary set of data sources.

In collaboration with the Sentinel Project, we're working closely with other divisions, particularly with CMS, but not exclusively so, to determine how the Multi Payer Claims Database can potentially support other comparative effectiveness work and other affordable Care Act initiatives and other data strategy initiatives across HHS. In particular, HHS is really committed to a new initiative that's focused on data transparency, on getting data out to researchers in a variety of ways, and we're charged in the Affordable Care Act with releasing a great deal more data that we have in the past. We're trying to see whether this Multi Payer Claims Database and other similar initiatives are a way to meet those needs.

For example, we're working to create virtual research data centers that will allow use of data without possession of the data so the privacy is protected and to disseminate additional public use files, which are files that are stripped of identifiers so that they can be used with virtually no privacy risk. We're exploring how the Multi Payer Claims Database and other initiatives like Sentinel can help support CMS initiatives around performance measurement, reducing readmission rates, and other delivery system reforms. We're also developing an HHS-wide data strategy that will think about how to incorporate ideas like the Multi Payer Claims Database and Sentinel and the new electronic health records that we hope will be coming online soon within a coherent framework in conjunction with existing HHS data surveys.

So, HHS has a long history of doing utilization surveys, provider surveys, and so on, and in this new era of a lot of claims data and electronic data coming online, it's really important for us to explore what is the place of surveys, what is the place of claims data, what is the place of clinical data in constructing a picture of the health care system and enabling policy

reforms going forward, and that's one of the big efforts that we're doing within the department.

Overall, a key departmental strategy which I think is evident in both the Multi Payer Claims Data and in Sentinel and so on is to think about how to best use new methods, advances in data storage and computation, in protecting privacy, and increasing availability of data just as more of this goes online to learn more from the health system all around us and to put that learning to work in the service of our programs. Together, these initiatives form an important part of the new research data infrastructure at HHS. (Applause)

DR. BLUMENTHAL: Well, good afternoon. It's great to be here. I want to thank Mark for his continuing efforts to explore opportunities to use information better to serve the health care system and Brookings and the Engelberg Center, and FDA for the leadership it's showing in this Mini Sentinel Network, which is an example of exactly the kind of use of electronic information that the Office of the National Coordinator, my office, is charged ultimately with promoting, and, of course, they are way out ahead taking advantage of existing electronic sources of information.

This conference focuses primarily on what are called in the lingo secondary uses of electronic health care information, and that may lead you to ask the question: So, what are the primary uses? And the primary uses are one of the Office of the National Coordinator's primary charges. We are not without responsibility for encouraging the secondary uses. In fact, that's very much on our radar screen, and we're very committed to it. But when the Congress created the Health Information Technology for Economic and Clinical Health, or HITECH Act, in 2009, they charged the Office of the National Coordinator with creating a nationwide, interoperable, private and secure electronic health information system. And just a modest charge. (Laughter) And first and foremost, working with CMS, they charged us with getting the nation's doctors, hospitals, and other health professionals to be meaningful users of electronic health records.

In a very basic way, our job is to make your health care better by giving you access to the benefits of the most modern information technologies in a private and secure manner when you go and see your health care professionals every day and when your families do the same thing. So, we are very focused on quality of care, improving the efficiency of care in

the personal health care system, but we want to do that in a way that enables any information harvested for those purposes, collected for those purposes, to be used for the kinds of initiatives that the Mini Sentinel and the Multi Claims Database make possible.

We have a huge number of programs -- not huge, but a substantial number of programs that are aimed at helping solo practice physicians, for example, in rural areas get to meaningful use of electronic health records. Ten and twenty-bed hospitals in rural areas get to the meaningful use of electronic health records. And, also, of course, larger practices and larger organizations. But we are also very much focused as part of that on making it possible for the information that enters their records to become electronic to be available for exchange across practices, across institutions, and ultimately in the process of exchange to become accessible for these other very important uses, the so-called secondary uses.

So, we actually are also spending a great deal of effort, increasing amount of effort on what's called exchange and also which requires something called interoperability, meaning that when data moves, it can be received and interpreted and incorporated into the next electronic modality so that when your cardiologist needs to communicate with your primary care physician, that can all take place electronically without any paper being involved. Or when the hospital, when your primary care physician wants to get access to the results of the test that you received at your hospital when you were hospitalized, that that can all happen electronically.

Once you begin to mobilize data in that way, you can technically if the standards are clear enough and the definitions are clear enough, the vocabularies are clear enough, you can begin to tap that data for so-called "secondary uses."

Now, we are involving lots of groups in that process. For example, we have given grants to all the states and territories to enlist their support in creating the infrastructure for health information exchange. We have set standards for electronic health records to encourage interoperability so that they use the same words for the same things that you can identify data in their records to pull it out, and we have also developed a process for certifying electronic health records to make sure they actually incorporate those standards before they are marketed. And

we've already certified over 230 electronic health records and modules to see that they can form to the standards that we've adopted by regulation.

The other thing that we've paid a lot of attention to is the privacy and security of information, and we have several federal advisory committees that has given us enormous assistance, and they are helping us right now with defining how do we protect, what policies are necessary with respect to patient information, with respect to security so that when information starts to flow in the health care system in the primary use, it can also be made available in a private and secure way for secondary uses.

Recently, the President's Council Advisors on Science and Technology, so-called PCAST, made a series of recommendations to us on this subject which we are actively pursuing and could play an important role in making this exchange of information more widely prevalent.

One of the things that we have to manage in this process, and I think it's an underlying theme for all of the work today, is the question of whose interest is it to create these data sources and to then use them. The fact of the matter is that for the local doctor and the local hospital, the local nurse, there often is no reward at all and considerable costs for putting data into electronic form and them exchanging it. That is a fundamental obstacle to everything that we are talking about today, and an obstacle that we have to solve as a society before we can realize the lofty ambitions that we're talking about.

What I like to say is that information exchange is a team sport, and you can be the best exchanger, you can be the Peyton Manning or the Tom Brady of information exchange, but if there's no one down the field to catch the information when you're passing it, you might as well hang up your cleats. We need teams, and those teams have to be nit together by business cases, by collaborative cases, by policy as communities to become nodes on this network that we're talking about. We do have responsibility speaking to the slide that Janet showed; we do have responsibility for creating the governance of the something called the Nationwide Health Information Network. We are responsible for creating a network and for creating a governance mechanism for it, and we are working right now on that process. So, I hope that we'll be able to work with Janet and other colleagues both in the private sector and the public sector to work

through that governance mechanism. The idea of distributed databases is very much on our mind, and it's good to hear that these are actually being made to work in real experiments.

There are huge technical and policy problems to overcome, but I have no doubt that we will get there, but it will require the collective activity of both public and private actors and it will require motivation to overcome those problems. And one of the things that I think we are going to have to work on very conscientiously is defining the business case that will result in the liquid information, the available information that the Mini Sentinel Network is taking advantage of and that all of us wish to have available so that our health care system can be improved.

Thanks very much for your attention. (Applause)

DR. NUSSBAUM: And it's really wonderful and energizing to be here and see all of us working together to begin to improve the quality of health care and what clearly needs to be a transformation of our health care system and the early and what we envision will be highly successful use of data models.

Wellpoint and its subsidiary health corps are really proud to be a key partner in the Mini Safety Sentinel Initiative. We're deeply committed to working with federal agencies, particularly the FDA and CDC, with whom we're working, to improve health care for the American people. Why? If we look at our own footprint, we have 14 Blue Cross Blue Shield plans, we cover more than 33 million Americans, that's 1 in 9, we work closely with the Blue's Association that has about 100 million Americans, so, that's 1 in 3, and it's that scope and breadth of the data, some of which has been talked about today, that gives us both the capability of working with partners and the responsibility to improve the quality and safety of health care for our nation.

And health plans today have critical needs that are not being met with knowledge. We have need for evidence, need for real world information to make decisions regarding medical and drug therapies, but also what are the best approaches to care for clinical conditions? We also need to extend the observations that you heard about today in drug safety to comparative effectiveness research. Janet, you've mentioned that, and Sherry and David. That's really essential to go beyond where we are.

So, I'd like to briefly mention three themes. The first theme, which has been the

focus of today, is the data environment; the second is a commitment of health plans to advance knowledge of what works in health care. Health plans haven't always taken that as a very meaningful commitment, but it is, and it needs to be. And it's also to collaborate with government, with industry, and with academic partners to achieve those goals.

So, let's first talk about the environment. We've advocated for not only collaboration, but a federal data environment model for Sentinel, and we strongly supported that type of model to advance comparative effectiveness research.

There's another great example that I know people alluded to today, and that's been the Vaccine Safety Data Link Project managed by Centers for Disease Control and Prevention, and that is giving our nation very important information on vaccine safety. So, why this federated model? Why have we moved there first? And it's really because each research environment and each research organization knows its source, knows how to manage that data and its complex systems, knows the apparent and then often the not apparent confounding factors, and has the ability not only to know how that data environment is managed, but if we need additional information, how to go to it, whether it's chart review, whether it's physician and hospital partners. So, it's really improving the utility and reliability of data.

The other issues that I think particularly in our political environment is that the federated data remaining local to the environment in which it's generated really allows a greater security than perhaps other models.

The third theme of this is, by its very nature, the collaboratives that have been described, and Mini Sentinel's a perfect example, is it maximizes the impact of a shared learning environment, and it's really as much the contributions of the data partners, the intellectual contributions, as it is the specific data that's going to advance foundational knowledge. So, it's the experience, it's the environment, it's the confidence in the data, and also the collaboration of federated partners. And we've been working in our company for over a decade to do a clinical outcomes and comparative effectiveness and safety outcomes.

And, so, what have we learned from that? First, we've learned that claims data is valuable for a number of initiatives, but not for all initiatives. So, we've been developing over the

last several years what we call an Integrated Research Network. We have about 4,000 hospitals and doctors now participating, and this enables us to perform much more robust research to use information, gather the point of care. David, to use the medical record infrastructure that is being built through your leadership. And, so, that's one way of actually taking this claims database and enhancing it.

So, we've got three projects underway in that area, we're working, again, with Harvard and Brigham and Women's Hospital and University of Pennsylvania, North Carolina, and a whole host of academic partners, including Indiana University and others.

The other theme of how can we make a difference in research is to collaborate with others. We're part of three; decide networks in the ARC sphere of accountability and influence. And that's the way we're going to get answers.

So, let me give you two specific examples of how we can get answers. I mentioned an earlier example of how we manage the COX-2 inhibitors, but when we looked at childhood asthma, we found that there were drugs that are least preferred or less preferred in any of the clinical guidelines, the clinical pathways for asthma, yet we found that the use of these drugs actually lead to reduced emergency room usage and reduced hospitalization when compared to the more generally appropriate beta agonist bronchodilators and inhaled steroids. So, what we did is what that information, which is published and which involved a lot of collaboration of asthma experts across the country, but we actually took this drug and moved it to a preferred tier, even though most health plans would not prefer it as therapy.

Back pain. It's ubiquitous. One in three of us experience it, we spend more money on back pain than other illnesses, but we look at over two hundred thousand of our members and saw how back pain was being managed. How within six weeks of non-neurologically sort of impaired back pain within six weeks. People were actually having thousands of surgeries, getting tens of thousands of MRIs, care that none of us would embrace, and we took that information and worked with the American Academy of Family Practice to develop some programs and also with Dartmouth Hitchcock in terms of evidence-based care.

Another initiative that is not only based on data, but on using this information a

far broader way is the work that we've done with the Indiana Health and Information Exchange, and Marc Overhage is in the audience, but with IHIE, Indiana Health and Information Exchange, we are part of what's called Quality Health First, and this is an initiative where all of the data from our health plan and others working with doctors and hospitals that generally are competitors in the environment drove a dramatic increases in quality. So, we took all of the information that we had, we measure a whole array of quality programs, we pay differentially for performance in these quality areas, and have made an impressive improvement in quality of care in Indiana. So, we were able to take and leverage the about $4 million investment that we made and improve quality to see scores dramatically improve on 10 clinical measures.

So, in closing, I believe that we have an opportunity based on the models that have been presented, collaboration that we can build, knowledge that we can gain together to significantly enhance and expand programs that drive quality and affordability of care. This is the power of the Sentinel System, this is the power of all of us working together, and we look forward to sort of harvesting the fruits of this work and working with all of you to continue to advance and improve health care.

Thank you. (Applause)

DR. TUCKSON: It's a great pleasure to be with you. I share my comments from the perspective of a Fortune 25 Health and Wellbeing Company that has a leadership position in the commercial Medicare and Medicaid and individual health benefits businesses, but also we are in GENEX, the largest data and analytics company. We offer our own electronic health record. We are engaged also extensively in the health information exchange business, and we look at this very broadly, and it is obviously exciting to us that this much progress is being made.

And what we also encourage as we experience this meeting is how thoughtful you are at being able to bring the necessary stakeholders together to think responsibility. We touch 650,000 physicians and other health professionals, 5,000 hospitals, so, we have a sense of scale, but we are really driven here and excited about is the importance of being able to meaningfully and responsibly improve the quality, the safety, the appropriateness and the cost effectiveness of the delivery system. I think you understand that we are at the tipping point, that

no way can we possibly afford the escalation in health care costs, especially given the drivers which are in the physician and hospital delivered care environment along with the fueling of technology and pharmaceutical innovation. This is where the issues are, this is where the problem is.

We have a gazillion people with preventable chronic illness who are being delivered into the hands of a delivery system that is more than prepared to continue to skyrocket costs out. So, if there's going to be something new, it had damn sure better work. (Laughter) It had better be cost effective, and we had doggone be sure that we can control how those things are distributed and disseminated through the delivery system.

We are interested in any ability to advance multi-payer data sources augmented by others to define and facilitate access to quality and/or the absence therein. We are very interested in having data and information to give feedback to the delivery system so it can ramp up its performance. We absolutely need to have data to be able to influence as we discussed in the previous panel patient choices and decisions. People have got to know what they should appropriately personally get access to and evenly what they stay away from, the good news and the bad news.

There are a gazillion people who are trying to these kinds of things. Good news and bad news. More than 100 requests on my desk right now. Please participate in data analytic, data aggregation activity for regional, statewide, or intrastate initiatives. Voluntary and mandatory. There's an HIE, there's a RHIO, there's Aligning Forces for Quality, there's the Beacon, there's the public surveillance and research, there's the regulatory activities, they're the primary care medical home and the accountable care organization demos. We love them all. (Laughter) They all cost money. Data is expensive. There are fees to participate and fees and costs to massage the data.

So, I love this meeting because you are saying we get it, we get it, we're not going to be crazy, we're not going to be irresponsible. We're actually going to all work together. Well, you better, because this has no chance to succeed whatsoever. None, if you don't. The data content elements, the data extraction formats, the data aggregation techniques, the files and

layouts and the formats, the structural measures for which you're going to evaluate quality and costs and whether or not it was a good outcome, all of these have to come together because, if you don't, it undermines the value proposition. Who in the world can develop a value proposition to scale this beyond the mini to the maxi if you don't do that? So, you have to line it up.

Because we have to be very serious about our responsibility to act on behalf of the people whose money we spend to access expensive health care assets, we have to think about these things from a couple of perspectives. Number one, the governance we talked about. Is it efficient? Please don't give us bureaucratic governances that make things tough. Are the people in the governance the right people? Do you have all those stakeholders at the table? And, above all, in that governance, is there accountability for the use of resources? You cannot imagine how many people get excited about ooh, ooh, let's do this. We're going to have a party. Mickey Rooney. Everybody's together. (Laughter) Are the responsibility of governance there?

Number two, the funding. What are the fees, what are the data management costs and are we keeping it to a minimum?

Number three, sustainability from a funding perspective over time or scalability, which you all obviously are, so, that's terrific.

Likelihood that it will get to the key quality and cost drivers. Everything isn't important. Knowing everything is not hey, did it decrease in emergency room visits? Did it decrease preventable hospitalizations? Did it decrease lengths of stay? Did it decrease readmissions back to the hospital? Now you're talking because that's what America needs. American citizens demand it. They can't pay for the rest of this stuff, so, it's got to zero in, it's got to be relevant. Everything isn't equally important.

And then you have to make sure things like new specialty drugs and new specialty pharma, and then there are the devices. So, if you contribute data, what do you get? If you don't contribute, what do you get? Data costs money. So, you got to level the playing field. You connect with registries, and what will the registries tell us? I want to know did that device by that company kill off my customer. Because I want to tell the rest of my customers please avoid that device. If it doesn't do this, what are we doing?

So, let's get specific. Can we get real? We have to be able to make it -- patients deserve real information to make real choices in real time about their health. We owe it to them, and I'm not going to be shy about asking for it.

And then we have to population specificity. Which people were supposed to get the thing? Did the bad outcomes occur? For what reason? So, I really want to know did the bad outcomes occur because the doc was no good. Technique was lousy? Bad patient choice? Didn't use it according to the prescribed mechanisms? Did the patient screw it up? Took it all kind of weird times in the day? Ate it with orange juice? (Laughter) I want to know whether or not it was -- and then I want to know about the outliers. I want to know whether or not the -- I want to know about early adopters. Hey, look, early adopters, now we know right at the point early on, hey, what happened? Is it just that you all were crazy over here, medical center number three, that we need to be able to drill in and understand? So, we want to be able to get at that.

And then, finally, I really want to emphasize this notion about getting to the patient-centered choices and decisions, and I'm glad that my colleague, Sam, talked about that because he's really, really right on. We get to have these conversations with people. Most people who think about health companies, most people do not take the time to understand what it is that we do. Somehow though you think we just pay claims in the back room and that's about the end of it. Now, thousands and thousands of people get talked to all day every day using every new technological device known to man to have a conversation about quality, about patient choice and decision-making. And, so, it is important for us to be able to take our capabilities and to describe that.

And, last, I'm really, really excited about preparative effectiveness research. We can't pay for crappy stuff. (Laughter) Doesn't work, not better than placebo, I could care less. That's the FDA, you all do that. (Laughter) Does it work better than the what we have now, from a total cost of care perspective, and then does it work better? Economically justify the economics of it.

Now, by the way, just so we make it clear, it makes me crazy. You're going to kill grandma if you know that it costs a lot of money. Like there's a business model that says hmm,

I'm going to really make sure that she gets sick and dies because the drug was expensive. (Laughter) You see, now, how is that supposed to work?

My point is that we give away expensive stuff. You got leukemia and you need the lead drug for Philadelphia Chromosome-Based Leukemia, hey, it's like fluoride, take it, please. It's expensive as hell, but total cost of care drives it all down. So, that's just dumb.

But what I really worry about is promising but unproven treatments because this is where the action really is going to be. There are so many new things coming down the road for which we cannot do traditional clinical trials. And you're going to have to have some other ways of assessing it. There are going to be a lot of patients who are not going to get access to promising things that the FDA says is cool but that is unproven ultimately in the way in which we would normally want. And, so, I think this process is going to be very important at giving us some opportunities to go after that.

So, I think this CER thing is hugely important to this. At the end of the day, ladies and gentlemen, we're excited about it; we think this is very important. I think you're doing all the right stuff, but above all, just don't screw it up. (Laughter and applause)

DR. McCLELLAN: Thanks. Now I'd like to open up the session for a discussion. So, again, as usual, if you have a question or comment, please go to the microphone, identify who you are.

While we're getting started on that, let me ask any, particularly the earlier panelists if they have any additional comments or reactions to what they're heard.

Go ahead, Janet.

DR. WOODCOCK: I'd like to say a couple more things about how I think we could move forward in constructing this.

Yesterday, we had a meeting of the OMAP, the Observational Medical Outcomes Pilot, where we presented a very large body of methodologic research on how to do these things, and I think going forward, the diagrams I showed, we need to have a very well-funded and vigorous research arm because I think we don't know how necessarily to do this yet and reach actionable conclusions which is what Reed is asking us to have, and I think we all agree --

DR. TUCKSON: Really? (Laughter)

DR. WOODCOCK: We want actionable findings, okay? Not more research is needed for the next 10 years. We want things, what we can make decisions on, decisions about care, decisions about patient safety and so forth.

And the second thing, I want to ask David about this. David, it seems to me that the Health Exchange Information Networks, of course, that's really needed because, for one patient, we lose all their data if the data is not linked to patient, we don't have good longitudinal data and we don't have data about say a patient has to go to the emergency room and then we lose that data somehow. But it seems to me that the network I was talking about is kind of like a metadata or whatever, it's on top of the primary. The primary is here, and the Health Information Exchanges are here with the primary data.

And then there's another different level for the secondary data, which is analytic type, and that's where I think we need a governance for that. You need a governance for Health Information Exchange and how that is done, but we also need a governance for how we're all going to access these secondary data. And I think the two are somewhat slightly different. There need to be, obviously, closely coordinated, but the idea of the secondary use is somewhat conceptually different, I think, than the primary information exchange. But maybe I'm wrong.

DR. BLUMENTHAL: Well, I don't think they're as far apart as you think if you have Distributed Data Network because you've described the Sentinel Network as a Distributed Data Network involving a fairly small number of data sources. I don't know what the exact number is. Richard can tell us. But let's say it's 20 or so. We're talking about the opportunity to create a Distributed Data Network with hundreds of sources, where the data resides in the local records of practices. The Marshfield Clinic or the 20-member group, or even a solo practice.

DR. WOODCOCK: Right.

DR. BLUMENTHAL: Because the patient populations are different and you want a representative information source. So, the rules that govern access to that information and the governance that creates those rules is going to be very, very closely linked and integral to what the uses of the data are. So, when the data request goes out to study a drug and a side effect

and you want to send queries out to hundreds of practices, thousands of practices, hundreds of hospitals, you are going to have to involve the folks who manage the exchange of information. So, I don't see the clear distinction. I mean, if there were a central database.

DR. WOODCOCK: Right.

DR. BLUMENTHAL: Then there might be a clear distinction, but we've already talked about the fact that we're dealing with distributed data, which I agree totally with because the critical underpinning for this enterprise is trust by the consumer and the patient in how the data is stewarded, and the closer you keep that to the people they trust, their physicians, their hospitals, the more trust you will have the in the secondary uses.

DR. WOODCOCK: Right. Well, I agree with that, but let me just say that you heard from both Reed, I think, and Sam that maybe sometime in the future what you envision will happen, but, right now, there's work involved in making these data available for analytic purposes, and we found that's one of the most important steps is that the custodians of the data are going to have to do additional work on the data to make it analyzable by the queries, and, right now at least, maybe they'll be cooperatives and so forth, but we couldn't reach into an individual health record or whatever because those data would not be -- and I know you're working on that. We'd be able to exchange the data, but I'm not sure we would know the data were usable. And some time in the future what you envision may happen, but I don't know when that would be.

DR. BLUMENTHAL: Well, I think there's going to be a transitional phase, and in the meantime, you clearly may need to have pockets pilots of the type that you're discussing. But I think to expand this to an industrial strength search and query capability will require a whole infrastructure that goes by the name of the Nationwide Health Information Infrastructure that under conditions of trust and interoperability enable the widespread search of information.

Now, there may be other interim solutions and also spin-off solutions. It doesn't have to be a uniform system. If there are networks of plans that have decided they can do this independently with their own resources and their own governance structure, there's nothing to prevent that from happening.

DR. McCLELLAN: So, I'll ask if any of the other panelists want to comment on this topic. It's a pretty important one. Any others?

SPEAKER: Mark, the only comment I want to make and I think there are schools of thought, but to emphasize what Reed said is today, we are being asked by many states that are developing their own state claims and databases, we're being asked by many different resources, the large employer and others, and while the good news is that we tend to follow common formats increasingly for data, we're tending to look at measures that are NQF and otherwise endorsed by professorial societies. All of that is positive, but the Herculean effort of trying to respond to every one of these initiatives, some of which were mentioned, really actually takes away from the capability and the investment to manage and analyze the data and make it meaningful.

So, I think, David, what my concern is that during this what you call transition interval is that how do we manage from these 1,000 points of light that are being created because they're not only light, but certainly costs and redeployment of investment and duplicate of function, and that's not going to really work at a time we're trying to get information more quickly and better managed cost.

DR. TUCKSON: So, let me just piggyback on my friend here. I think that what we're got to really understand as we listen to David, David is in an extraordinarily difficult position. Now, let's just be real clear. (Laughter)

DR. McCLELLAN: Congratulations.

DR. BLUMENTHAL: It's getting more difficult by the moment though. (Laughter)

SPEAKER: Reed, David had $40 billion. Most of us would love to be in that position. (Laughter)

DR. TUCKSON: Yes, by the immunizing effect of money does not protect you from the challenges of politics, and what David has to deal with is a physician and hospital community that is very anxious and concerned about every step that he takes. And he can't say it, so, I'll just say it and he'll look and pass it. (Laughter) And, so, when he tries to advance real movement in this space, he comes up against very strong folks, and I'm not saying that they're

concerns are not legitimate.

Let me be clear, I'm trying to be very neutral on that, but he comes against people who have concerns. So, the point being is that what at least is encouraging for us on this end of the table is the fact that we have the data there combined with we have a Don Berwick at CMS, and they actually happen to know each other. We actually are pleased that there is a Sherry who happens to apparently know both Don and David. (Laughter) What we have to do outside of government is to create an unassailable environment where they are facilitated, encouraged, and protected to come together. Right now, they aren't where they need to be, and what we have to be mature enough is to understand why they can't move in lockstep together and what it is that we can do to help immunize them so that they can't. And they are in a crappy position because they can't talk about it. (Laughter)

So, my last comment on this is that David is right; you have to got to get it right. Of course, everybody wants to have the protection so that the patient if you don't get the trust right, you are done. All that's right. But this interim period can't be but so long because the world is spinning and spinning, and there are consequences to those spins. So, what we have to do is help them to be able to give us the leadership that they're trying to do and overcome the hurdles that they're up against.

DR. McCLELLAN: All right, I have one follow-up, and let's assume that we get through the short-term issues to get to David's model. And I can see how this governance is going to take -- and this is in the PCAST Report and all, too, but take quality measurement for these individual providers and groups that are now going to be sharing interchangeable data, if we get there sooner rather than later because all these efforts are going to be successful. You can see a mechanism for making that sustainable, that because they're going to be paid and because they're going to be reporting on quality, they'll have some built in incentives, and hopefully to get to Reed's point, some real standards for what those secondary use quality performance measures would be.

And there's a foundation of NQF endorsement. I would say, as Sam and Reed know, that NFQ endorsement by itself doesn't necessarily solve anything like all your operational

problems for turning the data that you have electronically into comparable, meaningful measures. There's still a lot more work to do there, but let's say we get over that. There is a financing mechanism and presumably a governance that go along with it that look; these are the quality measures that are going to be reported. It's less clear, perhaps, or at least it's different, how it might be sustained with some of the safety uses and some of these other uses where there aren't going to be payers like Reed and Sam, I think, who are going to be paying directly based on some of these safety measures. I mean, this is much more of a public good. It's something that's going to provide some value for everyone.

And getting back to Reed's question, what do I get if I do provide a data, what do I get if I don't? Well, whatever comes out of these safety studies or comparative effective studies is going to be much more global. It's going to be information, evidence that's available and relevant to everyone. So, it does seem like even if there's one kind of governance that applies to all this or one kind of infrastructure that applies to all of this, someone else or someone is going to have to do some additional work on what the standards are for reporting that information and providing some kind of financial incentives or sustainability incentives for supporting it that's seems quite different from some of the other applications.

And I wonder if that sort of gets to the point that I think Sherry and Janet were making about different nodes, perhaps, on top of a core infrastructure. I just want to make sure that I'm thinking about this in a meaningful way, and, if so, what does that mean as we get towards this longer run? What's it going to look like and what does that mean for what we do now?

DR. WOODCOCK: Well, I think in some ways, this information for some of those nodes, if you would accept the diagram I put forth, is valuable enough that various stakeholders could band together to help support the generation cleaning, maintenance, standardization, movement to a common data model, and so forth that are required for those data elements so that say for research purposes, for perhaps pharmaceutical and device safety, and perhaps we don't have to set up independent registries. Perhaps once we have the longitudinal capability that David's talking about, we can follow these patients through their career of their implant or

whatever, but that's valuable and that should be supported by various stakeholders who have a stake in finding out that information.

So, I think that's one of the reasons I'm advocating for some commonality in the infrastructure so that there's an opportunity for everybody who's going to benefit from this to actually contribute to it, to make it happen, and that'll make it happen, I think, faster.

DR. GLIED: I think we're also thinking a little bit about how these kinds of data could be useful to participants in the various distributed data networks. Can we develop mechanisms for benchmarking your performance that allow people who participate to get something more out of it than those who don't? So, can we find a private goods piece to go along with public goods piece? And I think that still remains to be worked out, but it's a critical element in going forward, as long as we're asking you to participate voluntarily, we have to be giving something back.

DR. McCLELLAN: Good. I'd like to get comments. Go ahead, Jonathan.

MR. HARE: Jonathan Hare from Resilient Network Systems.

So, first of all, Reed, I just want to thank you because I'm all fired up. (Laughter) And I think what you hit on is let's identify the metrics that really matter, right? Can we get personalized decision point at the point of care so people can make decisions to improve their health and be rewarded for that? That means tapping into population scale data that doesn't scale; it doesn't matter if it's too expensive. It assumes ubiquitous consensus and trust among people who don't trust each other. It won't work. And I think the key is we need to figure out what are those metrics and then get a plan to get there and accept no substitutes.

I think what Janet Woodcock laid out is the right approach. That's the right philosophical approach. We're not going to get there with different networks, special purpose in each silo. It will never work. It's never worked in any other industry. It's not feasible socially or technically or financially. And the challenge is to get there; it's going to take some breakthrough innovation.

If there's one thing that's been demonstrated over the last 10 or 15 or 20 years of trying to exchange data is that what we're doing doesn't work, right? It's a miserable failure in

terms of ability to exchange clinical data for decision-making in a decentralized network just doesn't work, and I think one of the challenges in a government environment when the general model is with sort of grant-funded projects, the general approach since it's public money is well, let's convene a working group of the best experts that are typically drawn from the incumbents or consultants or other lobbyists or whoever that kind of been there, done that, and been on all the previous committees, right?

And then they're expected to come up consensus on what the RFP should look like. And that RFP makes sweeping assumptions about what the solution is or what it looks like, usually by some sort of standards. And the reality is these people, they have a framework they come from and assumptions and their own incentives, and what you come up with is something that is not a breakthrough. You never get sort of breakthrough innovation or really any kind of serious innovation through that type of process.

So, I have a suggestion or a different approach, which is rather than having RFPs and grant-funded things which sort of imply what the solution looks like, to say what are the goals, what does success look like? What are those metrics? Do like an X PRIZE, if you're familiar with X PRIZE. It was like eight years ago, somebody said if you can get a privately-built spaceship 100 miles in the air and down and then back up again within 2 weeks, right, you're going to win $10 million. I think there was probably quarter of a billion dollars that was spent on that. All sorts of crazy ideas. There was no consensus whatsoever, but they got the job done, right?

So, in health care that can look like if you can set these metrics, you need to be able to reach every patient, every clinician, every caregiver in the country, give them timely, convenient access of the data and the decision support they need, do population scale analytics or comparative effectives research for safety and so on, that's what we need. And then anybody who can actually do that, right, your reward is we'll use it. We'll create a marketplace. Payers will use it and pay for it to coordinate care and avoid bad outcomes. That will attract the people that would never even apply for a government grant. The people that have the resources and the capabilities to do this cost effectively, they're not going to get in line for a government grant. It's

just not meaningful to them, and they probably wouldn't be eligible anyways.

So, what I'm looking for from you guys is can you describe a process where you could all get together and say we're going to do with this little percentage of our time and attention and funding create an environment for innovation, attract people who think they can solve this problem to find that type of process and get it done in the next two years before the Republicans de-fund all this. (Laughter)

DR. WOODCOCK: A very small example, in OMOP, we did a OMOP competition, and we offered a monetary prize for those who could develop the best novel data mining against the database that we had made, and we got tremendous interest and novel ideas from folks from totally different fields than pharmacoepidemiology, and upon how to do data mining. So, it is possible to have competition drive some things.

DR. BLUMENTHAL: So, we have actually just launched an innovation prize award through the Office of the National Coordinator. It's not $250 million. (Laughter) But it's enough, I hope, to get some attention.

I'd also like to think that a part of what the Congress and the president did when they created the HITECH Act was to do some of what you discussed, and it's called the meaningful use framework. It's just evolving. We're only in stage one. They'll be several more stages. Each will set more ambitious goals for what the performance requirements are for electronic systems. And it's putting money, incentives on the table for the use of those systems or penalties for not using them. We're not prescribing the technology, we're prescribing the uses. And there is a lot of innovation going on, some of it will be good, some of it won't be good. But in effect the meaningful use framework has for the first time in the history of any health care system given the government -- and it is the government for those of you who are not happy with that, I'm sure that's disappointing to you, but it is the government. The Center for Medicare and Medicaid Services is saying we'll put $27 billion of taxpayer money on the table in extra payments for 4 or 5 years, and then we're going to start taking away money if you or unless you do the following kinds of things electronically.

Now, right now, the meaningful use stage one is about getting essential patient

information into electronic form. Because none of the things that Janet wants to do or that Sherry wants to do can happen until information is electronic. I mean, if it's still on paper, innovation is not going to be very helpful. So, we've got to get doctors and hospitals and patients to buy in to the idea of an electronic health information system. Then you can begin to build on increasingly demanding uses of that information.

And the meaningful use framework is simply a way of setting goals for electronic use. Now, it's going to have quality metrics in it, it's going to have I hope efficiency metrics, it's going to have exchange requirements, and I think down the line, it could also have a framework for secondary use. So, I don't think we're far apart. We are very, very hopeful and committed to permitting innovation technologically to blossom in that environment.

DR. TUCKSON: So, I just want to again come back and underscore David's key point, but when he says hopefully efficiency measures, and, again, this is where we all have to bond together behind David to give him some lift so he doesn't have to say hopefully. And I think that what you got, Jonathan, your question was provocative and more complex and it's beyond pay grade to try to understand it all, but I would say that Janet and Peggy and Don Berwick all together, they sat down in a room, and I'm sure they do, have a whole bunch of data that tells you where CMS cost curve is about to go as you overlay it against where are the next innovations in health care assets, both pharmacologic and technologic? They can show you how deep doo-doo they're in, and they're in deep doo-doo, and just as David is trying to find and give money for physicians to adopt meaningful use criteria, on the other end, they're getting ready every year after year trying to figure out how to pay physicians to take care of Medicare and Medicaid patients. So, whichever end of the balloon you want to squeeze, it's got problems.

And, so, CMS can't afford, and, so, what they absolutely, if you want to figure out where the focus is, focus on where the controllable costs are or where the early warning signs are. So, if there's anybody that wants to know right now what you have to look out for that causes you preventable ER visits, admissions, longer lengths of stay, and readmissions, they ought to know it.

And whether there are high-profile areas that you want to go after first or watch

as the new technology, which they know the new technology that's in the pipeline about to come down the track, they know what you have to look out for, and then, ultimately, they will be able to tell you what David just said, is secondarily, is to have a scalable solution that lets you query even the lesser important things, even though if you add them all up, everything becomes important. But, at the end of the day, okay, I want to ask this particular peculiar question that maybe wasn't on the original hit list, and eventually, you get to that scalable solution. But at least I think that the next time we sit here, I think we ought to have the product of the conversation between CMS and FDA that says let me tell you where we're in deep doo-doo.

DR. McCLELLAN: Another question.

MS. OZANIAN: I'm Rhonda Ozanian. I'm a Robert Wood Johnson Health Policy fellow.

So, my question is about the secondary use of this data, patient level data, and governance and the data partners. If you have to de-identify data beyond the firewall, patients don't stay in the same place, they move between health care systems, payers, providers. So, doesn't there have to be some relationship between the data partners to make sure that once you get beyond the firewall, you're not counting the same patients multiple times because you won't know?

DR. WOODCOCK: Some of those are technical problems, and we are looking at different ways we can identify patients say from registries and also from health care systems because, actually, we want to link those people.

MS. OZANIAN: Right.

DR. WOODCOCK: So that we have that longitudinal and outcomes data and so forth. However, I think what David is doing, those pieces are aimed at having the portability of the data so wherever a patient goes, they have their records with them. That's what aiming to fix that problem. Right now, those are paper records. Even if you're in the same health care system, you probably can't find out everything that happened to a patient.

MS. OZANIAN: And, so, those same solutions would apply to the Sentinel Project, as well?

DR. WOODCOCK: Well, as those data become available, which they are generally as long-term -- I think the dwell time right now in the data we had from OMAP was about 18 months or something like that in any given system except for CMS, where they have them forever. Once they've got them, they've got them. But so it's a big problem on not short-term outcomes, but longer outcomes. So, yes, that's part of I think what they're doing and for the primary data. The primary data has to be linked.

DR. BLUMENTHAL: Yes, you've pinpointed a very important problem, which is that without a kind of a common patient identifier that travels with the patient, there is going to always be uncertainty about who is who. There are companies that have built very successful businesses around algorithms for identifying patients. They're probabilistic, they never give you 100 percent certainty, but they can give a level of certainty that is tailored to your needs. They can give you 100 percent certainty if you're willing to give them the data, but if you don't have that data, they'll give you a probable match. And then so we're going to have to come to some consensus about what constitutes a match, what level of certainty we want for what uses.

For research uses, you may be able to tolerate rater uncertainty than for care purposes because mismatching a patient for treatment is a lot more consequential than mismatching a patient when that patient is 1 of 1 million who is being used for -- that just expands your uncertainty. Your standard error. So, I do think that we're going to find solutions for these problems. They won't be perfect, but they'll be, I hope, workable.

DR. McCLELLAN: Next question.

MS. JONES: Judith Jones, the Degge Group.

In addition being an epidemiologist, I've been a passionate follower of electronic medical records from the time they were introduced in the U.K. in the late 80s, and pretty wide use by the 90s, and I'm delighted to hear the plan now, but my question has to do a little bit with Janet's system diagram, which is really a crosssectional diagram, and it doesn't give you a longitudinal view. Obviously, one of the big, I think, deficits in all of our plans for electronic medical records has been the failure to incorporate thinking about those in our medical training and actually nursing and pharmacy training, as well. I teach in a couple of

medical institutions, and I consistently find that although everybody uses PDAs now, there is not any consistent training on either the health care system or on use of electronic medical records unless they rotate through the Veterans' Administration, which, fortunately, a lot of medical students do, but that's not until they get to their clinical years. I think if we look at the origins of how we're going to implement this, we need to pay attention to the medical education system and make a full-fledged effort to incorporate that. And I'd just be interested in your thought.

DR. BLUMENTHAL: So, it makes sense. The challenge is a little deeper even than I think you've laid it out because what we do not have in today's academic environment are the learning hubs that are taking not just the HIT, which is only an ends to itself, EHR is only a means to an end. It's more of being able to deliver the new reorganization of care delivery that allows you to take electronic and other information and then be able to interact with a patient so as to coordinate comprehensively their care in a way that delivers better quality, more appropriateness, more cost efficiency, and more coordination of care.

The place where that is occurring, the good news is that there is an entrepreneurial spirit in American medicine today which is going very unnoticed. We are seeing it popping up everywhere, especially as companies like Sam's, mine, and others and as the federal government sort of starts to intimate through responsible leadership like Don Berwick, you get the sense that the reimbursement is about to change. So, now you're starting to see physicians respond with new, you call it whatever you want to call it, accountable care organizations, whatever the alphabet soup is.

So, I guess the point would be is that what you're seeing are learning laboratories out in the land, but you're not seeing very much of them inside the academics environment, and here's the killer on it: The challenge is going to be strongly that the model of new reorganization and reimbursement is a model that saves resources and piles them back into physicians and patients' lowered premium because you are able to decrease the use of hospital services. It's going to be very hard for the academic center when the person that runs the hospital hears about what's going on.

DR. NUSSBAUM: Your important question raises though a much more

fundamental issue, and while it's directed at the use of health IT, think about what we're going through. The structure of care delivery is fundamentally changing, whether we use ACOs or integrated care organizations. Within the last few years, more than half of cardiologists are now employed by health systems. Most major markets' primary care capacity is entirely acquired by health systems.

The American Board of Internal Medicine Foundation at their meeting this summer basically asked the deans and others in medical schools are we prepared? Is our learning environment prepared for what we need to do in health reform? And you know what the answer to that clearly is.

So, whether it's all of these, it strikes me that we're operating with a lot of a green field of opportunity. So, comparative effectiveness research will give us very important information so we don't waste 30 to 40 percent of our resources on unproven therapies. Health IT, while today we may have -- and, David, you know I celebrate everything you've done because my concern about electronic medical records, until you got involved, was that we were creating bridges to nowhere. That now we're going to have bridges to somewhere.

So, the work of the FDA, I think we're at that critical point where all of these are going to begin to intersect. Today, they're appearing to be in their own path, but increasingly, thought leaders are beginning to find that common ground in their section. But, fundamentally, health care has to be reorganized and to get the efficiency, the capability, the performance that we need in our health system.

DR. McCLELLAN: I think we've got a couple more questions. We've just got a couple more minutes, so, if you could move on to the last. Thanks for that excellent discussion.

MS. PATRICK-LAKE: Hi, I'm Bray Patrick-Lake. I am a patient in the FDA Patient Representative Program, and I am the patient serving on the National Planning Board for Mini Sentinel at least for the next two minutes. I may be fired shortly. (Laughter)

So, when we talk about the primary mission of the Mini Sentinel Program, I think it's incredibly executing from the patient perspective because it is going to improve patient safety. I think we all get that. And then when we take it to the next level and we start looking at the

secondary uses and we think okay, we're going to improve patient care maybe through comparative effectiveness research, I think all of us from our different perspectives and interests can say that we're all here because we want to improve patient care.

When we take that to the next level, Dr. Tuckson, I think you're an incredibly impassioned speaker, but you made the hair on the back of my neck stand up when we start talking about comparative effectiveness research and then we say cost effectiveness, and then we say reimbursement and CMS all in the same sentence, and then somewhere in there, you say it's patient-centered choice.

Well, I have an HMO insurance, and I can tell you right now it doesn't feel very patient-centered. When I go in, I get a list of formularies. It might not be what's necessarily for my individual patient care, it might have a low side effect or a low profile for side effects, and it may be cheap, but it's not necessarily what's best for me as an individual patient.

And, so, I think the patients in America are very well aware that costs is huge and cost of health care is huge, but I'm just wondering how we are going to balance going forward if we start using this incredible framework for comparative effectiveness research. How do we balance that with the true patient experience? Patients are more than just a P value, so, where does quality of life come in?

Let's say we have two therapies, we have one that is an innovative medical device, maybe it's an implantable cardiac device and we know that it saves lives. But you can also put the patients on an anticoagulant for $10 a month. One's very expensive, and if you look at the P value, maybe everything is the same, but yet the patient that was on the drug for $10 a month is too fatigued to continue their job, to play any sports.

How are you guys going to, as you make decisions that do affect patients when you take costs into account, how do you balance that? And I'm not sure I'm getting that from where we are, so, maybe it's just where we go next and how the patient experiences preserve through all this.

DR. McCLELLAN: And I know this is a big question, but we need a short answer.

DR. BLUMENTHAL: Very quick. Very quick.

DR. WOODCOCK: You've got 60 seconds. Go ahead. (Laughter)

DR. TUCKSON: All right, well, first of all, don't let them do anything to you because you need that voice, and you're right on there.

I want to separate out the two ends. You've mixed two things together, and I want to separate them. Number one is I think we would all appreciate that you have to have responsibility in terms of making rational choices about scarce resources. The null hypothesis doesn't exist. If you don't get at the things I tried to get at, no one could afford anything.

So, I mean, at the end of the day, there's no other way out of it. You have to grapple with it. So, what you are really saying is how do you do it, and you're basically saying will the research on comparative effectiveness and other decisions that have to be made, will they be sensitive to including fundamental things like the patient experience with care, like the work productivity back to the workforce? All those kind of things. Can you get them back to work, people having a better quality of life? And absolutely that has to be a major part of the research protocol, the research questions, the health services research query, the comparative effectiveness research. So, I would just sort of endorse strongly your point of view.

I do not see them as incompatible. There is a necessary group of work that has to get done. How it gets done must incorporate everything you just said.

DR. McCLELLAN: Thanks. One more question.

MS. PATRICK-LAKE: Okay, so, just from this group, I --

DR. McCLELLAN: We are going to have to move on.

MS. PATRICK-LAKE: I'm sorry. I just encourage you to keep opening the door for patients and the patient advocacy groups.

Thank you.

DR. NUSSBAUM: Well, absolutely, and that's why, for example, Meryl Wineberg is key to everybody because every time we take a step, we don't anything without talking to Meryl. (Laughter) So, you got it.

DR. McCLELLAN: Thanks.

MS. ST. CLAIRE: Hi, I'm Chris St. Claire from Med Star Health. I was just wondering since you have several people have mentioned bringing in clinical data to expand the datasets, are the RHIOs going to have any interaction with these large datasets that you're collecting for all these other uses, like the D.C. regional health information?

DR. BLUMENTHAL: Well, the RHIOs, the so-called Regional Health Information Organizations, I think we change these names every two weeks, whether you want to or not, so, that name is already kind of moving out of fashion, so, we're now calling them Health Information Exchanges. (Laughter) But we have to stay employed. (Laughter) They are mechanisms for letting data move. They're the switching lines of the railroad, if you will, and you want data to go from institution A to institution B, doctor A to doctor B, and nurse A to nurse B. How do you get it from point A to point B?

Well, you need to have a kind of switching place, an operator who's putting in those plugs, if you remember those things. So, that's what RHIOs do. Now, they can do that as a purely mechanical activity, and it's not even clear that you need them, but, right now, they are one of the options for making that exchange happen. In the process of making that exchange move, they can reach in and take out the data and hand it to Janet under the right circumstances, and that's one model by which data will start to become available.

So, in a sense, because they are a hub where information flows through, they are one node in a distributed network which provides access.

Now, having said that, it means that they would have to in order to be trusted conform to all kinds of assurances; provide all kinds of assurances about the stewardship of the data if they were to have that responsibility. And we have not yet conferred as a society, and I'm not saying this is a public responsibility or a government responsibility; it can also happen to private sector. We have not yet conferred on them any kind of official role of that kind.

DR. McCLELLAN: Well, I'd like to thank all of our panelists and all of you for an excellent discussion. Thank you. (Applause)

We are coming to a conclusion this afternoon. It's been quite a day. It's clear to me that the Sentinel Initiative is making a lot of encouraging progress and has the potential to be

a model for how other collaborative efforts like this might go forward for effective secondary uses of data or an element in this broader system that we've just been discussing of providing much better evidence to guide our health care system in the right direction or that guidance is urgently needed.

But, clearly, there are a lot of issues that still remain, and one of the things that has impressed me throughout my involvement with the Sentinel process is how much of that progress comes from discussions like this, especially for a public-private initiative like this one. The ideas from stakeholders, the perspectives, the insights, the pilots, all of that has a huge impact. So, the fact that so much of this discussion was driven by you all, I can tell you is going to have an impact what we do in our future involvement in this and I would think where the Sentinel Initiative heads.

So, I want to thank all of our speakers today and panelists for their contributions. I want to thank Rachel Behrman and Julie Racuse and Melissa Robb at FDA for all of the work that they put in working with us to pull this meeting together. I want to give a special thanks to the staff at Brookings who helped with planning: Josh Pfeifer, Ben Martin, Erin Weireter, Lindsey Spindle, Lisbeth Rafferty, and Michelle Wong, Sally Cluchey, Josh Benner, and Larry Kocot. And most of all, again, I want to thank all of you for putting the time and the effort and the heart into helping to transform our health care system. Thank you very much, and safe travels. (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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