THE BROOKINGS INSTITUTION

FALK AUDITORIUM

THE FUTURE OF MEDICAL DEVICE SAFETY AND INNOVATION

Washington, D.C.

Monday, February 23, 2014

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P R O C E E D I N G S

MR. McCLELLAN: And I'd also like to welcome you to The Brookings Institution this morning. I'm Mark McClellan, I'm the director of the Health Care Innovation and Value Initiatives here at Brookings. I'm also a senior fellow in Economic Studies, and today we're joined by leaders from across the healthcare system, including patient advocacy groups, clinicians, health systems, the medical device industry, insurers, government, and academia, and all together for a productive discussion on postmarket evidence to support medical device safety and innovation.

Medical devices play a critical role in healthcare and it's essential to have access to reliable and meaningful information about their safety, effectiveness, and quality to make sure that they're used effectively today and to make sure that we improve the uses of medical devices as rapidly as possible for the future.

This information cannot only be used to inform decisions about patient care, it can also be used to support the mission of the FDA. The FDA is charged with protecting and promoting the public health my monitoring the safety and effectiveness of medical technologies, and this requires that the agency understand the risk and benefits of medical devices as they make regulatory decisions.

FDA has been actively working to expand and enhance its ability to fulfill this critical role. The FDA activities include a set of initiatives developed by FDA Center for Devices and Radiological Health, or CDRH, to make regulatory processes more efficient and especially to facilitate access to safe and effective medical devices.

A key part of those initiatives focuses on developing better postmarket, or real world evidence, on medical devices. And we're here today to take an important step toward better postmarket evidence on medical devices.

The CDRH Commission and the Engelberg Center for Health Care Reform at Brookings to convene a broad-based Planning Board. The goal of the Planning Board is to identify the governance, policies, priorities, and business models necessary to develop a sustainable

national system for medical device postmarket surveillance.

The Planning Board members were selected through a public nomination process in early 2014. The membership includes a diverse group of 22 representatives from patients, clinicians, payer and provider organizations, the medical device industry, researchers, and representatives from key government agencies, including FDA, the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, and the Office of the National Coordinator for Health Information Technology. And I want to thank all of them for their hard work together over the last nine months to develop this report.

Some of the members were able to attend in person today and I'd like to recognize them particularly: Kathy Blake, Joe Drozda, Dave Flum, Tom Gross, Matt McMahon, Dale Nordenberg, Carol Walton, Natalia Wilson, Marc Overhage, and Pat Schrader. It's been a real privilege to work with such a tremendous group on this topic.

The report released today is a reflection of that hard work. It includes the Planning Board's recommendations for the long-term role and structure of a National Medical Service Postmarket Surveillance System for the United States, and short- and medium-term strategies to achieve that long-term goal. A full copy of the report is available this morning on the Brookings website. We also appreciate FDA's support in this effort. FDA has a clear need to collect reliable and timely information on medical devices and CDRH has highlighted better postmarket evidence as a critical opportunity. But they're not alone. Everyone has a vested interest in improving information about medical products.

Patients and clinicians need information about devices to inform their clinical decision. Payers want to ensure that the products they cover lead to optimal patient outcomes. Manufacturers want timely and reliable feedback on the benefits, risk, cost, and other impacts of medical devices. And this plan was developed in response to concerns about the nation's ability to monitor the safety and effectiveness of medical devices, to meet the challenges of supporting medical device innovation, and inform the evolving, learning healthcare system.

In this context, surveillance means more than safety. It encompasses collection

and development of more timely information on the benefits, risks, and potentially costs and other effects of medical devices over the total product life cycle. This information can inform the development of new products, comparative effectiveness, quality measurement, product tracking and utilization, economic analyses, and other potential valuable uses.

I know the Planning Board is eager to comment on this topic and get your feedback on the report. That feedback starts now, this morning. The discussions today are intended to begin the process of taking this report and turning it into an effective set of next steps to address this public health problem, this national priority.

The best momentum for real progress is thoughtful discussion, constructive comments, as a basis for practical steps forward. As the report makes clear, progress in our healthcare system can't happen without the engagement of everyone who has a stake in better evidence on devices: the public and private sectors, clinicians, product developers, payer, consumers, and patients.

Now, I'd like to go quickly over the agenda for the day. Jeff Shuren, the director of the Center for Devices and Radiological Health at FDA, is going to start us off with some opening comments on the context for this report and FDA's activities. Then we'll have an overview of the report itself, by two of the Planning Board members: Kathy Blake from the American Medical Association and Marc Overhage from Cerner Health Services. Their presentation will be followed by responses to the presentation and the report by a panel of key leaders, including Omar Ishrak from Medtronic, Bill Murray from the Medical Device Innovation Consortium, Lew Sandy from UnitedHealthcare, Alan Guttmacher from National Institute of Health, Alan Balch from the Patient Advocacy Foundation, and Jodi Daniel from the Office of the National Coordinator, who's also a Planning Board member.

Then the second session will take a more in-depth view of some of the issues around the report. That will lead into another session on medical device innovation. That one will focus especially on how better postmarket data collection can be done and used effectively to inform development, regulation, and coverage decisions, including a rebalancing of the pre- and

postmarket regulatory requirements for devices. With a stronger postmarket system in place, some of the issues that currently have to be dealt with in the premarket side can now be dealt with, perhaps, more effectively in terms of real-world data on medical devices.

We're then going to have a break for lunch between 11:30 and 12:30. We'll reconvene here again at 12:30 for the third and fourth sessions of the day.

Now, reflecting the importance of the issues discussed in this report, the release is coming and that a focus on Capitol Hill, in Congress, on improving biomedical innovation: the 21st Century Cures effort in the House Energy and Commerce Committee and the Initiative for Healthier Americans, led by the Senate Health, Education, Labor and Pensions Committee. This session after lunch will feature key congressional staffers from the Senate and House committees that are leading these efforts on biomedical innovation, including Wade Ackerman and Grace Stuntz from the Senate Health Committee, and Clay Alspach and Eric Flamm from the House Energy and Commerce Committee.

Then, in our final session of the day, we're going to talk about a variety of current efforts related to medical device surveillance and how they can be leveraged for building blocks for developing and implementing this long-term vision. The panel to close out today's sessions includes leaders in medical device evidence development: Mitch Krucoff from the Duke Clinical Research Institute Registries Taskforce, Rich Platt from Harvard Pilgrim, who leads the Sentinel Initiative for the FDA, Carmella Bocchino from America's Health Insurance Plans, Joe Selby from the Patient Centered Outcomes Research Institute, and Sally Okun from PatientsLikeMe.

So that's an overview of the day. Before we get started, just a couple of other housekeeping items. As you all can see, this is a public event. It's being webcast live, it is open to the press. Panelists, I want you all to be mindful of our timekeeper, Pranav. Pranav, right there, right in front. He will remind you when you are approaching the end of the time. We're going to try to keep this moving along because of all of the perspectives and ideas that we want to get in today.

During this session, for those who are attending, we'll have opportunities to ask

questions near the end, following each of the panel discussions. Now, if you do have a question, you can just raise your hand. We'll get microphones to you.

And then, finally, just one other logistical issue, we've got coffee, tea, sodas, water available in the hall outside of this room, to the side. Then lunch will be on your own between 11:30 and 12:30. Our staff has a map of the local lunch options available at the registration table. Brookings also has a small cafeteria and you can bring your food back in here for lunch to eat because the cafeteria's not that large. And if you also go out to lunch, you're welcome to bring food back into the meeting room during the break.

Okay, I think I've covered all the logistics, so let's get right to it. I want to introduce Jeff Shuren, the director for the Centers for Devices and Radiological Health at the FDA. Jeff has served as a leader at CDRH for the past few years, but he's actually been at FDA since 2003, right? Or thereabouts. He's worked very closely with the Commissioner at that time. He's been the director of CDRH since 2010, and as CDRH leader, he has undertaken a number of initiatives, working both with his staff and with the broader public, to develop and implement a strategic plan for CDRH focusing on enhancing the Center's systems and processes for device safety and to encourage beneficial device innovation. He's also led efforts to expand the ability to reliably collect and use postmarket data to support regulatory decision making in public health.

Jeff, we're looking forward to hearing from you to kick us off this morning. Please come on up. (Applause)

MR. SHUREN: Well, good morning. Welcome, everyone. I am delighted to be here at this major milestone for establishing a National Medical Device Postmarket Surveillance System. It is a key first step, but it is a very big first step and, of course, there is much, much more to do. I'd like to start by thanking and congratulating Mark McClellan, his team here at The Brookings Institution, all the members of the Planning Board, and everyone else who has contributed to this effort. It's a big achievement and we're off to a terrific start. Congratulations.

I'm going to take a few minutes and try to put this in context from an FDA perspective, how we got here and where we are today. You know, if you think back over a

decade, we were looking at postmarket surveillance and our thinking back then was always on safety. How do we identify new problems? And our real tools were passive surveillance. We'd look at doctors, patients, could they identify a problem and be willing to report it into us or into the manufacturer?

And if we needed more information, we'd ask the manufacturer to conduct another study, gather more information. And we had a big challenge back then, being able to identify the device that may be associated with the particular problem because we had lots of manufacturers of the same kind of device and, you know, unlike drugs, devices are constantly changing. So the question is not only which device, but which version of that device? Were there modifications that were made? And it was very hard to do.

So much of the discussion back then was establishing a Unique Device Identification System, but all about on the safety side, and using that number to incorporate into medical device reports, so we better understood if there was a problem, what was the device associated with it? But there have been three major changes over time that are changing how we think about that postmarket data.

So, one is the evolution of electronic health information and the adoption of the use of such information, such as through electronic health records and the creation of a medical device registries and administrative claims.

The second is the development of advanced methodology. So, on the one hand, we now have tools to better capture real-world experience with medical devices. Then we have the development of the tools that let us make better sense of that information because we're dealing with observational data. It can be very dirty and very hard to make lemonade out of lemons.

And the third is a fundamental change in the thinking of the FDA. So CDRH has been moving to fully embrace the dual nature of our mission, which is to protect and promote public health. Protect by providing reasonable assurances of safety and effectiveness of the devices on the market and assuring they're of high quality, but promoting public health by

facilitating medical device innovation and speeding patient access to safe and effective devices. And sometimes those dual aspects of our mission go hand-in-hand, and sometimes there's a tension.

So if you think about it, if you want to show that a device is safe and effective, a very good standard, it's going to require time and money to gather that evidence. And you can see this reflected in the vision for the Center, that patients in the U.S. have access to high quality, safe, and effective medical devices of public health importance, first in the world. First in the world not because there's a competition between countries, but because it's a measurable outcome and it tells us if this is good technology. Remember, that's the first part -- high quality, safe, and effective.

Then we want to get it to patients as soon as possible. That's what that vision reflects. But here's the challenge. You want to show its good, but the more you ask for, the more data you need, the more challenging it is in order to get faster patient access to it, and there are tradeoffs there.

And that's then reflected in the need to strike the right balance in what you need for that product to go on the market versus what you may be able to gather after it has gone on the market. And you can see that in our strategic priority of striking the right balance between premarket and postmarket data collection.

Last year we proposed a program called An Expedited Access PMA. It's essentially breakthrough medical devices, something we've been piloting since 2011 as the innovation pathway and the ideas are following. If I have a technology that's for a life-threatening or irreversibly debilitating condition and addresses an unmet medical need, does it make sense from a public health standpoint to accept a greater level of uncertainty regarding the benefit-risk profile of that device, but still needing the standard of reasonable assurance of safety and effectiveness, and then gather the rest of that data postmarket?

That's a little bit of that tradeoff, right? But that makes sense from a public health standpoint, but think about how we would go about getting it. To get that data you'd go to the

company and you'd say, conduct a postmarket study. But, of course, once you throw technology into the wild, it's much harder to gather data through a clinical study. There's less incentive for people to participate, and we struggle with that.

And the second is, real-world data can actually be far more informative about that technology than what we may learn from a clinical trial. A clinical trial can be very artificial. If we want to know what the real benefit-risk profile of a technology is, then we have to see its use in the wild, in clinical practice. But you have to gather that data systematically and you have to be able to make sense of it. And if you can do it, you can fundamentally change how we introduce technologies and access technologies here in the U.S. And that is what is behind our proposal in 2012 for establishing a National Medical Device Postmarket Surveillance System. Not the old idea of simply surveillance for the purpose of "find a new problem," but rather also to better understand the benefit-risk profile of a technology.

Feed it back to providers and patients to make better informed decisions. Feed it back to developers to make better products. But also to leverage that information to reduce the burdens on the premarket side, the introducing technology here in the U.S.

And when we said a national system, we did not mean a system that wasn't an FDA system. Not something we would run, not something we would own, but rather one that is by, of, and for the medical device community. Governed by the medical device community and used by the medical device community with, at its backbone, electronic health information, particularly electronic health records and medical device registries, and then supplemented with other sources of information, like peer claims, and incorporating into them a Unique Device Identifier.

So now, we're linking the use of a device with a patient's experience with that device, not just medical device report, but truly in the capture of the day-to-day clinical practice and experience with that technology. And then to apply advanced methodologies to that information and foster the development for such methodologies, and then be able to analyze feedback that information into the system, that was the idea.

But to make it work there are certain key challenges. That data has to be

sufficiently robust and timely to be able to make, certainly, regulatory decisions, but other decisions based upon it and have the kind of safety net in place that you truly can introduce technologies earlier into the marketplace than you otherwise would.

And secondly, you need to make sure that that data collection and those analyses are sufficiently efficient and cheap -- dare I say such a word, cheap? -- so that you can do this in a sustainable ongoing basis within a system. Otherwise, it's not going to happen. It's one of the challenges with post-approval studies: it costs a lot of money to do, let alone that it's hard to get.

And the system has to be inclusive of members of the medical device community and transparent about what it is doing. And it's got to be pragmatic because there are tradeoffs. If you gather more data, it can cost more money. And different players have different interests and needs, but if we want to get the broad buy-in and trust in the system we need to have, then we do have to be inclusive, transparent, and pragmatic. And, of course, we have to protect the privacy and the security of confidential information, particularly personal information about patients, if we are to succeed.

Now, FDA is strongly committed to this effort. That's why we put the strategy out, it's why we turned to The Brookings Institution to pull together this Planning Board, and the Medical Device Registry Taskforce that will be reporting out in the near future, as well.

It is why we've also moved forward in establishing Unique Device Identification System that now is being incorporated into device labeling. It's why we are working with the Office and National Coordinator for Health Information Technology and other partners to incorporate the UDI into electronic health records and other sources of electronic health information. It is why we are working to develop advanced methodologies through the Medical Device Epidemiology Network of which we have been a co-founder in that public-private partnership.

And it's why I am very pleased to announce that we have hired Greg Pappas, our very first associate director for National Device Surveillance. Someone then who can have greater accountability and ownership for making this happen.

So we have a brave new world that faces us and, of course, we have the

opportunity now to take advantage of it. It is my deepest wish and hope that all of you will want to be people who embrace that dream and not only embrace it, but work together to make it happen.

So thank you very much for being here and, again, congratulations to all on today's release of the report. (Applause)

MR. McCLELLAN: Jeff, thanks very much for your comments to get us started. As I mentioned before, the Planning Board has been working on this project over the past nine months. A project of this type is always challenging, given the scope of the task, the need for inclusiveness, as Jeff highlighted, the diversity of perspectives that need to be included, but that's also a strength that enabled us to bring together a log of expertise and a lot of important considerations that need to be addressed.

And not only that, not only bring them together, but find ways to actually move forward together to accomplish those goals. The Planning Board took all of this on. It developed a shared vision of the characteristics and functions of a National Device Surveillance System, and, not only that, also some concrete steps on how to get there in the next few years.

I'm now going to turn to speakers from the Planning Board to provide an overview of the report. I'd like to introduce Kathy Blake, vice president for performance improvement at the American Medical Association. It has a tremendous record on working in activities involving registries and other sources of evidence to promote better quality care and better evidence on medical products.

And, also, Marc Overhage, the chief medical informatics officer at Cerner Health Services, who has been involved extensively in the development of information systems and the development of better evidence systems, and statistical methods for learning from complex practical data systems.

So Kathy, I'll turn it over to you to get started. Thanks.

MS. BLAKE: Thank you, Mark, and thank you also to FTA and to my fellow members of the Planning Board. So the Planning Board was charged with really designing and envisioning a 21st century system for a medical device, both development, innovation, and postmarket

surveillance. And we really see the system that we're proposing here today as an essential component of an emerging national healthcare information infrastructure.

We focused in our recommendations on a collaborative system that supports the development, regulation, and use of innovative devices. The system that we envision should be able to accurately, systematically evaluate potential medical device safety signals in near real time, measure the risk benefit profile of a device throughout its entire life cycle, and be able to develop information that supports pre and postmarked regulatory decision making. We believe that data capture should be an integral part of healthcare. This will minimize burden. We think it is essential to do so. The desire to improve public health and patient care are the key drivers for this system that we propose, and the data within the system should support a broad range of evidentiary needs. In developing the report we identified a set of assumptions about progress that we think will take place over the next decade. We believe that the country is moving towards a learning healthcare system, one in which healthcare is more personalized for individuals to meet their specific needs. A central capability of such a system is to be able to capture the patient's perspective to better inform and improve the ongoing delivery of care to them. We also assumed that the shift towards more personalized care will incentivize the development of better evidence, and that payment for medical services will increasingly be tied to results.

The Planning Board also made a number of assumptions about a very rapidly evolving health IT environment. We assumed that within a decade that collection of UDI data and connecting it to patients will be an integral part of healthcare. We also assumed that EHRs holding UDIs will be widely available across the healthcare environment and that different but interoperable health information systems will support the linkages of that key data on behalf of patients. We also realize that as a multi stakeholder partnership that for this system to succeed it has to earn and maintain the support of all the major stakeholders that are already engaged in Postmarket Medical Device Surveillance. And those stakeholders, which you will hear from a number of them today, include patients at the center, clinicians, healthcare organizations, manufacturers of medical devices, payors and providers, the medical device industry, and

government agencies, and others.

The mission of the Medical Device Postmarket Surveillance System, what we will call MDS, is given to you here, and it is our belief that the System that is based on this mission to fulfill this mission should really serve as a central hub to coordinate national efforts and to generate information about the devices that are used by patients and clinicians. The information generated should address and meet high priority public health goals and healthcare needs. Potential uses of the system include providing better information to patients, clinicians, health systems, and payors, being able to inform CDRHs regulatory activities so that they are able to ensure safety while at the same time accelerate product innovation, and be able to really facilitate the premarket approval and clearances processes and the expansion of indications for already approved devices. The system should mitigate potential harms by supporting a rapid response when device safety problems are detected and it should gather information about existing products so that that information can inform new product development and innovation. And most of all perhaps is the goal of improving health outcomes, but improving them by supporting decision making that is informed by real time, real world experiences with medical devices.

If we then look at some of the guiding principles, we will be guided by FDA surveillance priorities of course. This will be a clinician and patient centered or focused system. It should be integrated into larger national efforts. This is not stand-alone. It will be a multi stakeholder collaboration, it will be forward looking, and we assume and expect that it will continue to evolve. There will be clear expectations for transparent communication. We will focus on maximizing utility, minimizing burden, and be profoundly respectful of the need to protect patient privacy and their data.

Its primary function will be to provide better evidence of course to support all of the activities that I have mentioned. Secondary functions will be the expectation really to collaborate with others to meet shared high priority evidence needs. If we then look at those objectives and consider them more carefully, being an integral component of a broad healthcare infrastructure is critical. We will be part of but not the whole answer in terms of identifying current

and emerging activities and coordinating those efforts across the healthcare ecosystem. The system should develop a data infrastructure that is part of and consistent with and aligned with the health information systems that we see developing around us. And it should leverage interoperability standards.

The system should rely upon, should welcome, should use external expertise, collaborate with data partners, leverage existing efforts, and avoid duplication. We envision a system that collects data in a tiered fashion so that tier one would be a relatively small core set of data elements, tier two would like that data to clinical information that may come from EHRs and from registries, and tier three will link to more detailed device and/or clinical care registries. If we then consider what such a system would look like we, as has been said, think that the system should be a public-private partnership, it should be implemented and managed that way, and it needs to have sufficient authority and funding to support its activities. We selected this model because the success of this system requires the ongoing active engagement of many; CDRH of course, but the private sector equally so. And we believe that there is no single stakeholder, either federal or private, that could individually, successfully build and maintain this system by itself. So as such we also though don't see this as a stand-alone, but we see it as a coordinating function amongst very highly respected, well developed, very productive ongoing activities, as well as those that we expect to see developing over the next several years. And by service in that coordination function, by deploying assets and infrastructure that are available across the ecosystem, we think this will be a key element of reducing costs and minimizing duplication, but at the same time maximizing the sharing of expertise.

The governance principles are critical to the success of this system. We think that it will be built upon strong relationships that are based on trust amongst the key stakeholders. We think that trust will be fostered by having transparent and representative governance. We envision that there will be governance principles quickly put into place that will address conflicts of interest and mitigate their effects, assure transparent operations, develop reliable methods, and promote sustained participation.

In terms of the organizational components which you all see here, key is data infrastructure which is a coordinating function of a large number of already existing and soon to be developing data infrastructure partners. And as a long-term goal being able to establish the infrastructure board so that it is working with and fosters inter operable data sources and their use by many. The coordinating center will be responsible for stakeholder engagement and external engagement. It will work with and leverage the experience of external evidence developing organizations to be able to leverage their contributions. The coordinating centers will also identify organizations that will want and use for the benefit of all the data that is collected within the system, and the stakeholder engagement unit will be responsible for having that ongoing communication between the system and all of its stakeholders identified now, those in the future, to be able to ensure that this is an active live system that is put in place.

The Planning Board recognizes that the system will require significant financial resources to be sustainable. We also realize that there will need to be mechanisms in place to be able to provide resources, both financial as well as in kind support to data partners to encourage their participation. It needs to be explicit to them that there is value to participation in this system and to doing something perhaps different than what they are currently doing, and that we also believe that initially there will be a need for public funding to establish the system that we described for you today.

So I am now pleased to turn things over to my fellow Planning Board Member, Mark Overhage, and he will discuss with you the next steps. (Applause)

MR. OVERHAGE: Well, this is all easy, right. (Laughter) The Planning Board obviously has as Mark said only about nine months to do its work. And I was amazed and impressed with the degree of depth that we explored, a variety of the challenges that had to be met to evolve this system. And you might think of those in three buckets. The date infrastructure, which you heard a bit about, the methodological challenges related to how to leverage that data to the many purposes that Jeff Shuren identified, and creating value for patients and other stakeholders so that there is a sustainable business model for the operation that takes advantage

of the ecosystem of end users around these tools and systems.

So meeting these challenges we think will require a variety of steps moving forward. A specific program design for the public-private partnership that we described, probably pilots, which I'll say more about in a moment, and potentially working to evolve policy in the direction to support the operations of such a system. MDS should attempt to leverage existing building blocks, and I think Kathy said that we need to underscore that and be focused on scalable and generalizable approaches that build long-term capabilities of the system. So for example, the system should build on and coordinate with existing programs to minimize costs and make the best use of public and private resources.

So the steps forward that the Planning Board, or the strategies forward that the Planning Board recommends are a two phased approach. The first is, you can think of as an incubation phase, really taking these very complex set of issues and taking the direction that we have narrowed down of the many options, and starting to refine those into specific tactical steps to operationalize this system. And one of the key activities in that first phase that we expect to take one to two years, it to develop a robust plan for implementation of the MDS system. The plan at a minimum should include recommendations for developing the core system capabilities, and recommendations for the public-private partnership organizational implementation. In order to develop the core system capabilities there are a variety of activities that we think need to be incorporated into a plan, including defining the framework for the MDS implementation, identifying and starting to build the real relationships with the key partner organizations, making sure that the mechanisms to provide patient privacy and confidentiality protections are evolved and put in place from the beginning, and identifying and prioritizing pilot projects that will start to inform the process while building momentum for the MDS at the same time.

In terms of the public-private partnership organizational implementation, there will be some key decisions to be made. For example, such as who will be the potential organizations to host the operations of the MDS public-private partnership. Mechanisms for selecting the MDS leadership, management, and operational framework for MDS including the staffing and

information technology needs, and developing more refined financial projections, including budgets and potential funding sources. And finally establishing good and solid transparency and communication strategies, something that the Board has really spent a lot of time thinking and talking about ensuring that happens because it is so critical to the success.

We do think that during this time it is not just a planning and operations time, but pilot projects are an important part of this incubation period. These targets pilots should be used to inform more specific plans on how the MDS can best be implemented, as well as start building the foundation of a data infrastructure. And there were three specific pilots that the Board recommends we start with. First, our clinical data system supporting device safety surveillance, second, development of tools for routine surveillance of implantable device safety, and third, implantable device surveillance using patient reported information. We think these pilots will help build on existing work being done in a variety of organizations, including MDEpiNET and the Registries Task Force. On the basis of that plan, during that incubation period, that implementation phase that we expect to be at least five years, the first step would be selection of a founding governing board, and the members of its executive committee, which would actually instantiate and operationalize the public-private partnership. Then guided by the plan the governing board would set and oversee the strategic development priorities, and the staff in the host organization would start to build and maintain the broader stakeholder participation that's required, establishing the partnerships with other evidence development organizations and data partners, and developing the policies to ensure the patient's privacy is protected.

This may seem like a fairly broad set of directions, but it is actually quite narrowed down from the range of possibilities that the Board explored. And I hope that we have struck in the Board the right directionality and some specific enough steps to begin action while taking into account the level of certainty around the variety of moving parts exist.

And we really look forward to your comments today and over the coming months to help refine and improve this plan as we solve this very hard problem. So thanks very much for your attention this morning and I'll turn it back over to Mark. (Applause)

MR. MCCLELLAN: All right, Mark. Thank you very much for those comments. Kathy as well covered a great deal of information and content in the report in a limited period of time. Again the report itself is available on line in our website right now for anyone who wants to look at it in more depth.

Right now I would like to invite up the panelists for our next session onto the stage. While they are coming up I am going to introduce them. They have all had extensive careers related to medical devices and using them to improve the lives of patients here in the United States and around the world. The order that we will be hearing them from is the order that I'm going to introduce them. First, Omar Ishrak is the Chairman and CEO of Medtronic, and Medtronic as you all know has implemented a number of steps to take on the same kind of lifecycle approach of continuous evidence development that you heard described by Jeff Shuren earlier. Bill Murray is the President and CEO of the Medical Device Innovation Consortium, which is a collaborative effort to help overcome of the challenges in medical device innovation, such as providing more clarity about gathering evidence on benefits and risks to patients. Lewis Sandy is the Executive Vice President of Clinical Advancement at United Healthcare where Lew has been involved in a wide range of activities focusing on getting more value in the healthcare system, including through developing better evidence, both collaboratively and in efforts underway at United. Alan Guttmacher is the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Healthy were he has been involved leading a range of efforts about better postmarket evidence, including evidence on the effects of devices in children, and he has also been involved in the recently announced Precision Medicine Initiative that was part of the President's State of the Union Address. Alan Balch is the CEO of the Patient Advocate Foundation, a foundation that I think he'll describe in a little bit more detail to you. It focuses on patient centricity in the healthcare system and in further policy steps, like the ones that we are describing today. And Jodi Daniel is the Director of the Office of Policy for the National Coordinator for Health Information Technology where she's been involved in a range of issues using interoperability and electronic systems to support better evidence. She has been

very much involved in the recently announced ONC Interoperability Roadmap.

So we are going to be hearing individually from each of these perspectives on the report that you've just heard been described, and we are going to have some time for a discussion, including a discussion involving all of you here in the room.

So, Omar, let me turn to you first to kick off with some initial comments on the report please.

MR. ISHRAK: Yes, thank you. Look, it's a pleasure to be here, and I would also like to congratulate the members who put this report together, and it's a lot of work done over a very short period of time. It covers a lot of guiding principles that I think we can all rally around.

Let me summarize some of those to start with, something that is important to I think most device manufacturers. First, and actually the whole ecosystem itself, the comprehensiveness of a system like this, you know, the need for that is quite clear. It has got to be patient friendly and it's got to be doctor friendly so that people actually use it and it can be scaled in that fashion. To do that effectively I think the only pragmatic way to do this is to make sure that there is a real linkage to EHR systems because there has already been a heavy investment in that area, they already carry a lot of data, and to, for lack of a better word, modify them, upgrade them to include more data fields to cover the sorts of variants that we have talked about this morning seems like a reasonable approach.

The second important point certainly from a device manufacturer prospective, but really from everyone's perspective, and something that has been touched on but I just want to emphasize the importance, is the importance of transparency and immediate availability of this data. You know, you cannot have any manufacturer be in the dark while this data is collected by somebody and then produced when something happens. I mean first that's not responsible, and second no one is going to accept that. So transparency is pretty important, and immediate availability is very important.

And from a manufacturer perspective the other side of the coin is true as well, and that if it's transparent then everyone should have access to it. Now the things that you've got to

watch when data is transparent in such a fashion is the standardization of the data and standardization of the analytics that govern that data because although in the long-term credibility will arise from the nature of the reports that come out of analyzing this set of data, in the short-term you can get abuse, or you can get unintended abuse of extrapolation of views that may or may not be accurate and can create a whole series of problems which are complete unintended and distracts from the whole affair.

Third, and something that has also been touched on is the importance of providing effectiveness in cost data as well as safety. I think if you are going to build a system like this it is going to be comprehensive and that comprehensiveness must meant that the benefit, financial as well as clinical, is covered through the system. And I think that is a very important point because there is parallel movement which should be somehow coordinated or even integrated with this effort, and that's the movement toward value based healthcare. Value based healthcare is basically saying that one should get paid for outcomes, while outcomes means you understand the efficacy and you understand the cost and you understand the safety, safety profiles of what you are going to do. So including cost I think should be a pretty fundamental requirement, which takes me to my final point which is discussing how does one pay for this.

We talked about many different angles of this, we talked about public-private partnerships, but let me tell you this, that if you want something to get paid for in essence an investment has to be made if you are going to have a return on that investment. And if we will be granular about where that financial return is, and this cannot be -- you know, investment and in a qualitative return you might get some people whose arms are twisted to invest in that, but you will not get enthusiastic endorsement unless you see a real financial return. And so a real effort into granularizing that financial return to who gets it and when it happens is very important if you want heavy investment in this area. For that reason I think while building a scalable system and having certain principles around the standardization, one should really pick off certain areas of priority where one can see line of sight to that return, whether it be because device approvals are accelerated, because everyone is on the same page regarding the value of such a system, and

therefore because the device approval is accelerated there will be a willingness to invest, because the financial return will be obvious, or is it because you get a lower cost in some other fashion because of some kind of incremental innovation. All of that would work. The other angle would be that is there a way in which we can replace the cost of existing system. The existing complaint handling systems and so on are suboptimal. Can we find a way to replace those and transition the cost of doing that activity with an activity that is more around overall surveillance, includes all the elements that we've talked about. There are obviously issues with that because going from one system to another you cannot just drop one and go to another because there are certain things that a complaint handling system does cover and you can't suddenly shut that down, from everyone's perspective. So the transition of that is something that has to be worked through carefully.

I think finally you have got to get payors involved in this, to get the payment system involved so that -- that's really the only way in which you can get a financial look at this; a financial look from the overall perspective I think is optimal.

I think that's really all I have to say. Thank you.

MR. MCCLELLAN: Omar, thank you very much. I'll turn next to Bill.

MR. MURRAY: Thank you, Mark. And I too would like to thank the Brookings Institution, Mark, and the Planning Board for the generation of this important report.

Medical device innovation consortium is a public-private partnership between government, including NIH, CMS, and FDA, industry and non profits. Our mission is to advance regulatory science throughout the total product lifecycle for the benefit of patients. This includes premarket as well as postmarket activities. Our work is grounded in clinical science and engineering. Robust postmarket real world evidence is an important tool in advancing regulatory science. In particular this is, as Jeff mentioned earlier, allows us to rebalance our premarket and postmarket requirements, and we think that will help advance getting safe, effective devices to market earlier.

In addition it can help inform clinical trial designs for future innovations as real

world evidence is in context of uses incorporated into the benefit risk decisions. This spring MDIC will be publishing a framework report on research that we have been working with in coordination with FDA and other stakeholders on incorporating patient benefit risk decision making into clinical trials. And we think that a postmarket surveillance system can help further that work and can be an important additional tool in this area. We also believe that an effective real world postmarket evidence system will reduce time and resources needed for development assessment and review as these tools and methods are incorporated into both the development and in the review process. And finally we believe it can inform reimbursement decisions as evidence of value becomes part of the information that's provided.

A number of people have already said this, but obviously the concept is highly appealing. The reality of implementation though is complex, and so developing a clear value proposition for all stakeholders will be very important.

We agree with a couple of the key points in the Planning Board's implementation approach. To start with, fact finding and pilot programs. I pulled up a data point. Back in 2009 CDC did a survey on national hospital discharges. There were 48 million inpatient procedures. We have to obviously prioritize areas where there will be high value opportunities from all the stakeholders involved. And so developing a clear and measured value proposition will be important. And then ultimately defining implementation plans for those technologies and therapies where benefit risk and evidence of value of framework can be identified. A multi stakeholder partnership we believe is the approach to do that with active engagement from FDA.

Workflow as well at point of care will be very important. We have seen in the medical device industry the challenge with post approval registries is often times are very cumbersome and difficult to implement and costly. Not only for the manufacturers, but for the caregivers and the patients. So having a system that is a balance of the approaches where standard data needs can be provided will be important. And this integrated system with infrastructures with these goals that have a clear evidence of value will be very important for adoption, not only for the manufacturer but also for the front line providers and the patients, which

is a very key consideration.

I would also like to bring up a couple of additional considerations that I think are important. Omar touched on part of it, but real time transparent access to medical device performance will require a new paradigm for stakeholder engagement and communication. Early data trends may not always be clear, and understanding what the data are telling us, and translating that information into relevant and actual activities will be important. This can often take time, so the early trends and indications may not always be ultimately clear on what the implications are. So remaining diligent in analysis of data and coordinating and communication will be important. Again I think an opportunity as we go forward with some of the research that has started in the clinical phase with patient centered benefit risk can be important additional activity as we look at this in the postmarketplace where we can take and extend on benefit risk decision making with both patient and caregiver communications. We think this is an important area.

Second, postmarket data can have a major impact on future innovation. Significant value can be realized by utilizing information to inform data driven, first principle regulatory science work. So what we're talking about here is not only how to use this to inform the performance of existing products, but how then to feed that back into development of new technologies. We think that is extremely important. Robust, real world data used to develop new design tools, methods, and processes will help not only for product development, but also for the product assessment activity. For example, improved computer models of simulations used in development can be used to evaluate new designs, especially in those areas where empirical testing and (inaudible) may not be fully adequate. And there are number of examples which sophisticated new technologies where it's not always feasible to do testing of all attributes of the device in human. So we believe that modeling the simulation can be an important tool to help inform future decisions in device development and assessment, and it will be very important for future innovations as we go forward.

So thank you for the opportunity to participate. I look forward to a robust discussion on this topic.

MR. MCCLELLAN: All right, Bill, thank you very much. And I'll go on to Lew now. Thanks.

MR. SANDY: Well, thanks. I too appreciate the chance to react to this important project and this event.

I come at this from a couple of perspectives. Mark introduced me as from United Healthcare and I think most of you know United Health Group has a large benefit business; United Healthcare about 46 million lives, but we also have Optum, our health services company which serves all the stakeholders in healthcare, about 80 million people, and Optum participates in the FDA Sentinel Program as a collaborator. So I bring that perspective. Not only a payor perspective, but also a surveillance and a safety perspective as well.

I think the first point is absolutely we need a more robust postmarket surveillance system and we need it for multiple reasons. You have already heard several people say that safety is paramount, but not only for safety. And U think the most important thing I think we need, and Jeff mentioned this in his comments, is what we need is what I would call real world evidence. We need evidence about how devices work in the real world not just in trials and not just in carefully selected patients, but in actual real world settings. And we need other kinds of information besides safety such as appropriateness, cost, comparative effectives. Omar, I agree with your comments. We need to know a lot about patient selection, who is getting these devices, and we need to know much more -- we have very limited infrastructure on patient reported outcomes. I think that is really critical as well.

The other piece about this report, and Omar touched on this as well, is we need to understand that this is not happening in a vacuum in terms of payment and delivery reform. There is a very rapid and robust transformation of the payment system and the delivery system to pay for value, which raises the question how do you define value, and in whose eyes is that value calculus being done. And I think again probably the most important thing in that transformation is it is not only the payor's point of view that is important. As payment models move to hold delivery systems accountable for cost, quality, and patient experience outcomes, the delivery system's view about

value is going to be important. And also as patients are more empowered, as patients have more financial exposure because of changes in benefit structure, the patient's point of view is going to be critically important as well.

And just to drive it home, this is not a theoretical exercise. Some of you may know about an organization that we started as a joint venture along with some delivery system partners called Shared Clarity. Share Clarity is a joint venture that is doing exactly what this system is supposed to doing, is being designed to do. It's a joint venture between United Healthcare and delivery systems to actually do the kind of comparative effectiveness analysis that is sorely needed and this system will respond do. And so I think that show it's not theoretical, it's practical and it's here now, the demand is here now.

So I totally agree with the need for this. It is critically important, but I do have a few comments in closing to the report. I think the most important thing from a data infrastructure point of view, Mark mentioned this and Kathy as well, is being able to connect individual device identification information in an electronic format to an individual patient. That information infrastructure can be used for multiple purposes. How exactly to do that, how exactly to connect the UDI to an individual patient identifier as to be worked out. Whether it's through electronic health records, through claims, through some cloud based architecture, through registries. I think that's critically important. And then the report spends a lot of time focusing appropriately so on high level principles and governance, which is great, but I think we all know that the devil is in the details here. What is the scope of this activity, how will it be financed, who owns the data, who has access to the data, how is it going to be paid for. I think one of the things I'm struck -- your comments, Alan -- we know for example in the drug surveillance experience sometimes a safety signal pops up, a sort of possible one, and then when you do analysis you actually find there is no safety issue at all. Well, how would that work in a real time device oriented infrastructure? I can just imagine in this world of Twitter and CNN what is going to happen to devices and manufacturers in that system. That really has to be worked out.

Last thing is I just completely commend and applaud the approach of using pilots,

of phasing it in. Jeff mentioned pragmatic, that is absolutely right. The perfect is the enemy of a good start doing some things, and I agree with Omar, that actually show this can work, show there's a tangible return, that will build both momentum and energy for collaboration.

So thank you. I appreciate the chance to share those perspectives and we'll go from there. Alan.

MR. MCCLELLAN: Lew, thanks very much. And go on to Alan.

MR. GUTTMACHER: And I'm really going to speak I think from three perspectives, but still observe the time limits. The first is from an NIH perspective, the second is from the National Institute of Child Health and Human Development, and the third is from a personal perspective. From all three of those perspectives I would say that this is really a wonderful effort. I would commend both Brookings, the FDA for driving this end, the group that put it together for I think a really useful forward looking kind of proposal.

From an NIH point of view -- I think in fact I'm going to quote from the report on page 21. There is a really very good section which I think briefly captures in a nut what the NIH is about in terms of this kind of thing, and how the NIH should really relate the MDS. It reads, "The MDS could support the research activities of public health authorities and other public sector organizations such as the NIH. The NIH supports development, design, testing, clinical evaluation implementation of medical devices as part of its mission. A flexibly registry based system could provide rapid access to clinical populations to accelerate proof of concept trials and to test expanded indications for existing devices. Registry data could also provide the basis for hypothesis generation and support scientific investigation. An enhanced postmarket surveillance system could also facilitate research to identify and ameliorate the root causes of adverse events and device malfunctions." I really think that encapsulates it very well. I think one way to think about this is that for the MDS to be optimal in terms of what it seeks to do, for the NIH to work optimally, and for device development in our country to work optimally, the NIH really needs to be an integral partner in this, clearly under the leadership of the FDA, but working closely. And clearly in terms of the governments that's talked about in the document, et cetera, I think those

kinds of ideas are really welcome and wonderful ones.

Let me say something from the NICHD specifically. Part of our warrant is to be in some way the focus at NIH for research involving both women and children. And pregnant women and children, I think as many folks in this room know, when it comes to device design, deployment, et cetera, and certainly in terms of follow up as well, has some special kinds of concerns. The issues of safety of course are more complex for both pregnant women and children. The fact that children have this nasty habit of growing physically creates certain challenges in terms of devices, the fact that the market is often a very small one, whether we're talking about pregnant women or children, of course creates other challenges. And the toxicities can be particular in these particular circumstances. So as this system is designed I think it important that pregnant women and children be considered from the get-go as one of the user populations.

Another research focus that we have NICHD is rehabilitation medicine. And while I think those who are using devices for rehabilitation reasons perhaps are not a unique population, they are a distinctive one in that, as is true of some other individuals, they will be using devices for very long-term periods often. And I think it's again a real advantage of the kind of system that's sketched in the report to have the true launch to the long-term follow up to really understand the implications of having devices for years and years.

Now finally as a personal note as someone who has a device for years and years, as someone who has had a pacemaker defibrillator living in my chest wall for the last 15 years, I would make several points. One is I think the report nicely talks about the importance of the patient perspective. And it really is important and I would emphasis it needs to be built in from the beginning. When we think about who are the end users for medical devices, I think we often think of we medical providers who put them in because we often guide of course decisions about who will have a device, et cetera, and which device. But in fact the end use is actually the patient. And I can tell you as someone who has put in devices and someone who has had devices put in, those are two different perspectives. And the perspective of the end user I think is very important that it be part of this to begin with.

Another point that I would make is that as someone who had his defibrillator put in 15 years ago, had a rather rudimentary discussion with the cardiologist who wanted to put it in about the risks and benefits. I can imagine that this kind of system would lead to much more informed discussions than the one I had in the future, which would be quite welcome.

And then finally as someone whose life has been save a couple of times by my device, but also has had an experience where a device malfunction created some financial, physical, and I guess psychic costs for myself, I don't see this in the report but I think it's an important point, that for those of us who have these devices if you should have a misadventure at some point, I think it will make you feel much better about the misadventure if you know that that is going into a surveillance system that will inform future device design, use, and in fact improve devices and patient lives. I would have felt better had I had great confidence that that was the case.

So again from all of those perspectives I think it is a wonderful report. And I guess maybe I'm going to segue to the other Alan on the panel to talk more about the patient perspective.

MR. BALCH: Well, thank you for that segue, and I apologize for messing up the (laughter) nice order that we had until you get to me.

MR. MCCLELLAN: It's quite all right.

MR. BALCH: Thank you. Well, let me very briefly describe the organizations I represent so you know the perspective from whence I speak. I work as the CEO for the Patient Advocate Foundation and the National Patient Advocate Foundation. Now at the Patient Advocate Foundation we provide direct support to patients who have chronic life threatening and debilitating diseases. We serve about 100,000 patients a year and we do that through some form of direct financial support, which is the primary reason -- for any of us who serve patients out there you know the number one thing that most patients are struggling with is the financial component of their care. The other issue that we help quite frequently with is access to care issues, and that covers a range of different fronts. So we actually do some help with patients who have devices or

are trying to get access to devices thanks to the support from patient centric organizations liked Edwards Lifesciences. So what we do in that process is we really focus on trying to help one patient at a time. And what we do in that engagement with them is try to collect a lot of data information about what they are experiencing and the barriers they are engaging and confronting in the system. And as you can imagine, as you replicate that tens of thousands of times over you collect quite a lot of knowledge about what's happening in very real time. We then try to translate that as best we can into opportunities for advocacy and policy so that we can scale up that one at a time experience, and actually look for ways to help patients on a much broader scale.

So with that when we look at these types of reports -- and thank you for the opportunity to respond -- there are really three key flashpoints that we look for, and I want to applaud the Planning Board for hitting all of them in a very comprehensive way. One is patient centricity. It's repeated multiple times in the report and alluded to on the panel already, so I won't repeat that here. I was pleased to see a lot of thoughts about patient engagement. That would be second pillar. So even specifically on page 54 there is a -- for those of you who are on line who maybe have access to the report -- I don't know if anybody has in the room -- there is even a little subtitle here, "Engaging Patients." And it talks about not just engaging patients in the design and in the process and how they input data and the opportunity for patients to be directly involved, but also in the governance and in the development of it. And I think that's very important. So a lot of patient organizations including mine put a lot of emphasis on patient engagement and patient input and we're pleased to see FDA and other organizations looking at opportunities to enhance that. And I think it's critically important. On page 35 is the schematic if you will of the governance structure which includes a patient protection advisory committee. I also assume that at the executive governing board there's some vision for including patient representation. My only caution there would be I would like see the -- to be -- just the scope of that to be beyond just patient protection. I don't know what was entailed in that, but clearly the value there is to patient goes beyond just protecting the patient. And I think my other comments will flesh that out a little bit.

The third pillar is value. And there are actually references on I think its page 56, it says "Patient Value" which I think is really important. And I think that speaks to the fact that the -- yeah, there it is, subtitle "Patient Value." So you hit them all. And then it's not just in those places, it's throughout.

But I think it's a very nuanced subject, the subject of value. And I think there are some comments already that were alluded to about this. When we look at value we certainly focus on safety and efficacy, and those are very important things. But we also look at value in terms of innovation. So one of the things that we know is that patients really want value to better medications, better devices, and they want them as fast as possible. So I certainly applaud Jeff's acknowledgements in his comments. I think when we look at value though it's not just about efficacy, it's about how patients perceive value. And I think when you talk about things like patient reported outcomes you have to beyond, when you're looking at it from the patient perspective, some of those raw sort of clinical outcome measures that we look at and try to think about what brings value to the patient. And often times the value is not -- breakthrough is great. We love those, that's what we look for. But incrementalism and continuous innovation is also important. And if you don't think that's important to the market or to consumers I ask you is there a breakthrough between the iPhone 6 and iPhone 5? It is certainly an example of continuous innovation, but look at how the market clamors to change and upgrade from one step to the next. So there is definitely value in incremental improvements in technology and the benefits to the patients that I would just want to make sure that is incorporated into the thought process here.

And a final point I would like to make, and this is a bit of a cautionary tale, and I think -- I actually wrote the words you can strike a balance which Jeff actually alluded to, and Lewis I think your comments as well. You know, there is advantages to the clinical trial process in the controlled environment which we gather that there are also disadvantages I think have been alluded to. Once you transfer to the postmarket environment there is a lot of benefit to gathering real world data from that. We certainly applaud that, but also understand there are dangers there as well in terms of the signals that may just be noise. And I think from a patient perspective we

always worry about what's going to happen from an access perspective if you get a safety signal that somehow gets broadcast and then there's overreaction. And now patients who are benefitting from that device or that drug are now facing access and coverage issues because of that signal that may have been nothing ultimately or may have been isolated. So that's just a cautionary tale. I'm sure that will be worked into the thought process here.

And a final point I'll make is still around value and innovation. There is one reference to value or the benefit to this from an innovation perspective on page 18 that said, "Access to new and novel medical technology is an additional benefit for patients and consumers." And I think you kind of alluded to it, Jeff. I guess what I would like to see more of is how would a robust postmarket system like this, how would that make sure that innovation is accelerated. And I think the concept is that you do less on the premarket side because you have a much more robust postmarket surveillance system. So I just would like to make sure as we are building this it's a great opportunity I think if the concept is to not try to build a huge barrier on the premarket side, but really use the postmarket side as a way to then get products and devices to patients faster, especially those that show great promise. And then you get those in the hands of patients, have a robust postmarket environment in which they'll continue to evaluate those. I know the Planning Board does not have much control on what's happening on the premarket side, but I would just make sure that all of us in this room who value access to innovative therapies and expedited approval mechanisms think about making sure that if we're going to support this that we are making sure on the premarket side that we're not erecting a whole lot of other barriers and trying to build a really big system if we're going to try to do most of the heavy lifting on the postmarket side as it relates to devices, because otherwise I think you are going to lose some of the opportunity of faster approvals and support for the expedited approval process that a system like this might bring. I know it's a nuanced point and those of you haven't read the report yet probably are going I don't know exactly what you're talking about, but those of you who have hopefully it resonates with you.

The last point is we actually engage in the help equity initiatives, that the common

denominator between the patients we serve as low income, they have an average household income of less than $22,000, about 66 percent of the patients, and I would just counsel to make sure that as you're talking about patients engaging in the system, particularly from a data collection and an information perspective, that you think about cultural competency and how the different levels of types of patients that you want to engage from an income perspective, from a data sort of savvy perspective, and from a racial and ethnic perspective, because not everybody is on the same playing field at all when it comes to engaging the system, especially from a data capture and a data utilization perspective.

So I'm at the end of my time. Thank you for the opportunity to comment on behalf of patients.

MR. MCCLELLAN: Okay, Alan, thank you very much. I go next to Jodi.

MS. DANIEL: Thank you. First I want to thank Brookings and the FDA for including ONC both on the Planning Board as well as on this panel. I also want to compliment the Brookings staff who really helped facilitate a robust conversation and incorporated a lot of diverse comments in a report to come up with a really good product. It was a lot of work and it was very much appreciated.

I want to make three points. The first is about the connection to the work on health IT infrastructure more broadly that I'm involved with at ONC, and the second and third are based on observations and trends I've observed over the last decade in working with ONC and I want to make sure are reflected in the longer-term thinking on this medical device surveillance system. Some of the points have already been made by some panelists, as well as from Kathleen in going through the report so I will keep some of those more shorter.

So first, in thinking about the medical device surveillance system it's really important that this is part of the larger infrastructure and that's something that is separate and apart from a lot of the activity that's going on, and this has come up in a couple of the comments already. It is electronic health records, health information exchange, a nationwide health information network for information exchange, are all important foundations for a lot of activities in

a learning health system including a national medical device surveillance system. It will be dependent on availability of clinical information as well as patient reported data. Again something that we're trying to drive to make more easily captured in electronic form and more easily accessible. It requires sharing of the information and it requires that the information when it is shared is shared in a way that it can be used for multiple purposes. So for clinical care as well as for public health purposes, and in this case for medical device surveillance.

ONC recently published an interoperability road map. We just put it out in January, so if you haven't taken a look at that I encourage folks to do so; we do have it open for comment for 60 days. And it bridges from looking at how do we make sure that information is available nationwide for clinical care purposes, but in the long-term, in the 10 year vision, is to support a broader learning health system. The road map talks about aligning efforts of the public and private sector, again it was a theme that was in this report. And it talks about the fact that we have pockets of interoperability, but trying to bridge from where we are now with pockets of interoperable electronic health information exchange to a broader nationwide goal of electronic health information exchange, which I think when we're talking about a medical device surveillance system we have to be looking at making sure that information can be available from lots of different sources from all across the country, not just the areas where we have higher penetration of electronic health records, higher exchange of information.

There are four areas of focus, and I want to talk about these because I think there are similar themes that were in this report and that were in the discussion the Planning Board had. For instance, standards. We want to encourage that as folks are looking at taking the next steps on the medical device surveillance system that we're looking at the standards that are already being developed and adopted for other health IT related activities, and that those can be leveraged wherever possible, or where new standards may be necessary that they are compatible with the other standards that are being developed and that this isn't happening in isolation. Again, looking at compatibility and reuse wherever possible. Governance, which is something that we've talked about in interoperability and is something that was talked about in this report. How can we think

about connecting some of the thinking on governance for MDSS and health information exchange more broadly. Incentives for information sharing, again thinking about the value proposition that Omar had mentioned. And then privacy and security. Again we had some of the same conversations in the Planning Board discussion a has been happening more broadly with respect to health information exchange and use for a variety of public health purposes and a learning health system.

So the overarching point I want to make on this is that we have to make sure that the efforts here are connected or at least complementary with the activities that are going on more broadly across the country on health information capture and health information exchange and health information analytics. We're going to have to connect a lot of the disparate activities if we want to get to that broader vision of a learning health system, and I think that this effort can be an early example of how we can leverage the infrastructure that we're building for health information exchange more broadly to support improvements in knowledge, research, and products as well as healthcare.

Okay, so the second point I wanted to make is about consumer information and I think both of the Alans on either side of me have made those points very clearly as well as some of the other speakers, but we have really seen a shift in healthcare from a provider centric approach to a more provider and patient engaged approach over the last decade since I've been working at ONC, but the shift started happening I would say a few years ago where this has become more central to the conversation rather than sort of an oh, yeah, and. I think it's really important, and this came up a lot in the Planning Board discussion and is represented in the report, but I wanted to reiterate it that making sure that the patients are part of this system both in collecting and contributing information as well as getting back information so there is a value to the patients I think is critical, and I think will help prove success of these efforts.

And the last point I'd like to make is about future proofing. That as we're setting up and thinking about a medical device surveillance system we have to think about the fact that the technology, the way data is captured, the way that data is being exchanged, the way patients

are engaging with technology and information, is changing so rapidly, and it will be changing as we're trying to put this in place. So as we're thinking about this, making sure we're thinking about not creating systems that kind instantiate the status quo but that can adapt over time. We have seen just in the last five years I would say changes where everybody has mobile phones, smart phones, and have M health apps, remote devices, wearables, Internet of Things, so many changes in such a short period of time. The way we think about capturing data, the way we think about sharing data, and the way we think about analyzing data is going to change dramatically in the next decade. And as we're developing this system we should be thinking about how best to make it nimble enough that it can adapt with the changes in those areas. I think also some of the changes that we're seeing will improve efficiency and potentially reduce costs in collecting information and analyzing that data. And we want to be able to make sure that a system that is put in place can take advantage of those efficiencies as well.

Thank you.

MR. MCCLELLAN: Thanks, Jodi. And thanks to all of you for your careful and thoughtful consideration of the report. So of you may have been very impressed with Alan's specific page annotations. I do want to let you know that we did actually give the panelists an advance copy of the report so they didn't have to come up with all of this just in the last few minutes. But they all took a very diligent look through the report and I was impressed by how much the comments focused on connections between activities that they all have underway and the recommendations in the report. I wanted to follow up on a couple of those things starting with something that almost everybody mentioned which is the need for laying out a clear value case for this new public-private collaboration around national postmarket device surveillance. And to Lew and Omar in particular since in building on your experience you all already have efforts underway that pertain very directly to the kind of safety benefit as well as other information relevant to medical products, relevant to the shift towards value that you both emphasize in your remarks. And I wonder if you would mind expanding a little bit on how this effort, based on your own experiences and your sense of where we can go from here, how this effort can best reflect the

need for all of these types of evidence coming together, and as Jodi emphasized, using data that are collected once for multiple purposes. In particular FDA is focused on the risks and benefits of medical devices for its regulatory mission of protecting and promoting the public health, but you all have also emphasized issues related to costs, to resource use, to value in the real world. You already have activities that are underway. Lew, you mentioned Shared Clarity. Omar, I know you all have pilots underway focusing on this shift towards a real emphasis on value. How does this national effort connect to and best build upon these efforts that you all have underway already and how can we recognize that there are some issues and evidence coming out of the system that will be particularly important for FDA, but other aspects that are going to particularly important for other stakeholders, patients, clinicians, value focused healthcare systems?

MR. SANDY: I will make a few comments, Mark. Thanks. I guess the two things that come to mind have to do with -- to your point I think one of the principles is it's always good to build on what's already out there. I just think not just from a technology point of view but from an experiential point of view. Shared Clarity for example, some of the things that I guess could be lessons learned, first it's an example itself of collaboration across sectors. So I guess I would sort of learn more about how that works. The second thing is it's a pretty focused effort. It is not trying to boil the ocean, it essentially does a Pareto analysis around what areas should this effort focus on that will have the highest return, that will give the kind of use case, that value proposition that Omar mentioned.

The other one that is -- well, I'll put it out there because I'm not sure how it fits -- Share Clarity is not just an effort to actually do comparative effectiveness research to inform the stakeholders of that effort, it's also an effort that is foundational for a volume purchasing arrangement. So the delivery systems in that group have come together to say we're going to compare devices along different kinds of outcomes, and when we find the one that we like best we're going to see if we can get a better deal from the manufacturer for that particular device for our system, just like any other group purchasing arrangement. I think that's kind of out of scope for an FDA led surveillance system; however, I just think it's important to keep in mind that that is

of interest because it is part of the value proposition itself, its part of the value proposition for all the stakeholders.

So I think there are some lessons learned and again I just would learn from the things that are already out there is I guess my summary comment.

MR. ISHRAK: I think including innovation into the picture is pretty important, and that's the way you can get quick traction from a lot of different stakeholders. And by that I mean the value proposition that innovation brings, if you can have a comprehensive, multiple stakeholder alliance of that and define value in financial terms and what each stakeholder gets from it, I think you could use this kind of system as a platform to drive that.

Today when we try to create our value based programs we essentially look at three or four steps. We define a disease or condition, we define a time horizon over which we can get value, we try to under those circumstances baseline current status in terms of benefit and cost, and then have goals regarding how we can improve those. Now if you really try to follow those steps you are actually limiting yourself today if you limit yourself to just two parties because often the time horizon will be limited because by definition a lot of the value sometimes resides much later than the delivery system gives value for. So if you build a system like this and include lots of others, follow a certain framework, it will broaden the sorts of activities that we're doing by far because we're very limited.

MR. MCCLELLAN: And this is a question I think everyone on the panel might address, but let me specifically focus on some comments that Bill and Jodi made. Bill, you emphasized that some of the activities today for developing this postmarket evidence are pretty -- I think the term you used was cumbersome in terms of the registries that are in place now. They don't do what Jodi laid out in the -- are described in the vision for an interoperability road map, of a quick ability to capture from electronic system the key information that's needed in a standard way to put into the kind of frameworks that we're talking about here. This is for both Bill and Jodi, so based on your experiences so far any suggestions on how the public-private partnership around medical device surveillance can best and most quickly facilitate reducing those costs and fit in with

these other existing efforts that obviously all share the goal of developing better evidence at a lower cost, that turns out to be challenging in practice.

So, Bill?

MR. MURRAY: In the report it suggests both fact finding and pilot initiatives, and coming back to evidence of value for all the stakeholders, so I think to the extent that when you get to the point of care clear evidence of value for patients, for care givers, for the manufacturers. And that's where the benefit risk paradigm I think comes into place. So for those technologies where there is a real opportunity to have an impact when the data are collected. So collecting data for data's sake is not necessarily going to be where the benefit is. Collecting data that can be actionable afterwards I think is going to be extremely important. And using benefit risk for that I think is an important --

MR. MCCLELLAN: And that's very much driving what you're doing now, focusing on clinical trials where you -- let's get the evidence collection where the benefits outweigh the costs.

MR. MURRAY: That's exactly right. So rebalancing pre and postmarket, and also in the patient centered benefit risk assessment. And one of the things that came out from some early research that FDA did in the obesity field is that patients had a higher risk tolerance than maybe the agency did, and actually the manufacturers in some respects. And so bringing that into the equation I think can help inform where the opportunities and real benefit can be in the early stages.

MR. MCCLELLAN: Jodi, that fits with where ONC is headed?

MS. DANIEL: Yes. And I would two comments to your points, Mark. One, as I mentioned there are areas where we have a lot of interoperability in the country and a lot of sharing of health information, and others where it is more rudimentary. We also have some challenges of getting information from one place to another as opposed to within a particular region. In the report there is conversations and folks have mentioned having pilots, and perhaps it would be wise to start pilots in areas where the technology advancement and the sharing of

information is more ingrained into the clinical setting, where they are working a little bit more with engaging patients using digital technology, so that we can start taking advantage of some of the kind of the areas where they are a little bit ahead of the curve in this space. And I think that that might help structure the locations or the area where pilots might be most effective.

The second point I would make is that the report talks about a governing body or a governance structure, and one of the key areas of focus for interoperability road map is governance for health information exchange more broadly. Obviously because we are trying to walk before we run we are focusing in the next couple of years primarily on clinical exchange of health information, but we want to do that while thinking to the long-term as well so that we're not setting up structures that are policies or practices that are limited to that use case, but that can go to broader scenarios of a learning health system including medical device surveillance.

So I would encourage if we're taking the next step and thinking about governance for an MDSS that we make sure one, to connect with my office, but also as a we are trying to set up a governance structure for health information exchange more broadly, that we connect the dots, perhaps include somebody from FDA or somebody who might be involved in trying to set up that governance structure into the broader governance structure for a nationwide health information network.

MR. MCCLELLAN: Thanks. Alan, do you want to comment on this?

MR. GUTTMACHER: Yes. You mentioned at the beginning, Mark, the precision medicine initiative, and I think in some ways in terms of the last question if it goes forward as people imagined, you probably know that the larger element of it is a million plus person longitudinal cohort. And while clearly it has a different focus, somewhat different structure from what we're talking about in terms of the MDS, many design characteristics, at least the desirable ones, are quite similar. And there certainly should be conversation back and forth depending upon the timing of each of these, I think learning from each other and perhaps even doing some things jointly in terms of the design, clearly in terms of the interoperability and other kinds of features that one would want to have in both system. And also once that gets launched even though it's only a

million people -- first of all I think many of us suspect it will grow to be much more than a million people -- many of those people will have medical devices. And while this certainly wouldn't replace the MDS those folks will have built in this system very robust phenotypic and other kinds of medical data, et cetera. So to take advantage of that, whether it be as pilots for some for what MDS might do, or simply to accrue even more in depth data about some of the folks who have the devices, I think it's another resource that shouldn't be over looked.

MR. MCCLELLAN: Alan, thanks. That's an interesting idea for a potential early pilot. Let me go to the other Alan -- Balch. The report as you mentioned does talk about potential pilot activities involving new kinds of patient collected data which seems I think it certainly was the Planning Board's view that if you really want to shift to a more patient centric system that early pilots should focus on exploiting these now rapidly expanding but as yet not very systematically used sources of data on risk, benefits, costs. You're focusing on a lot for patients. Any further thoughts on how to really make sure that that fits into the early pilot efforts since that seems like everybody here wants to focus on practical steps forward?

MR. BALCH: So just to be practical and not necessarily that we would -- we're happy to be in the conversation potentially, but there are other organizations out there as well like ours that are in the trenches directing with patients every day doing some sort of real world data collection. So I would encourage the Planning Board as you're looking at the initial pilot proposal and the incubator period to look at opportunities potentially. Now we don't do it at any level of sophistication that the government systems do or the clinical systems do, but it would be an interesting thing to at least look at to see what opportunities exist within the patient advocacy organization space to collect real time data or try to capture some of that and help it at least inform anecdotally perhaps what the system is gathering.

MR. MCCLELLAN: Thanks. I would like to open up this discussion to those of you here in the room. So we are going to have microphone going around. If you have a question please just raise your hand and then I will try to call on you for any particular topics. I see one up here. And if you could say who you are and then ask your question quickly so we can get on to a

number of comments.

MS. YOUNG: Thank you. My name is Dee Young. I have two questions. One is the public-private partnerships trading information almost everywhere, every study, every project. I just wonder how do you value or decide where is the beginning point and where is ending point? How do you share public and how do you share the private (inaudible). Whether the public really have percentage share of their profit?

The second is about security. I think this kind of IT probably have a lot of deterrent elements, but I just wonder if there will be hacked or interrupted or manipulated by unauthorized person. And how do you determine the patient care from their own based on the treatment at that point and the potential storage and benefits?

MR. MCCLELLAN: Thank you. So two very good questions on public-private partnership, how do you do that effectively, and how do you make sure there's an appropriate role for the public and the private side. Bill, do you mind if I turn to you since you all have some extensive experience on that recently and then other people on the panel are welcome to comment as well.

MR. MURRAY: Since we're a public-private partnership I guess it is appropriate for me to answer this question. And its engagement of all stakeholders, and the challenge on the public side, on the patient in particular, is going beyond the individual case to a more systemic approach in finding organizations that have a patient centered approach to the systems aspects of this. And so we've engaged with groups like the National Health Council, Faster Cures, National Organization of Rare Diseases, as groups that are working out on and advocating for patients. And then the public group obviously as I mentioned before we have NIH, CMS, FDA at the table, and then we have industry partnerships. So it's really bringing all of the constituents together and the opportunity is to have shared voice discussion as opposed to if you will (inaudible). It's getting everybody together and identifying and agreeing that this a problem we want to work on, and then brining the stakeholders collaboratively together to do it. And I think our experience has been -- and we've seen some recent results in terms of surveys that would say that this is having a

positive impact in terms of both improving the quality and performance of devices, but also on the innovation pathway, especially on the regulatory side. The reimbursement is still a little bit of a challenge.

MR. MCCLELLAN: Yeah. Just to add that -- and, Omar, if you could comment on this well, on another point that I know has been a big issue for you and for the other public-private partnerships that we study is transparency, so making sure that it's easy for anyone who is interested to get access to what's going on and there's an opportunity for full participation. And then kind of a reminder that because these public-private partnerships accomplish some things that government can't do it's not diminishing the role of the public sector, so FDA in these cases still has exactly the same responsibilities and authorities it had before and the intent here is to provide more support, more scientific evidence, more technical clarity, and have more resources behind accomplishing those goals.

MR. MURRAY: Yes, that's a good point, and thanks for bringing that up. We work in the pretty competitive space on regulatory science, and so it does not at all have any involvement or scope that goes into the product review and approval mission of FDA.

MR. MCCLELLAN: And here too is envisioned for device surveillance, this is evidence that FDA can use, but it's still FDA making the decisions, the regulatory decisions, not any public-private partnership. Omar?

MR. ISHRAK: Well, I think on this point there are two aspects of a public-private partnership and we've only really touched on one here. And we've touched on the governance aspect, that that's what we really talked about, that everybody is involved, that everyone's view gets engaged and you govern it through both public stakeholders and private stakeholders. I think, though, there is another aspect to this which is more specific which could be a sort of an adjacent public-private partnership building off this model which takes into account very specific value propositions. And there, if I can take an example, two examples, one being where you get accelerated device approval. Well, clearly the FDA has to be involved in that, that's the public part of it if you like and the private could be the delivery system, the manufacturer, and the payors who

could benefit from that accelerated device approval, but you better tie down what it is you're trying to do and what value you get from it, and create a real venture between these organizations so that each of their financial benefits or other benefits that they are looking for from this, they can get in a very clear fashion.

Another example could be just working with Medicare or Medicaid in some very specific area where there is a public organization who is actually a payor. And so working together the delivery system and the manufacturer do to come up with a partnership that delivers again some kind of value based on this kind of system is another kind of public-private partnership. So there's one which is governance and another which is true business creation.

MR. MCCLELLAN: Identifying that shared value.

MR. ISHRAK: Identifying shared value and creating a business around it. I don't think the two are different, but they are not mutually exclusive. In other words we can build one on the other.

MR. MCCLELLAN: And important to consider both. And just if we do have time at the end -- I will give you all a little bit of advance warning -- I was thinking about a lightening round final question to this point on okay, what are some -- give us an example of this kind of high value area where the MDS public-private partnership should be thinking about its initial focus.

But before we get to that, very good question about protecting privacy and confidentially of patient data. Does anybody want to comment on that one?

MR. ISHRAK: I think that's actually a very important point. And I think maybe in the governance structure and stakeholders we've got to get some real experts who are focused as functional experts on security (audio skips) that one.

MS. DANIEL: I will comment. I think it's actually a really important point. It's something that we are struggling with as well with respect to health information exchange more broadly. When we talk about interoperability of health information and sharing of health information, the technical challenges are there, but the real challenges are trust that the system will work as intended, that the information will be secure and protected, and it will be used in ways

that meet people's expectations. And I think it's actually one of the most critical things that we need to deal with, both for this system as well as for health information exchange more broadly, is how do we ensure a level of confidence and trust that the information is protected at the right level and that we can't prevent all security breaches from every happening, but what's the right level of security that strikes the balance between making sure information is available for important public health needs, but also protects the information from unauthorized uses. So I think it's a very critical question. There are conversations at the White House on this topic, on the Hill, and I think it's one of the things that a governance organization, a governance body will have to address. It's something that has occurred in the health information exchange efforts that have taken place to date where everybody has agreed to a particular level of security so that the information can be share comfortably between different partners. So I think you raise an important point and it's something we should make sure is appropriately addressed.

SPEAKER: And that we be transparent about whatever that level of security is --

MS. DANIEL: Correct.

SPEAKER: -- so that everyone involved in the system knows both what it can do and what the limitations are.

MS. DANIEL: Correct.

MR. MCCLELLAN: Right. So this is highlighted in the goals of the governance part of the organizations as you all noted. We'll also come back to this topic this afternoon I think when we have some discussion more extensively around how this effort fits into other efforts to develop better evidence while protecting patient privacy and confidentiality in the healthcare system. For example, I think Rich Platt will probably talk or may take a bit about some of the efforts that have been undertaken in the FDA Sentinel Initiative on Drug Safety in which the patient identifiable information largely stays at the source and that what comes out of that system is really just the summary information on patients exposed to a drug and the rates of adverse events.

So, other questions? Yes, up here.

MR. DILLON: Ken Dillon, Scientia Press. I'm wondering what is the international

dimension of all of this if any. Do we have things to learn from other countries, are they coming to us to learn, are we collaborating with them in any way? Surely the manufacturers are dealing worldwide.

MR. MCCLELLAN: Comments on that? I know many of you are involved in global efforts, Omar, Lew, others.

MR. ISHRAK You go first, Lew.

MR. SANDY: Why don't you go first. (Laughter)

MR. MCCLELLAN: It's a very polite panel, isn't it?

MR. ISHRAK: It's a tough question. Look, obviously there are governments around the world and healthcare systems around the world where similar efforts are taking place. I think the UK with -- and also some other activities are going on there. I have done some useful work and we are learning from those, but at this stage I think you've got to do this country by country because it's complex enough even within one country. You start bringing in global stakeholders into the same programs, it's just going to get too (audio skips), but you can learn from others and do parallel approaches with some selected countries where they have a desire to do this. But we can achieve a lot just by doing it just within the U.S.

MR. MCCLELLAN: So data sources, data infrastructure, and governance national, but international opportunities to develop methods, compare findings, look at best practices.

MR. ISHRAK: We can both try to certainly from each other, but if you make it an international data source will make it very difficult.

MR. MCCLELLAN: Lew?

MR. SANDY: I would add I think probably the one thing that comes to my mind that we can learn from international efforts have been around registries. Internationally the use of clinical registries is much more advanced than in the U.S. There is broader depth and scope of those registries to really inform patients of informed practitioners about what is best. Having said that I do agree with Omar. I do think we can learn from that, but each country has its own

regulatory approach, and they have their own views around privacy, different regulatory structures around privacy. So I think we can learn, but I think we have to start with what works best in the U.S. given our environment.

MR. MCCLELLAN: Time for one more question and I'm going to -- back here.

MS. MCCOLLISTER-SLIPP: Hi there, Anna McCollister-Slipp. I have a company called Galileo Analytics, but I'm here as somebody who lives very close to here and is a nerd and as a type 1 diabetes patient. One thing that I often said is that the best people who can report issues with our devices are the patients. And while diabetes devices are different than some of the other implantable devices there doesn't seem to be that much of an effort to incorporate the knowledge of the crowd of patients and the community of patients. And I was wondering -- I mean as for those of you like Jodi who worked with me on FDASIA work group, one of my favorite models that I used to talk about is adopting sort of an app store approach to issues reporting so that we could get a constant iteration and a feedback loop between the users and the manufacturers, and enable this constant iteration that has propelled consumer technology so very, very effectively. And I was wondering if the Planning Board and the others involved in this effort at this point has looked at any kind of crowd sourcing ask model. Obviously it doesn't exist now at FDA, but the technology has changed tremendously just in the past couple of years and I would love to see the sort of -- whether its patients or physicians, the sort of crowd sourcing based model so that we can find out issues faster. And I think that would be better for agency, that would be better for patients, and physicians.

MR. MCCLELLAN: Yes, I speak on behalf of the Planning Board, I can say that they definitely considered and want to incorporate in this program crowd sourcing or other patient reported information into the systematic approach for surveillance. That hasn't happened yet, but the potential is there. I think Sally Okun may talk later on today about some of the adverse events and other information that patients like me capture as you all probably get more adverse event reports at this point than the FDA. But I would like to hear from any views on the panel about how to go about incorporating this kind of information. Very good, challenging question.

MR. BALCH: I think it's a great concept, I think it's worth considering, and I would just sort of dovetail that with my earlier point about there is a lot of opportunity from the application and sort of crowd sourcing and social media component, but there are still a lot of people that have devices and have need for these that that kind of technology, that kind of approach won't work. I'm sure you didn't mean to suggest that would be the only thing, but I think as you're doing those kind of things that could potentially reach a certain patient population in a very direct and real time interactive way which might be interesting to consider if not anecdotally, you know, but also to consider other ways to reach more difficult -- and that's probably the -- that's a challenge in and of itself.

What's even more challenging is how do you reach those populations that aren't as connected to that type of technology and aren't going to engage. And the only reason I bring that point up is because I think there are certainly access barriers, there's much to learn from those who are engaged in that sort of social media environment, but it does tend to be -- if any of you do on line research kind of know the difference that you get statistically between an on line population typically and say a phone based survey or if you're sort of taking calls from patients who have a need. Of course that's selection bias, so again can't be part of a robust system, but I do think you do start to encounter the patient population that is most likely to be out of the access loop as well and encountering a lot of barriers, not just from a maybe safety or efficacy perspective, but are encountering other barriers that are wrapped around that.

So I just I think to make sure that that whole perspective and the continuum of perspective from the patient population needs to represent everything from those who are accessing the system through the hospital system, those that maybe can provide information from some sort of crowd sourcing of social media, but there has got to be -- and it's really hard to do -- how do you reach that patient that is most likely to be on the periphery of the system and getting lost in the system or falling through the cracks of the system. They have a lot of value to add too. And I only bring it up because I think you're seeing this -- we do worry a lot about health disparities and that's a very important point, but I think the risk with accelerating innovation is you don't want

to as part of accelerating innovation is accelerate the gap between the haves and the have nots, and those who have access to good coverage and those who do not, you know, who may have coverage but may not necessarily have good access. So I know that's another one of those -- boy, if you had an answer to that question -- I call them the grassy knoll questions or comments like I'm just throwing out something that nobody knows how to do, but hey it's nice to talk about it. It's the Brookings Institute, we can be sort of academic here.

MR. MCCLELLAN: Well, we definitely want to include that. Jodi?

MS. DANIEL: I would make one point since I was on the Planning Board as well as on the panel. There was a lot of conversation about how we bring in the insights from patients, the information from patients into an MDSS. And there is a lot of support for that and for trying to do that right and do that well. I don't think that the Planning Board necessarily identified the best way to get patient information. And I think to Alan's point there may be multiple ways of doing that and not just one way. Social media may be one way. You know, maybe there are mobile health tools that are another way, et cetera. But one of the points that was made in the report is that in the governance structure it's critical to have patient representation on that to help raise those issues and to help identify what might be the best mechanisms and the best ways of trying to get the patient information and the patient perspective into the analysis and into the information that's being shared for an MDSS. And so I think you're one step ahead of where the Planning Board probably was, but there was a strong recognition that patients needs to be part of the discussion, the governance, as well as the data and the output so that it is benefitting -- one, we have the best information possible and two, that we're providing a benefit to the most important entity in this whole thing which is the patients that are benefitting from the devices themselves.

MR. MCCLELLAN: We are about out of time. It has been a great discussion focusing on practical considerations and next steps. Lightening round as I warned you before. Final thoughts very quickly on specific things that should happen in this process to make sure we get to that clear value proposition quickly.

Omar, start with you.

MR. ISHRAK: Well, first like I've said before pick up specific projects for defined value propositions with clear stakeholder benefits and go forward, but actually the last comment raised certain thoughts. And the way I'd like to go with that is to say that speed and agility in this process is paramount because the sources of data that we have today two years from now, five years from now will be different. And we've got to have a system that adapts to that otherwise you'll build a system for 2010 in 2025, and that's not going to work. So speed and agility is the one that I would say that get moving on something (audio skips) defined value and go do it.

MR. MCCLELLAN: Great. Bill?

MR. MURRAY: We talked a lot about evidence of value and benefit risk and I think to go along with that or to complement that is identifying where once we put this basic infrastructure in place, where there is also clinical diagnostic infrastructure that is already established and developed that can be useful tools of information. So if you're developing a hypertension device having blood pressure is an important thing, but if we're developing a new breakthrough technology there may not be the analytics in place yet. So identify areas of focus where there's analytics available that will be valuable when you get done with a process.

MR. MCCLELLAN: And actually answer the practical questions. Lew?

MR. SANDY: Two, safety and innovation. I would like as soon as possible to be able to have a robust system that uses the UDI so that if there is a safety issue we can alert the population of patients that has that device, either to notify them or for a recall. So that's number one.

And then the second on is innovation. Very typical kind of conversation, United Healthcare will have, an innovator says we have something that is better. Yeah, it's much more costly but it's better, and we say well we actually don't have any evidence that it's better or we have insufficient evidence that it's better. If this system can help create the infrastructure so that when someone says it's better in this respect, this respect, this respect, we can rapidly get that answer so that we can have an informed decision at a policy level, that would be a real win.

MR. MCCLELLAN: Thank you.

MR. GUTTMACHER: I would say that one of the real benefits of this would be better research of many different types, and therefore we should have researchers of many different types be involved in the design of the system to make sure that happens.

MR. MCCLELLAN: Thank you.

MS. DANIEL: So I think my key point and take away is making sure that as we're taking the next steps that we're building on the infrastructure that's already starting to flesh out for health information exchange more broadly. Looking at the standards that already exist and reusing them wherever possible, reusing the infrastructure wherever possible so that we're not reinventing the wheel, and that we can improve efficiencies in the system and put patients at the center of this whole system because we will get better results and more value to the patients if we do.

MR. BALCH: A similar comment, I think the Planning Board was very much on the right path already by really making this a very patient centric effort. And I think the more that that continues throughout this whole process, that the patients are at the center, not just in terms of the value that they may derive as one of the end users, but really as an active member and an engaged member of the process. And not just your typical patient, but trying to cast a pretty broad net to capture a pretty broad patient perspective representative of the different types of income levels and racial and ethnic disparity issues across the organization. I know that's hard to do, but I think the end product will represent more something that will be useful to all patients if you look at it from that sort of approach.

And the other point that I would make very quickly, and I've made it already, so I won't belabor it, but the patient value pieces, make sure that as you go through this process thinking about patient reported outcomes and clinical evidence that the value -- you think about how, and we have some data that we can share, and others do, about how do patients perceive value, which is often times a very different thing than thinking about the outcomes data or the efficacy. They are inter related but you can get a very different answer from a patient when you ask them did you value the care that you received. So just to give you a little anecdote, when we

asked that question of our patient population, it's kind of like when you ask people do you approve of Congress? No, no, don't like Congress. Do you like your Congressman? Oh, I love him. So we get the same sort of response. Do you like the system, how is it working for you? No, not working for me. How is your care, did you value you your care? Oh, 10. My provider was a 10, my healthcare team was a 10. Well, I got great value of care, even in patients who may not be seeing the outcomes, that are not in remission. So I think that's just an interesting point to keep in mind, that value from a patient perspective may be a different way to look at it than how clinicians or providers or other evidence based groups may look at it.

So thank you for the opportunity.

MR. MCCLELLAN: And I would like to thank you and the rest of the panel for the very thoughtful and constructive initial feedback on the report. It gives a good foundation for going forward. Thank you all very much. (Applause)

MR. McCLELLAN: I do want to emphasize that the kind of feedback that we heard here, this initial feedback on the report, is something that we'd like to hear from many more of you on. The report is available. FDA will be providing an opportunity or a notification about how to make comments or provide input on the report to guide the efforts from here on out. I'll say more about that later as well.

Right now, though, I want to turn to a topic that's already come up extensively in the context of this medical device, Postmarket Surveillance Systems, and that's how it interacts with medical device innovation.

So, as you've heard today, medical device surveillance is about identifying and addressing potential safety issues involving medical devices much more effectively than in the past, as well as understanding the benefits of medical devices in actual practice more effectively than in the past.

But as the last panel emphasized, in order to help create the maximum value from this system, it would be very beneficial to have an infrastructure that can also help provide more rapid answers about greater value, and that can potential have important implications for creating

a more effective and perhaps more balanced system for regulating medical devices in both the premarket and postmarket context.

So, in this session, we're going to try to focus much more on medical device surveillance and its implications and potential benefits for medical device innovation, and with that I mind, I'd like to introduce three people with very extensive experience and expertise on this critical topic.

Aaron Kaplan is a professor of medicine and cardiology, and he's the director of the Dartmouth Device Development Symposium, Director of Research for the Cardiology Section of the Geisel School of Medicine and the Dartmouth-Hitchcock Medical Center.

Ross Jaffe is a managing director at Versant Ventures. He's also been very much involved in the medical device innovation collaborative and a range of other issues across not just the investment industry but the broader community that is focused on accelerating and proving the process of medical device innovation.

And Mike Mussallem is the chairman and CEO of Edwards Lifesciences. You already heard Edwards' reference earlier for its involvement in efforts to develop better evidence. And just as a reminder for those of you who don't know, Edwards has been a central player in the TVT Registry for Transaortic Valve Replacement, one of the most extensive examples we have in the United States today of an extensive Postmarket Surveillance System that has provided a lot of insights but also a lot of potential for learning on how we can do this better and more effectively going forward.

So, once again, we're going to start with some brief opening comments and framing comments from each of our panelists, and we'll have a little bit of discussion before breaking for lunch.

So, Aaron, let me turn to you first.

MR. KAPLAN: Thank you Mark.

First, I really appreciate the opportunity to participate and want to echo other folks' congratulations to both Brookings and the committee for their leadership and the work. This is a

very important area.

As Mark told you, I'm Aaron Kaplan, professor of medicine at Dartmouth. I'm an active interventional cardiologist. In fact, I'll be on call this weekend for the Cathlab, which will be focused on providing acute infarct care to patients in Northern New Hampshire and much of Vermont.

I'm also a medical device entrepreneur. One of my companies is developing the first dedicated coronary stent to treat bifurcation lesions as in the final phases of the IDE PMA process.

The clinician in me understands the importance of this interventional cardiology community. We have been very fortunate in terms of the rapidity in which we've had available new data and new technology which allows my group this weekend to provide acute infarct care to patients, which has changed demonstratively over the last 10 years and over the last two decades have really improved dramatically the outcomes of patients with acute infarcts with dramatic reduction in mortality and reduction stay, providing real value to the community.

As an entrepreneur, I know how important these efforts are as well. As an entrepreneur, I can tell you that I'm involved in some early-phased companies and that this is among the worst environments I've seen in the last 20 years for launching new enterprises. I know Ross will talk about this in a more informed manner, but one of the reasons is the long cycle length it takes from initiation to getting investment, to getting things into the clinic and the market, to get the kind of feedback that we need that really drives the innovation cycle. This is crucial, and I think that this report, which really focuses on leveraging very large investments in the electronic medical record as well as in UDI is crucially important.

I'd like to give two examples of where the postmarket has served us well -- one where it served us well and one I think where there's a real benefit for what we can do.

So, one that's been alluded before has been TAVR. As interventional cardiologist, I've seen a dramatic change in how we treat patients with aortic stenosis, really addressing a real important unmet need in that the postmarket portion of that with the TBT Registry has been very

impressive, and this has taken real leadership from CMS, FDA, the academic community with the STS, and other organizations and from industry.

Mike and his crew have done a lot of work on this, working very closely as well as has Medtronic, and I see this in my team that is delivering -- actually, on Wednesday we'll be treating three patients, two of whom we would not have been able to treat without that.

And the learning cycle: We're doing things differently and presumably better -- and our outcomes show that today -- than we were doing a year ago.

A case where it hasn't worked as well I think could be in left atrial appendage closure. This is a device which provides an alternative to oral anticoagulation in patients with atrial fibrillation or a high risk for stroke. This is a huge problem. The chances are among us overwhelmingly that one of us will have afib and require stroke-reduction therapy; and in this room, there are probably 30 of us. The stroke risk in some of these patients is nearly 50 percent, and these are huge strokes. Anyone who's taken care of or had a loved one who had a stroke -- a huge emotional problem with a very large health care burden. These new devices have been in the clinic for 10 years.

There's an emerging set of data that I think there's consensus opinion on that there's an important role that the first generation device can play today. However, the FDA is in a terrible spot.

Jeff, I don't (inaudible) you're in a difficult position on your team in terms of deciding what to do here going forward, because despite this consensus opinion there are some real issues in terms of the data provided to us. And there have been three panel meetings, and the inability to get this into the clinic has absolutely stopped next-generation investment. The other players are waiting to see how to get clarity, how to get to the clinic. And this has had a very chilling effect.

There's no doubt that the vocabulary that could be provided to FDA provided by things outlined in this report would allow the flexibility to really move forward in this to be able to learn to address an immediate unmet need but also provide the innovators with the ability to

respond to what is seen in a real effective manner going forward. So, I see some real, very important relevance to what's going on here in terms of really driving the innovative cycle. And working -- what we're all trying to do is to provide better outcomes for our patients in an effective, efficient manner.

MR. MCLELLAN: Thank you, Aaron. I'll turn to Ross next.

MR. JAFFE: Well, thank you, Mark. It's a pleasure to be here, and I really want to congratulate the group. I know how being involved in the Medical Device Innovation Consortium I work on, patient-centered benefit risk -- I know how hard it is to sculpt the fog in some of these areas. Great, simple idea, but getting to details could be challenging, and I think you guys have done a great job.

As Aaron mentioned, I want to come at this from the point of view of someone who was involved in early-stage innovation. We live in a credibly paradoxical time with that regard. Everybody wants innovation. I don't think there's anybody's anti-innovation if we can develop technologies that will improve medical care.

And we live in a time where science advances and advances in materials technology and information technology allow us to do some amazing things. At the same time, as Aaron mentioned, we're in the worst environment for funding medical device innovation since 1995 or before, and the reason is, to some points Omar made earlier, in order to build these technologies, you have to build a sustainable business around them. You have to be able to track capital to them that will allow you to build those businesses.

The timeframes to develop technology and get them through regulatory approval, through reimbursement, into the market (inaudible) successful businesses have stretched so long that we can't attract capital to them in the way that we could even five years ago.

So, why have those timeframes stretched? Well, part of it's been regulation and some changing timeframes of reimbursement that occurred over the last decade. I think Jeff and his team at FDA deserve a lot of credit for recognizing that and really taking concrete actions on the regulatory front to improve that process. Over the last several years we've seen an

improvement in the predictability and timeframes to approval. So, that's getting better. But the timeframe that's really getting worse now is on the reimbursement side. The challenge of an innovative technology, which often needs a new code as well as coverage by public and private payers -- the timeframe to getting that is stretching longer and longer and longer and often takes us anywhere from two to five years after update approval to get reimbursement in place, allowing companies to actually build a sustainable business.

What used to be a 5- to 7-year process a decade ago to build a company through to liquidity so we as investors could return our capital (inaudible) investors is now an 8- to 10- to 12- to 15-year process. And because of that, we've seen an over 70 percent decline in the funding of medical device startups since 2008, and we're literally at the lows that we haven't seen since 1995.

And so we all want innovation, but unless we can improve the return on investment for investors, we won't attract the capital to fund that innovation.

The Postmarket Surveillance System could be a great boon for this process, or it could create additional problems for us, and it really depends on how it is used by particularly the payment community for looking at these technologies. If it is used in a way that says wow, we have this new safety net so we can know that if we have a problem with safety or lack of efficacy, we'll detect it early. We can stop paying down the road without (inaudible) to pay earlier. That would be great.

If it improves coverage with evidence development programs and abilities to partner with industry to sort of cover things early and get it into the market in a covered way, that would be wonderful.

But if it's used in its excuse to wait and see, then we have another -- we can wait and see how long it takes until we have this evidence from the system, then it's going to be a negative.

I think, really, the discussion needs to be about how we can partner with the payment community, both CMS and the private payers, to use the system, to improve the ability to

get innovative technologies into the market in a timely way.

What we need -- we've seen CMS come out with recent guidance about its coverage, what it calls coverage with evidence development, which I would call coverage for evidence development in the sense that the guidance really suggests they're going to pay for clinical trials; they're not going to pay for the use of the technology on the label in a broader population.

We've also seen, Mike, that your group has gotten experience where CMS has actually paid in a form of coverage with evidence development. They pay on label while you're doing ongoing studies, and that's a system that could work. So, we have an interesting time here where beyond the postmarket surveillance aspects of this, we really need to think of how that plays into the reimbursement aspects of it.

I'll stop with that.

MR. MCLELLAN: Great. Thanks, Ross, and we'll go on to Mike.

MR. MUSSALLEM: Thanks, Mark. It's my pleasure to be here.

You know, I work in a company and in an industry where our employees are turned on by the idea that they can do something to impact patients' lives. This is really what gets them going. People consider it a privilege. And this subject gets to be so important, because there is so much at stake.

Now, I have tremendous respect for Aaron and Ross and the rest of the participants. I take a little bit of exception to something that you said, Ross. You said everybody agrees that innovation is important. Although I think maybe everybody says that, I'm not sure everybody behaves that way in our system, and right now you've got a system, when it's designed in such a way that you believe that, boy, if we can just move everybody to best care or if we can just move everybody to the most cost-effective care or if we can just eliminate those mistakes, then we'll have a better system. And that's all true. Who can argue with that?

And we have a surveillance system, for example, in medical devices that mostly is around finding safety signals, finding things that are wrong. But if you believe that we can make

health care better, that we can innovate and make it better and better and better, then you'll say, well, wait, we need a system that does more than just make it safer. We need to find a system that allows us to learn and to get better. That makes the system more complex. If it was easy, we would have already done it. But now we're asking the level of complexity to come up.

And then when you add the complexity of medical technology innovation and the fact that it's iterative, it makes it even more complicated, right? Because if you're studying a biologic or a pharmaceutical, you finally decide on what that molecule looks like, design a great study, and you see how it comes out.

In medical technology, often we'll do our best work, we'll design a study, but once the study begins, then we start really learning. We learn something about: What kind of training is most effective? How do you best do your imaging? What patients really respond and don't respond? How can we make these devices better? How can we lower complications?

The list goes on and on, and what you want is a system that allows us to learn and iterate and get better and better. So, it almost sounds like an impossible way to get at this, but I think that through this report there has been really some thoughtful efforts. It was mentioned that we were part of this TVT register, which is a study of transcatheter valve patients, and basically it studied every single patient in the United States that's gotten a transcatheter valve.

Now, that was very difficult and challenging to get into. It took incredible cooperation with the FDA and CMS physicians, like Dr. Michael Mack and others, to help weave this together in some kind of comprehensive registry, and we end up having a lot of very bright data that comes in from that, and we're able to learn and improve, and we've already seen the benefits of that because these patients that are getting transcatheter heart valves are getting much better therapy today than they got five years ago when the technology was introduced. And this is a result of the learning that's taken place.

Now, having said that, it's not necessarily scalable and practical for all medical technology. We've had the benefit of -- we're sort of a company and there are some others in this space that have this long-run point of view that can take this high-investment road. There are

some issues with the transcatheter technology as well, so we've hundreds of data fields that have to be filled out manually. Well, that's not ideal. When you hear about this vision of the future of, gee, can't get it populated from electronic health records? Now you're talking about something that can be cost effective, large-scale learning, get all this evidence that can inform us and allow us to innovate, and move this in a much better fashion.

So, we've got the opportunity to do better. We've got I think a good case study for some learning and extending it to larger populations but there's still much to be done in that regard.

One of the things that I feel broadly about, similar to the comments that are made, is we need to try to just take the barriers out of the innovation process. Part of it is the development of this evidence needs to be more economic than it has been in the past. And this is where there maybe is a key role for registries and other bright ideas like that.

Also, the economic incentives need to be more set up to encourage the innovation, and I think there are creative possibilities for doing that. There are some bright ideas. The use of coverage with evidence development can provide some vehicles for that. (Inaudible) have to be carefully thought out with a lot of collaboration and thought about what's important from the patient's perspective.

And then, finally, the right policies that are being envision by FDA: Then they say, hey, I want to go further than just looking at safety but also how do we bring technologies to patients that are important to them? This is key. And turning that into practice: There's actually a great example. You know, when I listen to patients in the U.S., often what I hear is: Okay, why do those innovations go overseas? Why don't they come here? Why do I have to go there to get those innovations? That's because if I'm making the tradeoff in a cost benefit way, I'd like to be able to be involved and get access to that newer technology. So, for example, there was some brightwork done on a new frontier. There's a group of patients with mitral valve disease that have just horrible qualities of life, that get readmitted to hospitals on a regular basis, and so forth, and some new therapy that might be able to help them, and through the efforts of the FDA they've

found a way to be able to encourage manufacturers to have a multi-center study right here in the U.S. where we'll do some feasibility work. That's the kind of enlightened policy that I think helps take a positive step forward in this world of welcoming innovation and bringing that to the American patients that care most.

So, I think the acid test of all of our work is going to be when you actually have this conversation with a patient or a patient's family and you explain this system that we're creating for surveillance, for medical technology in the future, and it doesn't resonate with them. Does it? They say: Yeah, that feels about right for me as a patient.

Thank you.

MR. MCLELLAN: Mike, thank you. Thank all of you for your comments.

You've teed up a lot of the significant challenges in device innovation now and also some potential opportunities and cautions as this medical device surveillance effort moves forward.

I do want to push a bit, picking up on the last panel's emphasis on specific next steps. What are the first priorities for addressing some of the concerns about innovations within the goals and context of the Medical Device Surveillance System -- maybe things that can be incorporated in early pilots?

You all particularly highlighted the importance of not just thinking about the regulatory issues that FDA needs to address around better evidence on safety and effectiveness more quickly as medical devices continue to evolve but also issues related to coverage and the kind of evidence that the payers may want. And I wonder if you could help put a little more specificity on where these efforts might start to address both of those kinds of concerns?

To pick up on some things I heard in the previous panel and here, one of the pilot areas highlighted would be -- that I think Lew mentioned -- a faster, more reliable way of identifying safety problems and then notifying patients of the connection to UDI tracking or something like that. Does that sound like it makes sense?

Secondary, picking up on comments from Mike and others, is a more

automatically populated version of the TVT register, one that doesn't take so much time and effort to fill out lots of fields manually but would still quickly and reliably capture key information to help with that. And a lot of people call the cycle (inaudible) cycle product development.

There really is a continuous improvement process for devices, right? You start out in one place and, unlike a drug molecule, these products do continuously change. The question is how you make the most important changes as quickly and as low cost as possible to get to better outcomes and fewer complications. So, collecting these kinds of data more reliably or data could feed into that more reliably is clearly something that could be beneficial but right now seems pretty costly. So, maybe I can just ask you all about further thoughts on it. Let's push this a little bit. Given the challenge that you've raised, how can this system, as it undertakes its early efforts, show that kind of payoff, not just for safety and effectiveness for patients but for improving the innovation process for medical devices.

MR. JAFFE: One thing -- somebody mentioned earlier the perfect (inaudible) of the good, and I think the important thing is to take some first steps.

In a prior life, I used do outcomes research based on claims data, which is the best we had at the time, and the question I had wondered was whether there was a way to use existing claims data to identify potential problem areas that can be then drilled down and also do that in context of working with people -- groups like certain integrated health care delivery systems -- that already have pretty good information systems to start exploring some of these areas. And I don't know -- I'm not heavily involved in that anymore -- but I would try to look at people having existing infrastructure to at least start pilot projects on a small scale around certain technologies where there is in evidence either a safety concern or efficacy concern that you're going to identify potentially from claims data.

MR. MCLELLAN: Some of those groups are particularly concerned about value and are shifting their payment mechanisms, as we've heard earlier.

Aaron or Mike, comment?

MR. MUSSALLEM: You want to go? Otherwise --

MR. KAPLAN: Yes, I mean, I think that the problem is that these issues are very device and indication specific, and I think the strength of the TVT was that it brought things together in a very circumspect manner as a very relatively -- should be careful here -- relatively easy population to define a first-in-class device that lent itself to it. And that's not always the case.

But there are other examples. I alluded to one wherein part of this kind of rebalancing where you put your approval that really recognizes that the ability to prospectively get an understanding of how first-in-class devices in particular are being used and be able to work under a CED will allow us to get the data actually that we really want, because I think that there -- one thing I'd like to emphasize is that the data coming from randomized trials are really from a bubble.

There's a real -- from my experience with the stent company, the people in the randomized trials were actually a slightly different population in that the sooner we can get objective data on what's going on in the postmarket, that's really what we want. So, very specifically, to put that -- we now have the ability to really have a far more effective early postmarket surveillance to really be able to give FDA the understanding of or the kind of comfort about safety and efficacy and then also obviously working with the payers.

I think the payers -- they always say, well, look, we're looking for data and, you know, look at the cute infarct angioplasty. Reduced mortality in the '50s was 30 percent for someone coming with an inter-infarct. Now it's 3 percent. That was a very iterative process. A lot of things that went into that -- a real ecosystem in that if I went up to you today and said I have this idea for a stent (inaudible) some of that Medtronic dealing with balloons, says we're going to do this, say, oh, show us how you're making with the payers, show us that we're making people's lives better.

We'll do this big randomized trial to show that it saves lives in the acute infarct angioplasty. That happened 20 years later, and the amount of -- that's when they get there. So, I think that there needs to be a recognition on the payers that there needs to be investment there, too, because if they just sit back and say, look, we're looking for the data, and I think the problem

is that we won't get the return on some of our other investments, and that really gets in this technology forward.

MR. MCLELLAN: And more clarity about how these systems could help answer those payer questions.

MR. KAPLAN: Right, and they really --

MR. MCLELLAN: At a lower cost we're really helping move this forward.

Mike?

MR. MUSSALLEM: Yes, you know, anybody in this debate is going to say, gee, we need the evidence. The problem is: How do we get that and who's going to pay for collecting all that evidence? If there's an ability to look back at old data, terrific. We can find ways to mine data. But if it's an innovation and we're looking for evidence that hasn't been created, we need to find ways that you would find companies that would actually be willing to invest in collecting the evidence.

And to do that, there probably needs to be a few principles. One is not make it so costly. You know, early on in a development you'd say: Boy, there might be 300 different variables that could affect the outcomes of these patients; I'd better collect them all. But as we get smarter, could we take it through 30 variables or even 3 variables? So, that part of it is part of the equation.

The other part of the equation is sort of the governance of this, and I think Lew brought this up that in our world of cable news and Twitter and so forth: If you're collecting real-world evidence how much do you react to a single incident that happens when there are hundreds or thousands going on every day. These are the kinds of things that would scare innovators to some extent, that there would be overreaction. Can you put a governance over registries, such as you'd say: No, I have thoughtful clinicians without vested interest that look at the data in its totality say what is truly a signal, what is possibly an aberration, and to do that reporting on a thoughtful, clinically, scientific, and relevant basis.

Those are the kinds of things that would encourage people to take the risk, to

make the investments, to fund evidence collection.

MR. MCLELLAN: Thank you, and I want to thank you all for that response. I asked a long question that required thoughtful answers, and as a result we are at the end of the time for this session. So, we are going to break now. I'd first like to thank the panel, and then I have a little bit of logistic information for all of you. But first thank you all for bringing up these very important extensions of the core issue that we've been discussing today around medical device surveillance. Medical device innovation is a critical topic, and I appreciate its tight interactions with the surveillance activities that we'll hopefully be following from this meeting. Thank you all very much.

XXX BEGIN PANEL 3 XXX

MR. MCLELLAN: Good afternoon. Once again, I'm Mark McClellan from Brookings. I'd like to welcome you back to today's session on the report for the National Medical Device Post Market Surveillance System.

We've got two very interesting panels coming up before we conclude today. The first, as I mentioned earlier, will be a panel with key congressional staff discussing the current legislative activities and possible activities related to medical device innovation and regulation. And then the last session of the day is going to focus on extending out some of the ideas we've talked about today in terms of both implementing a Medical Device Surveillance System and in terms of ensuring its effective interaction with many other steps taking place right now in our health care systems toward better evidence. So, we're going to go through both of those issues.

Now's a good time for our panel to come on up to the stage while I introduce them. We're very pleased to have with us some very busy people who are leading congressional committee efforts on issues related to medical innovation and postmarket surveillance. They're from the congressional authorizing committees that oversee the FDA. They really oversee a broad range of activities related to health care policy and especially by medical innovation policy. They include staff from the Energy and Commerce Committee in the House and the Health, Education,

Labor and Pensions Committee in the Senate. They have been very busy lately in particular on issues related to medical device innovation and the safety and effectiveness of medical devices.

We're going to talk about some of those activities right now. We're going to talk about how those activities relate to the issues presented in today's report on a postmarket medical device surveillance system. I do want to emphasize that the views of the panelists are their own. They don't necessarily represent the views of any particular member of Commerce on what may or may not actually happen in legislation, and we've asked them to speak as freely as possible in this process with that in mind.

So, I'm very pleased to introduce Wade Ackerman, Senior FDA Counsel for the Senate HELP Committee; Grace Stuntz, professional staff member on the Senate HELP Committee; Clay Alspach, the Chief Health Counsel on the House Energy and Commerce Committee; and Eric Flamm, FDA detailee who is serving on the House Energy and Commerce Committee as well.

We're going to start out this session by giving a little bit of perspective on what is going on now related to these issues in the Senate and the House. So, to do that, I'm going to start with Wade and Grace to talk about current activities in their committee, including those related to the Medical Device Surveillance Report, and then turn to Clay and Eric to talk about the House Energy and Commerce Committee activities, including the 21st Century Cures draft legislation.

So, Wade and Grace. We'll start with you all and then we'll go from there.

MS. STUNTZ: Thank you, Mark, and thanks for having us here today -- again, off the record, in case that wasn't clear enough for the beginning. (Laughter)

So, after (inaudible) November and Senator (inaudible) going to be Chairman, one of the things he wanted to look at was how do we get drugs and devices to patients faster. I think both with Chairman Upton's effort and speaking to folks back in Tennessee, that's something that was going to be a big priority for him as chairman and as one of his top three and probably his biggest health care priority.

But I think as all of us know, that's not necessarily a new problem. People have been trying to find ways to get drugs and devices to patients faster since the '92 user-fee agreements, the 1997 FDA law.

The 2004 Critical Path Report from FDA raised a lot of those concerns about what FDA needs to keep up with emerging and FAST science. So, the way that he wanted to start the process over in the Senate was he wanted to write a report -- and he worked with his colleague Senator Burr from North Carolina -- that sort of laid out what is the current framework. And I think the *Brookings Report* today does that great for the postmarket space and devices.

It's really helpful for us up on the Hill to actually know the current state of play before we start trying to change anything or improve upon things: What programs exist now? What have we been trying to do for the last 10 years to solve these problems? Has it worked? Has it not? Do we have the data to know if it's working or, if it's not working, how do we get that data? I know Brookings wrote on that, as well, in February.

And so now it's sort of the innovation for the *Healthier Americans* report that came out in January from Chairman Alexander. And Senator Burr tried to sort of our best shot at laying the broad framework of what exists sort of all the way from the NIH basic science side to sort of FDA and their tools.

In every -- it seems in FDA space we legislate either every five years on a schedule of user fees, and we have sort of a hard deadline or, as in the meningitis outbreak, there's a public health crisis that requires urgency. I think we are all excited that we're taking this year that's sort of -- knock on wood -- sort of between those two events to really take a step back and look at -- you know, every five years we've added more authorities, we've added different reporting requirements, different postmarket systems, different premarket tools.

What does the whole system look like? And is it where we want it to be? The answer might be it's fine and don't -- you know, the Congress don't mess it up, right? Or it could be well, we could consolidate here; we might want to strike here. Some additional (inaudible) would be necessary, and so the report really tried to lay out those questions, and we really want

folks to say in those comments that we will be sharing with the whole bipartisan HELP Committee -- you know: Here's where Congress should be focusing on helping; here's something that Congress could the start the dialog about but maybe shouldn't be legislating; and here's something that Congress should stay away from or it isn't really a high-priority problem.

And as some of you may know, the House is hoping -- started about six months before we did, and so we're hoping to start our own process in the Senate. I think Wade will talk a little bit about how that will work. It is going to be bipartisan with both Chairman Alexander and Ranking Member Murray leading the HELP Committee to come up with what we can do to help here, whether it's getting new things to market, whether it's sort of making sure FDA's job is as easy as it can be, because they as well want to get new innovative therapies to patients.

So, how can we help them? Sort of, I think, an unusual question for Congress to be asking, but I think here on both sides of the Capitol, it is what we want to ask: How can we help FDA, NIH, America's biomedical research ecosystem, do better?

And we look really forward to working with the House and then also, starting now with our Senate team, bipartisan HELP Committee process that he's been around has worked very well for the past few years, although it takes a little longer. But it's now a favorite way to talk about that.

MR. ACKERMAN: Sure.

And, again, thank you, Mark and Brookings, for having us today.

As Grace mentioned, I think some folks in the (inaudible) may be familiar with the way we've been successful in the Senate HELP Committee in getting legislation in this area done.

But for those of you that aren't, I think its worth just a moment explaining about how that looks. The HELP Committee has very active members who are engaged and have a lot of priorities and history in the space, and that goes for the staffers across the committee as well. And just last week we kicked off this Innovation Working Group to look at some of these issues, and what the Working Group is really is just a group of staff from across HELP Committee offices who get together. We're going to start by sort of making sure everyone's speaking the same

language and bringing in a lot of information. We started with NIH officials briefing the committee staffers last week.

I think this week we're moving to FDA, Dr. Shuron, with the device issues. Next week, we'll be talking about drug issues and biologics issues. And NIH and FDA will be coming in and doing a duet, so to speak, on talking about development of medical products from the stage of invention to the time that those products reach patients. So, that will be Phase 1, so to speak.

And from there, really what happens is the staffers come in and roll up their sleeves and start vetting policy thoughts. We get out white boards, and we have a very transparent process. You can follow it by going to the committee's website. In the past when we've reached places where there might be language to discuss, we've released those for public comment. In the past we've also released questions that'll depend upon where the process takes us, but it's a really deliberative and thoughtful process, which I think recognizes the complexity in these areas. And we've really had a lot of a success in the past. I don't know -- you know.

MS. STUNTZ: (Inaudible) been with a committee since 2011, and this is the same way we did the user fee buildup in 2012. We had draft discussions for every sort of title of that bill, and I think it made the process better having people put in comments where compounding and track and trades do very complex issues. That's sort of the same. We've got every member who's interested in compounding come give us their thoughts and their ideas, and that went through a lot of different phases and vetting processes as well. So, looking forward to working with you all and look forward to your questions.

MR. ACKERMAN: And I think I'll just -- one last comment. Yes, it's a very deliberative process, and I think stakeholder input and things such as the paper that was released today -- those things are critical as we go through this process. My boss, Senator Murray, was very excited to be in her new role as Ranking Member of the HELP committee and working with Senator Alexander on this initiative. But just to underscore the importance of stakeholder feedback, it's a long process and we work very closely with FDA through technical assistance through these processes to reach -- again, we've been very successful in the past reaching

consensus policies.

MR. MCLELLAN: Thank you all.

So, I'll turn to Clay and Eric.

MR. ALSPACH: Thank you very much for the invitation, and thank you to Mark and his team for all their input during 21st Century Cures and to those in the audience as well. There are a lot of familiar faces, so it's great to see you today and we look forward to a good discussion.

Again, I'm Clay Alspach. I work for Chairman Fred Upton of the Energy and Commerce Committee.

About a year ago, we started the 21st Century Cures Initiative -- "we" as in Chairman Upton and Congresswoman Diana DeGette -- and the idea behind the 21st Century Cures Initiative is very similar to what Grace outlined and is to really look at the whole entire cycle for cures and treatments from discovery to development to delivery to try to better understand really where we are, get a landscape view of where we are in this country in helping patients, but also in that conversation is to figure out what more we can do.

So, it's been a very helpful process. There's been a great discussion, and it's involved eight subcommittee hearings. We've had 12 roundtables across the country -- four here in D.C. We've also put out some white papers where we've gotten some great comments. And I want to say thank you to all those in the audience -- I know Dr. Shuren's here. He was able to participate not only here in D.C. but also out in Michigan, coming to Chairman Upton's district. And we can't thank you enough for all that.

And from that phase of the 21st Century Cures Initiative, we better understand kind of where we are in this country and as well in respect to each area and what we can do, but also through your help to try to figure out what more we can do, because as something we've talked about through the 21st Century Cures Initiative, there are almost 10,000 diseases out there, and we only have cures and treatment for 500 of them, and that's just simply not acceptable. We need to work together, roll up our sleeves, and figure out what more we can do.

So, like I said, we had that whole process, trying to get input, and that process will continue. But what we did last month is we put out a discussion document where we collected ideas and every facet of the cure cycle to better, basically, hopefully further and accelerate that cycle.

And I think one important part of this process as I look at it -- we've had an opportunity to work a lot together on the FDA side and a lot of focus every five years as an FDA, and the fingers are pointed at FDA to say, hey, they're the roadblock, we need to figure out what to do.

But I think one thing that would hopefully separate this process is trying to step back and realize that, you know what, this is an entire cycle. It's not just development. There's a discovery aspect, and there's a delivery aspect as well. And one thing that you do on the delivery side, for example, or the development side, may have an impact on another part of the cycle. And that has been a very -- at least on a personal level -- it's been a very interesting, challenging part of this process, and I thank everybody in the audience for helping us better understand that.

And one thing I want to say is we look forward to continuing that process, because that discussion document was just that. It was some ideas that were put out, and we know that there are better ideas out there. We know that every single idea in there can be improved. But that can't happen by just -- we sit in Rayburn House Office Building. The greatest ideas aren't coming out of there. The ideas are coming forward from the country. They're coming from the relevant agencies here in D.C. or have offices around the country. We need your help, and I want to say thank you for those who have reached out already.

We've gotten a lot of comments on the discussion document that we put forward, but we also look forward to continuing to get that feedback. And I think that's kind of where we are today with this conference. There's an idea put forward on the table.

This whole thought of real-world evidence and better postmarket collection of data is really where I think we need to be headed in the 21st century. But how to do that, that's where we really need help, because it's -- like any idea, some ideas sound great at the 50,000-foot level,

but really the details are what matter. How to operational it is what matters, and this discussion today will hopefully put us in a place where we can better understand that and possibly push it forward as we look to these different shifts. So, thank you very much.

MR. MCLELLAN: Thanks, Clay. Eric?

MR. FLAMM: Thank you, Mark. It's a pleasure to be here, so fourth time saying the same thing. (Laughter)

Mr. Palone, the Democrats who on the committee are also very supportive of the effort. We also think it's important to look at the total scope of discover, delivery, developments -- not in that order, of course.

Our primary hope out of this will be to get more money for NIH and FDA to improve research. We see that without getting more money, there isn't really going to be a lot of change. Our focus relative to FDA is, I think, first to NIH -- to remove any barriers, and that's something that both sides of the aisle are looking at. It's something that's not controversial; it's not partisan. It's not always easy how to figure out how to do it. Some of the barriers don't seem to be as easily amenable to congressional efforts, but we will try.

We're also looking to make sure we don't undermine any of the C evidentiary standards that FDA (inaudible) determining safety, through determining effectiveness. I don't think anyone on either side of the aisle has any intent to do that, but stakeholders see this as a great opportunity to get everything they ever wanted, and because it's not a user-fee cycle, sometimes they think they can get things during the user-fee cycle they might have to pay for. This isn't a negotiation with industry talking about user fees so maybe they can get things that they couldn't otherwise get without paying for them. So, we're sort of looking out to make sure, and "we" meaning the House side, but we haven't having FDA and NIH in sometimes twice a day for two-hour sessions, sometimes five times a week, considering FDA is not located at NIH and neither of them is located downtown. It shows how important they see this both from the perspective of improving things and from the perspective of making sure what looks good doesn't end up making things a lot worse.

We're also looking to figure out ways to make better use of the science -- you know, real-world data, real-world evidence, big data, biomarkers -- how can we make better use of them. I think there have been proposals that take things too far in the sense of assuming that all the research has been done and now it's just a question of why hasn't FDA implemented then? Why hasn't FDA created approval across the seas that make use of them and speed them in the drug regulatory framework. And I think we've heard from FDA that those are premature, that they're not going to help, they would actually slow things down, they would distract FDA from doing its review processes to do things that it's not equipped for and that really isn't in the scientific community's domain, particular in biomarkers developed (inaudible).

So, we see a lot of potential here. We see a lot of risks if we don't (inaudible) really carefully. That's why meetings like this, stakeholders like you, are really important. I think both sides of the aisle share the same policy goals, and we just have to work really hard to make sure that what we achieved doesn't undermine the great successes that have been going on, particularly at FDA.

MR. MCLELLAN: Thank you all for the comments really. It's interesting to hear sort of the breadth of similarity in interest and goals for this process that all of you have expressed.

I do want to push a little bit on the postmarket side, since our real real focus here this morning is -- as you all pointed out, this is one piece of the whole 3D discovery, development, delivery infrastructure. There's one that historically hasn't gotten very much of the resources of the FDA side and where, compared to other countries and systems, we're sort of a bit behind in terms of infrastructure. So, I want to put you on the spot about the report released this morning. But maybe if you all could comment a little bit further on what you've heard so far about real-world evidence, development of postmarket systems.

Clay, I think you mentioned that there was a lot of interest in developing better postmarket capabilities, better real-world evidence capabilities. Any further insights so far about what you've heard on kind of the postmarket side, especially for medical devices?

I think one important element -- and Eric touched on it during his comments -- is

how challenging and difficult it is. I think that as we go into it, we don't want to underestimate how difficult and how challenging it's going to be to get to that place and to get to where the science is there and the data collection systems are there. There's a lot of information, I would say, that's being collected on the postmarket basis now, especially on the device side.

But I think one intriguing part of the report was the identifying -- you know, here are the data systems, here's the information that's being collected. What if we were able to really harness that and make it win-win for everybody and reduce the cost, the collection cost of it, and I think that's a very intriguing part of the proposal and I think something that was very attractive to us as we looked at it as well.

But with all the information that's out there, how data are being utilized in not just health but in other areas as well -- that's what's intriguing. You know, we talk a lot about the premarket side, as you indicated, when we talk about medical device user fee or prescription drug user fee. But, one, I know -- I think -- Jeff, Dr. Shuren, brought it up in our initial roundtable and FDA's been talking about it; others have been talking about it -- the balance between premarket and postmarket. And we may be able to -- I don't want to say "lessen" the premarket burden, but it may be that on the postmarket side we may be able to collect more data, to have more -- just a better sense of confidence as to -- and I say "we" as in when the regulators are doing that -- to get a better sense of confidence when they clear and approve those products. I think that would be a very good benefit of this, not only to make they're safe but also how effective they are, too.

So, I think the report has a lot of great aspects to it, and we look forward to continuing to (inaudible).

MR. MCLELLAN: Other comments?

MS. STUNTZ: I'll second sort of Clay's remarks. I think that's -- the last thing you'd want to do is create a brand new postmarket surveillance system that's costly for (inaudible) set up and doesn't incorporate the data that's already being submitted by companies. And, you know, there are all new issues of setting that up without knowing how it works with everything in the bigger system and how things across the core net and different registries that companies and

especially (inaudible) are using, and if the current reporting for adverse events isn't useful -- if it's not is there a way to make that system more useful so those resources at FDA and others are spending can be used to do a system that's sort of more effective? Those are the questions that I think we hope to answer, and I think your report goes a long way in helping identify the key pieces and look forward to hearing on -- you know, when you have the solution, you can just let us know and then we'll go from there. (Laughter)

MR. MCLELLAN: Sound simple. (Laughter) I appreciate the openness.

Any other comments? Great.

I'd like to open up to those of you here in the room. Any questions or comments for the congressional staff up here?

I did have one more while you are thinking of that. You know, I've -- you all have framed both the HELP efforts and the Energy and Commerce efforts around innovation and taking advantage of 21st century progress, and it is a really comprehensive focus, though, covering all the 3Ds, and I don't recall seeing that put together in quite that comprehensive of an approach. As you all mentioned, this is kind of on the off-cycle between the FDA user-fee legislation, which has been really focused on FDA and its role in regulation and maybe supporting innovation and other legislation that may come up in response to things that happen in the world -- drug-trafficking issues and safety issues and the like. Do you see this being an ongoing priority for the committees now? Is it kind of a reflection of how important not just biomedical innovations become but how important it is to take a more systematic look at what Congress and all of us can do to support effective innovation? Is this part of a bigger trend?

MR. ALSPACH: One part of this initiative is -- and I thought you said it well -- I mean, we had the 2006 NIH Reform Act where we had the user fees or in the SGR vehicles are oftentimes or some kind of Medicare reform. But as we're looking at those, we're only looking about that one part of the cycle. So, I think with 21st Century Cures and with Chairman Alexander and Ranking Member Murray's initiative, one thing we're doing is we are looking at an entire cycle.

I think one of the policy goals that you'll see as part of the these, at least the 21st

Century Cures, is that how can we put a process in place so that we can maintain and look at that cycle when we're not looking at one of those pieces of legislation, because sometimes it comes every five years. A lot of times in Congress, it's just -- how Congress operates is we are focused on that public health crisis or that latest patch. But if we could put some systems in places, some policies in place, that will have an ongoing effort to look at how those cycles are working together, I think that would be a really positive impact of this issue.

MR. MCLELLAN: Do the rest of you see that in a similar way, or --

MR. ACKERMAN: Well, I can just add -- and, Grace, I think you (inaudible) as a sort of -- you know, it goes without saying that also the committees, there are a lot of ways that we engage in these areas. There is legislation, of course, and that's what our working group in the Senate at least is looking at now, but we also continually do oversight of these issues and have other levers that we have at our disposal. As Grace said, there are some areas where we may find that authorizing changes need to be made. There may be some areas where they don't. There may be some areas where because Congress is engaging, the conversation is able to be had externally at the agency and other places that sort of move (inaudible) in the right direction. So, all of those activities sort of are relevant here I believe.

MS. STUNTZ: It's sort of hard to speak for Congress as the future. (Laughter) You know, I can't tell you that there is some big patient safety issue that the drug or device creates that we're not going to have FDA come up and point and them and say how dare you. But I think -- because we've seen that happen in the past -- but I think it's the conversation, that Congress is having this conversation about what is the appropriate risk benefit, and it sort of helps the FDA and others have that discussion and feel more comfortable, you know, making sure they are using the best (inaudible) in getting these things out and that hopefully it's not just sort of Congress pointing fingers and it can be more of a working-together dialog.

MR. FLAMM: I would say that one of the most influential outside groups, with respect to Congress, is the drug industry and the device industry, and in the past they have focused on FDA. What we heard a lot of at the roundtables and hearings that we held during 21st

Century Cures was the drug and device industry saying FDA is no longer -- and the investment communities, D.C. community -- FDA is not the problem anymore, because they're moving away from FDA, they're looking at how can we intensify better ways to use clinical trials, to get data in a way that if you have biomarkers that show this indicates that this is the right patient group, that you can use a smaller-size clinical trial patient group and then you can have better answers. So, the drug industry is looking more at the discover side, and then they're finding on the delivery side, well, FDA does very fast approvals based on sometimes what some insurers and other outside groups tend to think of as the minimum amount of data necessary to be able to get the drug or device to patients, and then CMS is, well, that's not really enough data for us to decide this is where it's paying for our patient group. So, then they're seeing there's really a need to focus on the delivery side. Given the influence of the drug and device industry, I would guess that there will be a continuing focus on both discovery and delivery as well as the FDA (inaudible).

MR. MCLELLAN: Very interesting. So, we have time for one more question up here. Sharon?

MS. NORMAND: Thank you. I'm Sharon-Lise Normand. I'm a professor for Biostatistics and Health Care Policy at Harvard, and I also lead the Methodology Center for the Medical Device Epidemiology Network -- MDEpiNET.

So, I had a question that focuses on the delivery aspects, and it strikes me as extremely odd that we can assess the delivery of drugs in looking at large claims databases because of the existence of national drug codes. And forever we do that. We assess things. We've learned a lot. We can't do that with medical devices. And I know it's warned that perhaps I shouldn't raise this issue, but I'm --

MR. MCLELLAN: Nobody warned you not raise this issue. (Laughter)

MS. NORMAND: I'm not looking at you. (Laughter)

MR. MCLELLAN: I don't think they want to hear everything. (Laughter)

MS. NORMAND: I'm very struck why we don't have or we're not going to sort of mandate that in claims data there's UDI. If you want to assess the delivery of how medical

devices are delivered and how safe and effective they are, it seems to me that you need to be able to track those things in claims data.

So, my question is: Don't you see that as something quite important, and is it something that you're thinking about in order to assess the delivery of health care in terms of the general public health?

MR. MCLELLAN: As part of this process or more generally? Any thoughts about getting UDIs into action? Everybody's generally for it.

MS. NORMAND: Yes.

MR. MCLELLAN: But it's like one of those things that turns out to be difficult to actually make progress in practice.

MS. STUNTZ: Yes, I'll start. It's definitely on our radar. I don't think we want -- you know, (inaudible) companies don't want to make the investment to put UDIs on devices and have them never be used for them or for other purposes.

We work closely with our Finance Committee counterparts on this, as they have jurisdiction over some of the other issues based on jurisdictional differences in HELP and the ANC, but as something that we've talked to them about and were talking to agencies about as well, and so it's on our radar whether statutory fixes -- that's not -- we're not there yet in our thinking but, no, it is something that folks in (inaudible) Center are talking about, and I think some centers have sent letters and (inaudible) for sure.

MR. FLAMM: I think we all agree that it's really important that sort of late NDCs have been around a lot longer. And how you do it and how expensive it is and how much resistance there is given the expense will affect what we're able to do. I don't think anyone here disputes the importance.

MR. MCLELLAN: I think, from this panel, that the level of interest in addressing some of the issues that we've been grappling with on this report and in the discussions this morning -- the level of interest is clearly very high. So, a lot of recognition, the importance of developing better evidence from practice and a real willingness to hear about practical solutions to

get there, including on some of the challenging issues like UDI implementation and how to get this device surveillance effort off the ground. So, this is going to be a continuing process, but it's terrific to see the level of engagement from you all, from the members of Congress, around what is a key part of getting to a more innovative effect of 21st century health care systems. So, thank you all for joining us this afternoon. Thank you all very much.

MR. MCCLELLAN: So Greg is a Fellow and Managing Director of the Engelberg Center here at Brookings. He leads all of our efforts related to innovation by medical sciences. Of course this is the critical component, but only one component and you're going to hear from him and some really distinguished leaders about a topic that we've already started today, how we can start building this long term system with some initial steps, but as you'll hear, there are a lot of efforts already underway that can potentially fit very well with this one, so I'll turn over to Greg while the panel is coming on up.

MR. DANIEL: Good afternoon everyone. Thanks Mark. The planning board report outlines the future of the medical device system, MDS, as part of a larger national health information infrastructure. And we heard that theme throughout all of the panels, that this system should not be built from scratch as a standalone system, that it does need to incorporate all of the lessons learned and relevant capabilities of other existing systems that are producing medical evidence across the United States. In addition, the planning board felt that starting off with a two year incubator project that would be geared toward answering critical important questions that could help inform the more complete MDS implementation plan as well as do some early feasibility pilot studies that might help answer some of those questions and begin to lay the infrastructure framework for the foundation.

This session is intended to start the conversation on how can we leverage current efforts, what are the next feasible steps to actually building towards that national system. We've asked many of the leaders from these existing programs to be part of this panel to discuss how to start partnering and to create the foundation for the MDS long term system.

It's my pleasure to introduce the panelists in the order that they'll be speaking. Mitch Krucoff is Professor of Medicine and Cardiology at Duke University Medical Center and Director of Cardiovascular Devices Unit at the Duke Clinical Research Institute. Richard Platt is Professor and Chair at the Department of Population Medicine, Harvard Pilgrim Healthcare Institute. Carmella Bocchino is Executive Vice President of Clinical Affairs and Strategic Planning at America's Health Insurance Plans. Joe Selby is the Executive Director of PCORI and finally Sally Okun is Vice President for Advocacy, Policy and Patient Safety, at PatientsLikeMe.

Before we begin with the, or, go head Mitch, I'm sorry. Do you want to kick off the presentation? (laughter) I know you're coming from -- you've been heavily involved with a lot of MDEpiNet at meetings to date, and I know a lot of the efforts that MDEpiNet has been doing in terms of pilots and methods, are very related to building that infrastructure for the system.

MR. KRUCOFF: Well I'm very happy to be here and thank you Greg. And it's actually very exciting to be in the room, although in the morning I've been across town at the CRT meeting, so I apologize if anything I say is redundant. But I think, as I looked at this part of the program, though, the work leveraging, I think, is worth exploring, in that on the one hand, it implies that we are leveraging things because something we already have is incomplete. So obviously we don't have a medical device system in place right now. We don't have an infrastructure that would support such a system right now. Our traditional device evaluation is very segmented and fragmented and most importantly, redundant. And that tends to do two things. It makes safety information harder to evaluate when we do it in pieces because the real safety events are rare. And the redundancy is what adds cost and time, which is something nobody wants.

So the other side of leveraging is that it also intimates a sort of opportunity and openness and then opportunity that through collaboration, we could do better than we're doing right now. And I think there was an African proverb shared with us last week that applies here. To go fast, go alone. To go far, go together. And frankly, as a practitioner, I'm an interventional cardiologist and I like to have medical devices for my patients and I have family who are patients; I think we need to do some of both. We need to go fast, but we also really need to go far. And for

the national system, I think the opportunity to strategically link systems that already exist, without any question, could yield better than we have right now. Longer term, I think more seamless systems and more seamless tools can evolve, and again, doing both, to me seems to be the sort of center of at least our focus and since my boss of 27 years is about to become Jeff's boss, maybe we can even talk the same language.

I think it's also important to recognize that a lot of the ways we talk about this, start with some very high level, what we call essential principles. So if you're going to link data, if you're going to guard data, if you're going to understand the quality of data, these are principles that apply to all medical devices. But at the end of the day, if you're going to use those principles, we have to get them down into more general categories, because frankly, what we need and what we need followed up in an OB/GYN device environment, is different than a cardiovascular environment, or an orthopedics environment.

And even within general treatment areas, within cardiovascular, what we need from a coronary stent, or an aortic valve or a defibrillator, are different still. So we have to have some way to not only advance this general sort of holistic approach in novel terms, but also to bring it down to the actual devilish details that are required to be successful with regards to these medical devices and their evaluation. And in parallel with that, we need to build something that frankly, in my opinion, we don't have yet, which is an environment that cultivates this kind of collaboration. We traditionally have worked in different silos, stakeholders do their thing so manufacturers do their thing, patients have their space, regulators, payers, et cetera. We need to cultivate actively an environment that creates a consensus about where the system goes, and I think the planning board has certainly been a step toward that end and I guess I see my role here today, because the MDEpiNet program has also moved over three years of being funded out of the epidemiology branch and the (inaudible) efforts to bring forward the methodology center. You heard from Sharon Laser Harvard and the Infrastructure Center under Arthur Draken at Cornell. We have moved now to the establishment of a sustainable public private partnership in MDEpiNet and that's where we got our role specifically to bring forward an environment that could cultivate

consensus, not from individual stakeholders but as the ecosystem that device evaluation really is.

The public private partnership shift for MDEpiNet really connotes two changes in composition and focus. One is the shift from specific stakeholder granted funded projects to an ecosystem approach. This is where the emphasis on precompetitive collaboration, experience expertise. This is where alignment with efforts and priorities like the FDA's priorities for medical clinical trials, or a clearer way of balancing pre and post market requirements. This is where the planning board, which Brookings has orchestrated so fabulously, and the MDEpiNet's National Medical Place Registry Task Force, which we are deliberately coordinating to align our efforts, to build on each other's ideas, and not be going back and forth.

The second big compositional and shift I think in MDEpiNet in moving to a public private partnership is also in the recognition that traditionally and even today, a lot of the emphasis we're talking about is in the post market environment, but as somebody who was around when the total product lifecycle was first put forward conceptionally by FDA, we have to recognize that no one piece of the TPLC works by itself. The stronger that any one piece is, the stronger the other pieces are, and the degree to which we can use registry infrastructure to link all the stages of a total product lifecycle, a registry fundamentally means you're using the same terms, the same definitions, the same data structure throughout the total product lifecycle. This puts us forward.

So I'm going to end with just sort of three examples of focus areas that MDEpiNet has engaged in that I think are very relevant to the way I read the draft of the planning board. Focus area one is just in leveraging existing data from claims and discharge summaries for device evaluation, research and surveillance, just to look at how valuable is data that is routinely available if we were smart about accessing and leveraging it. Focus area two is in infrastructure and international infrastructure and the development of consortia that allow everything from local to national registries of the identical device spaces to contribute information to one another, and there the International Consortium of Orthopedic Registries, the International Consortium of Cardiac Registries and the International Consortium of Vascular Registries, are already underway through the MDEpiNet infrastructure center.

And lastly, just looking at the themes around which methodological improvements and this is really the Harvard Center's focus, dealing with missing data, dealing with mixing data sources, dealing with the medical devices, not just the device but the operator who puts it in, dealing with hierarchically structured data, understanding ultimately, putting all this together, to understand benefit risk and accrue knowledge over device lifecycle. These are methodological issues, methodologies that also could help us very much understand how not to just go from pre-market to post market, but how to bridge them so that as we build additional post-market data, we increase knowledge.

So I'll end by saying that this has really been the focus of what MDEpiNet as a public private partnership is concerned with, that the think tank incubator programs we run and particularly in cardio-vascular and orthopedics but growing very quickly into other device areas, are focused on developing essentially an ecosystem based learning laboratory to launch pilot projects that on the one hand have very specific granular disease specific, device specific questions to be answered, but simultaneously and by charter, are also required to make sure that these are programs that give us much more generalizable principles of how to move forward, linking the pieces that we have, long term and short term, toward a system like the national device system. Thank you.

MR. DANIEL: Great, thanks. Rich.

MR. PLATT: Okay, thanks. So I have the real privilege of leading the FDA Sentinel System and being the PI of the coordinating center for PCORnet, and I see these as highly complementary activities that can contribute substantially to the topic today, and I'm delighted that Carmella and AHIP have been strong partners since the beginning of our work in Sentinel and Joe is the leader of the PCORnet activity, so I'm glad that the three of us have an opportunity to offer perspectives.

So I am convinced that the future will be terrific. I think our challenge is to work in a --

MR. DANIEL: That's tomorrow, right? (laughter)

MR. PLATT: The tomorrow -- how do we deal with tomorrow and next year, partly because the only way we get to that wonderful future is through tomorrow and next year, but partly because there are questions that need to be answered right away, and I'd submit that through the activities, not only the ones that Mitch described, but through the work that Sentinel and PCORnet are doing, the glass is partially full. And as we say in New England, you can accomplish a lot with a partially inflated football. (laughter)

So I'd say that there really are three major areas which I think the combination of Sentinel and PCORnet can make three important contributions. One is around post-marketing safety, the second is the harder challenge of assessing effectiveness, and then the third is creating the better capability to do randomized trials in the post-marketing setting, and those are all, I think, going to be essential, because there are some issues around effectiveness that I think will only be answered by imbedded pragmatic trials that answer questions about how treatments, devices in this case, work in real world settings with people who are actually being treated. Several of our speakers, Lou and Clay, said the devil's in the details. So let me mention three details that have consumed a great deal of the time and energy of Sentinel and PCORnet.

The first is the fact that as challenging as data issues are, the governance issues are probably more challenging, and so I think finding effective ways to address the governance topics is going to be an ongoing challenge. I think Sentinel has made great strides by finding what, after the fact, have proven to be simple governance rules, but it took us a long time to get there.

The second is that although we are in a revolution with regard to the amount of data that is captured electronically as part of patient care, it isn't in its native form, useful for the kinds of purposes we're taking about, so we're always going to have to address the issue of fitness for purpose and I'd say both Sentinel and PCORnet have invested mightily in that topic of making routinely collected electronic health data useful to support FDA's need or PCORnet's needs and if you ask how large is that investment, it totals more than a quarter of a billion dollars in the kinds of activities that are going to be critical for supporting device surveillance in a post-marketing setting.

So I certainly subscribe to the idea that we should take advantage of the investments that have been made to support these additional activities.

And then the third area that's in the devil in the details category, is the one that Eric Flamm just mentioned, which is the evidentiary standard is very high. It is higher for regulatory decision making than it is in normal academic environment. So the standard for the academic environment I live in is good enough to move the field forward, good enough to be the foundation for the next piece of research we do. It's usually not, can you regulate on it. And we've put a lot of thought and a lot of resources into making the quality of the data and the use of the data be good enough to support these activities.

So I'll say just parenthetically that there has been appropriately been discussion about who will pay and to whom is it worth the investment to build out a device surveillance system and it's way above my pay grade to say who should pay for it, but I'm convinced that the investment is well worth it. I think it's a no brainer to say as a society it would be a big mistake to have an activity like this fail to progress because we can't agree how to support it, particularly if we take advantage of the very substantial investment that FDA and PCORnet have already made.

Finally, I'll say I subscribe fully to the idea that we should just -- there are some things that we can just start doing now that will move us forward, even if we don't have a complete blueprint that's available. PCORnet and Sentinel are, even as we speak, engaged in a pretty deep discussion about what would it take to link data that originates from either from clinical settings that PCORnet represents or from health plans and to make them available in a bidirectional way to support inquiries that are of interest either to FDA or to PCORnet but that work is almost certainly the same work that is going to be needed to (inaudible) the kinds of linkage that we're talking about here, and so we ought to make sure that we, that that work group performs its work in a way that supports these activities. I think there's a great opportunity. I thought that the pilot studies that are proposed in the document that's being released with this meeting are spot on. I think that the one that talks particularly about the opportunity for linking clinical registry data to data that's Sentinel already has is -- it might not be low hanging fruit, but relatively speaking, it's among the

earliest things that we could undertake, and I think that it would make a lot of sense to start talking now about how we might do one of those kinds of linkage in the private health plan space to sort of understand what it would take and what we can do.

MR. DANIEL: Great, thanks, Rich. Carmella?

MS. MS. BOCCHINO: So I'm pleased to be here today. I want to congratulate the planning board on a really interesting and thought provoking report and I actually even am here going to repeat some of the issues. I should have let Joe go first, because the health plans are working both with Sentinel as Rich has said, but is also doing a lot of work with Joe and PCORnet and has been fully embracing comparative effectiveness research and the importance of comparative effective research. Joe gets lists from our members all the time about the studies that may need to consider as they go forward, because they see so many gaps in the marketplace of where there's not enough evidence, and they, health plans, very much have been active participants as Rich has said, in Sentinel, in other post-marketing surveillance studies, because it's important to them to know the long term effect -- not only safety, but effectiveness.

The evidentiary standard for coverage is high. I will be honest with you. I have this conversation with Jeff Sharon and his team all the time about both pharma and device manufacturers want to know why FDA approval is not just enough. Why can't it just translate into a coverage policy? And part of the challenge is because those devices or drugs have been done for specific trials on specific populations, and what happens once they get FDA approval, they get disseminated and used across populations that there were not studies for. So it's important to the health plans to know how the use of both drugs and devices in the post marketing era for populations where they have not been studies, or for populations that have multiple chronic conditions and a lot of complexities to them, are they still going to have the same effect or are there other safety things? And there are publications replete with the number of unfortunate drug recalls we've had to do and device recalls we've had to do because of things we've learned in the post-marketing era. And so our members are going to embrace post-marketing surveillance, whether it's Sentinel or whether it's PCORnet in the work that we're going to start doing with them.

You know, the medical device surveillance system brings together multiple data sources and multiple stakeholders, which is going to be really important for its success, so it's administrative data, it's clinical data from EHRs and clinical registries, and I'm going to actually address the UDI question on claims in a few minutes, but if we look at the longitudinal information for specific populations on clinical registries, there was a great article in health affairs today on the trans-catheter value therapy registry that just came out to show how you can use patient reported data as well as procedure level data to actually give the additional information back to clinicians about this. So clinical registries are a really important piece that our members have embraced and our members report to. Sentinel, as Rich as said, has been very effective for assessing drugs, port-marketing surveillance. Many many of our members have been engaged and more are getting engaged. We've been talking to Mark and his team about adding some additional drugs that I think we're about to begin to move forward on and our members continue to, whether it's Sentinel or the work they previously did in the vaccine safety data link project, are looking for ways to assess the long term safety and effectiveness of drugs and devices.

So in regard to UDI, the greatest value from our members would be to actually incorporate UDI in clinical data such as registries, EHRs, and Joe's going to talk about PCORnet and the opportunities for device surveillance through electronic records, and how our members are actually talking to them about how you blend, as Rich has said, administrative data with the PCORnet clinical data, so that you get a much better picture. There's no doubt that there is a value for putting UDI on claims, but just having a field on the claim form for UDI does not make it so. The providers have a unique characteristic of pushing back and not wanting to report data that they don't think is necessary and a UDI is not going to be necessary for reimbursement at this point in time. We're having problems right now with ICD10 moving forward because many of the physicians do not want to incorporate ICD10. So just putting a field on a claims form is not going to give us the data that we need, but using it in registries, using it in EHRs, showing the value of it, we may be able to move this forward.

There's shortly a clear opportunity. We see UDI as a promise for the future. It's

going to actually provide more precise reporting on what works, what doesn't work and hopefully help with some timely recalls. There needs to be standards so that things are compatible, as Mitch has said, write the same language, we collect the data in the same way, we report out the data in the same way so that we can learn, and our members are eager to prioritize particularly those high risk devices such as implantable. Thank you.

MR. DANIEL: Great, thanks. Joe?

MR. SELBY: Well, you are going to see some overlap in comments between the three people right here who live, actually cumulatively work together for 30 years or so. But I will try to speak a little bit more directly from the PCORnet side, start by just saying that I was, am very appreciative of the invitation to be here and very appreciative of the work that the planning committee did and of the vision that was laid out this morning. And what struck me is that everybody agrees with the vision, down to and including the fact that UDIs are essentially. So everyone buys the vision and there was some allusion to the barriers in the comments from here this morning, but there was a lot more conversation about it in the hallway, so the people who've been kind of see different parts of the gaps between the vision and reality, so it's going to be a slog. I think another thing that was very clearly noted this morning, was that no single entity can do it by itself, neither financially nor politically from a governance point of view, so it's really going to take everybody at the table and all the resources that we've invested in and with respect to devices, even many resources that weren't originally built to study devices, can be martialed, and PCORnet is one of those. And just to be crass for a minute, Rich preceded me a bit, but just PCORnet alone -- PCORI has invested, or by September of 2015, PCORI will have invested 300 million plus in building PCORnet, so that's really a reflection of our Board of Governors' conviction that this infrastructure for doing comparative effectiveness research has to be rich. It has to be large. And it has to be really imbedded in delivery systems. PCORnet has 11 at the moment, 11 clinical data research networks, large delivery systems, networks of delivery systems, each caring for at least a million persons, in total, 26 million at this point, likely to be larger when phase two starts. It has 18 patient cog research networks, active organizations of patients with single

conditions who are professedly interested in being involved in research now, and they inject the essential element of patient centeredness into PCORnet.

PCORnet is, I like to say it's a second generation data network. It builds on the shoulders of efforts like the HMO Research Network and Sentinel. It is, in contrast to those two, it is electronic health record driven, it is not claims driven. About six months into it, it became very apparent that those who have access to electronic health records data, don't have access to claims data, so I want to be here in case anybody misses the point that it takes both clinical data from electronic health records and claims data to create a cohort, to even have denominators, to even know who you're studying. And so that's essential. We are working hard both with Sentinel and with the FDA on identifying ways to link and work PCORnet and Sentinel together. PCORnet bringing very rich clinical data, Sentinel providing claims data on some of those patients who are cared for in the CDRN and PPRN sites. PCORnet, PCORI, is also working closely with AHIP because there are other health plans. And more than that, we are trying, and this is the second characteristic, we are aiming for a system that actually engages the key stakeholders. The mantra that there has to be something in this for everyone has been mentioned three, four, five times. We started off with that in mind, and we need to involve health plans, delivery system leaders, clinicians and patients, and maybe the most difficult group are the clinicians actually. They are the most isolated in some ways.

The third way -- so we are working with AHIP in fact to bring about this involvement of health plan leaders, along with the CDRN supervising the delivery system leaders. We envision a time when system leaders and health plan leaders will sit down together to tackle these governance issues and to identify research questions that they are jointly interested in seeing conducted, studies that are of enough interest to them, that in fact they will support the conduct of those studies and the data sharing that's needed.

The third is that PCORnet is the first national data network to be really aiming to support both imbedded clinical trials, post marketing clinical trials, perhaps even someday pre-approval trials, but certainly in the beginning, post-market effectiveness trust, and large

observational studies. So if we're building a large resource, we believe it needs to be useful for both purposes. Synergy, as I mentioned is essentially bringing all the resources we have into play. Sentinel and PCORnet have actually established a working group that meets weekly to begin discussing the technicalities of how we could do data exchange. The CTSA's NIH funded NCAT's overseen academic center based clinical research networks that are very interested in speeding up and making more efficient clinical trials are a partner with us and we work closely with them. We actually overlap with them remarkably.

I have to say a word about registries. If PCORnet is one thing, it's miles wide and inches deep. It has the data in non-standardized from the electronic health record. Registries by their nature aim to get detail data. There is a perfect marriage between a large national resource like PCORnet, possibly linked with Sentinel and other health plan data, and registries that have that more detailed data. Registries will never have the comparator populations for example that are sitting right there in the broader data, so a lot of opportunities to link with registries. Challenges -- governance -- I just want to say one thing. We need to get delivery systems, health plans that are clinicians and patients talking together. We totally subscribe to the notion that there has to be something in it for everyone and we keenly believe that by putting the patient at the center and by asking everyone to speak directly to what does the patient need to know in this area, is a secret sauce for getting a different kind of conversation going. I just have to say very quickly, methods are, methods, methods, methods. If we really want this kind of research to change practice, to reach evidentiary standards, we have to have a continuous focus on methods.

And finally, learning health system is where we'd all like to be. There's a big challenge in getting, I think, systems to think of the learning health system as something that compares to devices or a device to medical therapy. Right now it's more, how do I make my system perform more efficiently. So there's both a challenge and room for conversation there about what a learning health system means to the different players that we've mentioned. Thanks very much.

MR. DANIEL: Great, thanks Joe. Sally?

MS. OKUN: Thank you. First of all, thank you so much for the opportunity to be here and participate today. I also want to congratulate the planning board. You have a wonderfully articulate document that I think is well put together and I, like Alan, actually have some pages noted in my notes, after having reviewed it, that are quite specific to patient value, patient engagement and very much the focus on patient centricity. So again, kudos to the group. Let me start by saying, for those of you who are a little unfamiliar with PatientsLikeMe, I'm not here to represent our 300,000 members who today are adding data on over 2300 different conditions. Someone's adding a bit of data every moment of the day, and we're now amassing 25 million structured data points on the site. So I'm not here to speak for them, because I didn't have time to go to them and say, here's the report, what do you think. We do that, however, with the patient focused drug development meetings that are held on the 20 conditions that FDA is holding for Cedar and we actually provide very systematically collected data on the very questions FDA is interested in getting answers to, and bring that into the public document. I will certainly follow up with this document after we're done and get that into our community and try to get some input as well. But I think what I can do is offer you three reflections on areas that I think are of importance here that will give you I think a sense of where we, at PatientsLikeMe might look at a document like this and think about how do we begin.

So the first would be to take the report in context to our core values at PatientsLikeMe. The second, I'm going to give you a personal anecdote as well. I think it's always important to get that perspective. And then a path forward, on the pilots that have been proposed, and I think we have some really wonderful opportunities to harness non-traditional agile, innovative companies, such as PatientsLikeMe in ways that haven't been harnessed before.

So first, the first core value PatientsLikeMe has is patients first, so clearly the document in its mission statement has not only put patients first, it's actually the only stakeholder named in the mission statement. So I think that's actually quite significant. However, I would add one more word. I find words to be quite powerful and what I found here was that by leveraging the experiences of patients to inform the decisions about medical device safety, very important, but I

think what's missing is the word, having, leveraging the experiences in the participation of patients, so that they're really feeling more included and inclusive in the entire experience.

Other values that we actually hold quite dear have to do with openness, so really thinking about, not only do we need to capture data and do it well, but we also need to figure out ways of giving that data back to the original data users, and ultimately to the end user of that particular device and be sure that we have a way of being able to do that in a way that's understood. We need to be thinking about transparency and I think it came up this morning, with the notion of how do we protect people's privacy and confidentiality. This conversation is taking place at meetings I go to all the time. Let's learn from each other and collaborate on how to answer those questions. But first and foremost, let's be honest. We cannot assure privacy across the entire systems of a national data set without the actual risk of potential hacking that we don't have control over. What we can do is assure people we will protect them to the highest degree possible and we will hold all of the data holders and the data partners to those high degrees and standards. Ultimately with that said, another core value of ours is ensuring trust. We feel that without trust of our patient members, we wouldn't have a company at all. So one of the things that's very important for our patients is that we don't surprise them. They know what we're doing. They know what we're working on in terms of trying to answer important questions that matter to them, and I think in order for a national surveillance system of any sort to have the trust of the public, of America, we have to figure out ways of ensuring that trust every step along the way. One way will be engaging them very proactively as participants, and not simply as being placed at the center.

Finally, our last core value, and one that we all take quite seriously, is actually part of each of our job descriptions, is create wow, and that I think, this document can do. Let's be bold. Let's be audacious. Let's get beyond the patient centricity and intentionally start calling out patients as partners, not just partners in this whole system, but as data partners, sources of data, and that we can start to create that in ways that we haven't done before.

Building upon existing systems I think is critically important and we would support

that absolutely. I think the personal story I want to share with you is, a family member of mine had an MI a couple of years ago, wonderful care, received two stents. Most recently had an injury to his wrist and needed to have an MRI. He has carried his little card about his stents in his wallet all along, and when he went to go see whether there was any concern about having an MRI with this associated with it, the instructions were that there wouldn't be too much worry so long as the field strengths were 1.5 tesla and three tesla. The static magnetic field gradient of less than 900 gauss per centimeter, extrapolated of course, was all important information that needed to be considered. So obviously not a patient centric document by any means, and something that we do need to be thinking about. If we're going to give patients these and say, hold it in your wallet, we should at the very least help them understand what it's for and why it might be useful at some point in time. It was very clear that he needed to check with someone about an MRI but it wasn't totally clear what that was about. The other was in hand writing, it tells where those stents are with abbreviations, not with a description at all, so for your information, he has one at the PDA and the RCA. Now I happen to know what those are, but does my family member? No. We can do better.

So finally I think what I'd like to then call for is the opportunity for us to think about innovation in the pilots. Pilot number three is a wonderful opportunity for working with a company that's innovative, agile and ready to go. We have a patient facing research platform already built. We've invested a lot of time, ten years of work into this and we have patients who are engaged and ready and want to be a participant with this. So I would call upon us to look at the non-traditional players, look beyond the usual suspects. We feel that we're very much in parallel and complementary to PCORnet and we love the opportunity to work with many of their partners on a regular basis, on a variety of different projects. But what we see here is an opportunity to go beyond that. Let's think about what we can do in a patient powered research network that's actually divorced in some ways from the traditional system and see if we can't harness that data in a slightly different way using methods that we haven't even thought about or tested yet. We're actually actively working with the FDA right now, and thinking about ways of being able to have them better understand our data. We're hoping to have a research collaboration agreement in

place with them in the coming month or so, or actually sit down with them and teach them about this data and help them understand how they can use it beyond the individual case report. Let's think more broadly. Let's start to think about this data as a rich source. So we can test data capture methods. We can use design science, which is what we are actually quite skilled at, and thinking about what are the user centric ways of collecting data. Why not gather data that we really need and not data just in case we might need it, and that's not necessarily a patient centric approach. So being clear that we have the opportunity to start thinking about creating and filling the gap for patient reported outcome measures in an environment such as PatientsLikeMe. We have an open research exchange platform that was funded by the Robert Wood Johnson Foundation in order to develop patient reported outcome measures within the platform, using constant elicitation all the way through to validation, so we have the platform there. We're ready to go. We're ready to have challenges from the industry, not only drug, but as well, devices, to help us think about getting beyond the generic PRO's that we typically are using and think more about the nuanced condition specific and device specific, because we heard already, there are some very specific issues that we need to think about.

Consider innovative post-market opportunities, similar to what we've recently done, in the idiopathic pulmonary fibrosis area, that had two brand new drugs just recently approved last fall for this really devastating condition. We happen to have about 3000 members actively engaging with idiopathic pulmonary fibrosis. We actually contributed a lot of their insights to the patient focused drug development meeting that was held in the fall, but what we did with them, is we created a launch monitor, so that at the moment those drugs went to market, we actually had questions and a survey process already set up so that patients could tell us about their access issues, they could tell us about their early experiences with the drug, what were the side effects that they were starting to experience and really start to gather some very pro-active information from the insides of real people with co-morbid conditions, with other kinds of experiences outside of the clinical trial population that could actually inform us about some of this information much more rapidly and more agilely.

And then finally, I'd really like to press on this issue of considering patients as true data partners. They should have the same opportunities incentives as well as responsibilities and roles, as any other data partner in this system. And when we do that, we actually give them credibility that their data matters enough for us to see them alongside other data partners. So I would call upon us to think about that and actually would challenge that in each pilot there should be an opportunity for patients as data partners, so that not just the third one that I'm speaking about, which I think is well suited to patients like me, and other collaborators, but I think overall it would be important.

And lastly, let me say how pleased I am with the notion that we talked about a learning health system. One of the things that has troubled me over the last couple of years, first of all, as a clinician, but then also now as an innovator in PatientsLikeMe, is that we have actually fallen to default too often on the triple lane, which actually is not patient centric. It's really provider centric. The learning health system is completely patient centric, but I can tell you now, unless we find ways of creating environments for patients to be full, invited and welcomed partners, we won't achieve the promise of a learning health system. So I call upon us to take that seriously, to see this as an opportunity that we have unprecedented before. We have not had an engaged public the way we have. We haven't engaged everyone yet. We still have ways to think about how to do that, and I think Alan raised that this morning, with people who might not be as connected, but the digital divide is closing. It's getting smaller and smaller all the time. And we have opportunities now to test new methods and new ideas, and I welcome the opportunity to work with the planning board as well as FDA and Brookings on any ways that PatientsLikeMe can assist in that. Thank you so much.

MR. DANIEL: Great, thanks Sally. And thanks to all the panelists, for such terrific comments. Before we turn to the audience for some questions, I do have a couple pointed questions to all of you and I think all of you brought up the specific pilots that were proposed and in chapter form we heard on earlier sessions this morning, the importance of doing something early, doing something relatively soon to start generating value on participation and motivating that long

term sustainability. In case you all haven't had a chance to look at the pilots, just very briefly, one was designed to ask questions around standardized ways of collecting UDIs across multiple hospital systems and linking those UDIs to important long term outcomes, either through linking to Sentinel or to long term outcomes registries.

A second pilot was around identifying a small core set of clinical data elements that could either be informed by EHRs or by claims data, a core set of clinical elements that could form perhaps a common data model, that multiple health systems or payers could routinely collect, that could form the basis of surveillance system in terms of its content. And then finally identifying feasible ways to include patients' perspective, not just patient outcomes and patient generated data, although that will be an important part of the system, but also including patients into the governance and into the participating in the system.

So the other thing that we heard, is that while these pilots are important, it's also important to make sure that as we do these pilots, that we do answer these technical questions, but we also do so in a way that motivates participation, that we can see some early value by payers participating in these pilots, or by patients participating in these pilots. So now come my questions. So to Rich, I'm going to pull you out first, because you've specifically said and this very much helps me, some things we should just start doing now. And so I'd like to ask if you can expand upon that a little bit now in terms of Sentinel, how can we get some meaningful device surveillance within that system in the short term?

MR. PLATT: Well for the -- Sentinel brings good information on essentially all medically attended care, and so it seems to me that what it can contribute is high quality information about certain kinds of outcomes that would be of interest. What we need to do is marry that to information about the exposures that we care about and for the moment, the best way to do that is likely to be from registry data. So then the question is how do you put them together. And I'd say the 60 second version is, first you have to think through sort of the technical piece of how an organization that has data that either comes from an EHR, from a registry, for a moment, let's talk about a registry, identifies those individuals in the Sentinel data set. Our work

group is talking about that. What's it take to identify the people in common? It's pretty clear that each of the Sentinel data partners would tackle that in a slightly different way. Part of the white paper we're developing is going to sort of lay those out so that we can develop a statement of principles about it. Then you have to ask how much data would you have to transfer to do meaningful kinds of follow up and it's pretty clear that the more data that gets transferred, the more complicated it is, both to protect that information and also to get buy in from both parties, that this is information they want to transfer. So we're thinking about sort of a graded way of doing this. It might be enough for instance, if the simplest question is, what is the rate of device failure, or what is the rate of re-hospitalization for this condition. It might be enough to say, in these periods of time, how many individuals in this registry population were re-hospitalized, had revision, without necessarily transferring a lot of data. You could say we want to do more than that and put together the complete linked data set. It's a higher level of effort that would let us then ask a larger set of questions. So that's the general drill. And I think we could start that, we could really start that now. The foundation, these issues of how do you do these things, are ones that Sentinel and PCORnet are wrestling with right now and I think they apply directly. And if there's a willing partner who has the kind of device exposure information that would make this real, I think we could talk about that as an early work example. Okay?

MR. DANIEL: So I guess to, and all of you can chime in on this one, but particularly, maybe Carmella and Sally, is thinking across all the potential uses of the system, what could be just safety, but should, and we heard from multiple panels including the planning board, that this is a system much more than just safety and could support innovation, could support further characterizing the benefits and risks of a potential product. So thinking about these early pilots, how can we sort of engage payers and engage patients in a way that could generate more additional momentum and motivation to continuing the longer term build of the system?

MS. MS. BOCCHINO: So the health plans, and clearly Joe knows this, because as I said, we send them lists all the time, have really identified where there are gaps in evidence and where they want information and so I think part of the conversation that Joe had talked about,

about this new partnership we've established with the plan is to look at where they see the gaps in this evidence and are there registries or other sources of data where we can start filling gaps without doing you know a very expensive long term file which will take us forever. I also want to make a plea for building on the systems that we have, Sentinel and PCORnet as opposed to building something anew, to start doing this. I think it's -- we've got systems that are in place that have gone through the growing pain of people learning how to work together and come up with common standards and governance and definitions that I think we need.

And I'll give you one important example of, since Rich brought up registries, about registries that I think brings very much in the patient perspective. There are several different joint replacement registries out there right now. And they're all working to try to come together to actually merge into one registry within the United States, so that we don't have all these different. But I'm going to speak specifically about Kaiser's joint registry that was set up several years ago and actually does have patient reported outcomes into the joint registry. And they were actually able to focus on which devices over a two and three year period were most effective, had less problems, had less complications, resulted in exactly what Rich was talking about, less hospitalizations, less return to surgery, which they, because they're a delivery system, as well as an insurer, led to making decisions about what devices they were going to use in the hospital for orthopedic surgery. And I think that's the power of everything that we're talking about. If there is information out there, how do we harness that and broaden those longitudinal studies. They went as much as to ask consumers about functional status and you know, how quickly their functional status approved in different areas, how quickly they returned to work, what their perceptions were relative to the experience. All of that is the valuable information that I think we can contribute. So I think there are examples out there and we have to figure out a way to harness all of that information into something more of a larger longitudinal study.

MR. DANIEL: Okay, great, thanks. Sally, anything to add to that?

MS. OKUN: Yeah, thank you. Wonderful comments, and I think I would just add to that, and that's when you're thinking also from a patient perspective, a lot of the opportunity that

we've provided within the PatientsLikeMe platform is a longitudinal perspective that's really about what it's like to live 24 by 7, 365 days a year with whatever it is you have and with whatever it is you have that might also include a device somewhere in the mix. So I think the opportunity is, as a novel data source, within which we have data that's not quite what you're used to, we've actually spent a lot of time and investment in thinking about how do we take our data and transform that data in the common data models appropriate for an end user, so we've been able to map that to the appropriate ones. We can map it to PCORnet. We can map it to the OMOP experiment. We can map it to different places by going through the transformation model, recognizing that we couldn't come up with one common data model, because we were such a diverse environment. So our hope would be that we get the opportunity to experiment and start to test, how can some of the data that we've collected and we've actually already gone to ICD10 because we are agile and innovate enough to be able to do that quickly, but we can map it to ICD9 if we need to. (laughter) But it's that sort of thing. It's an environment within which if you intentionally invite people to engage in some things that they haven't been invited to engage in before, you'd be surprised at how many will say, yeah, I'm in for that. But you have to give them the experience in such a way that's meaningful to them and gives them something back and useful and ultimately at the end of the day they can see that their participation has some real contribution, so.

MR. DANIEL: Thanks Sally, and Joe, any comments to add to the sort of, I know pilot three came up a lot around maybe in what can we do to start engaging in patients, or at least patient data, into meaningful device evidence development, and I know that your system is building and you have -- we will have the opportunity to bring in a lot of that important data so any next steps from --

MR. SELBY: It's certainly a goal and the intent of PCORnet to engage, integrate, patient data and particularly to look for situations where collecting patient data also has utility from a clinical point of view so that its -- so that the systems ultimately buy off on the value of it. The other thing I just wanted to comment on, so yes, without a doubt, and in devices, I think we were discussing this at lunch, in devices more than a number of other areas, I would say, patient

reported data might be the essential data for evaluating and particularly in comparative effectiveness in studies. But Carmella mentioned Kaiser Permanente where I used to work and it's just you know, in some ways, what we are looking for here, is an integration of data, like Kaiser Permanente enjoys, and the reason they enjoy it is because they've kind of aligned everybody, whether you're a clinician or a health plan executive or the head of the medical organization or running the pharmacy, you're aligned and so the secret sauce for us is to figure out those areas in which we can align, which will then facilitate more integration of data and the capacity to do patient centered research.

MR. DANIEL: So I'll pick on my first panelist last, and Mitch, you thought you were going to get off the hook, but MDEpiNet has been doing just a tremendous amount of work in the area of methods, how to better do device surveillance, how to better build registries. In fact tomorrow is an MDEpiNet, the Smart Informatics think tank, which I think is a two day event, you will be talking about specific pilots that are designed around infrastructure, around methods, so maybe ask you to speak a little bit more on the overlap, the three pilots that were presented in this planning board report, certainly overlap with the building infrastructure and methods development. Can we say that we're off to a head start with MDEpiNet's pilots and that there is a lot of momentum already in some of these pilot ideas, that that could sort of dovetail and promote the development of a system like the MDS?

MR. KRUCOFF: So I do Greg, and I'll be repetitious enough to agree with I think everybody, that the pilots that the current document and the board has set out, I think really put three very important and fundamental stakes in the ground. I guess I don't see them as three pilots so much as three portfolios, because frankly within each of those, and as I said earlier, I think to really make this happen, we're going to have to recognize that there are levels of movement forward that are really the long term right solutions but they are going to move more slowly because they will require a greater level of coordination and consensus to move them. Before that happens, I think demonstrating smaller quicker successes that clearly fit within the pilot umbrellas as a portfolio, that's frankly where I think MDEpiNet probably has some stakes in the

ground that are very good fits to the, what I would call portfolio of pilots that the planning board document proposes. So for instance, and I think having, again, worked for a guy for 27 years who is relentless about achieving the balance of complex collaborations but relentless about the word balance, is as we have moved finally into a sort of a patient centered orientation, that doesn't mean that it's time to leave industry and manufacturers behind, or other stakeholders behind. It means that you know, the key term is partnered. It's not about shifting ownership from one stakeholder to another; it's about finding the real win-win. And better, faster, less expensive devices, reaching the bedside faster, then a business model that is attractive to manufacturers because that's where the genius of innovation actually starts, this is what all of us ultimately want to be, because everybody in this room sooner or later is the patient, or somebody in our family. It doesn't matter what your profession is. We all go that route. So starting from that perspective, I think keeping the balance, a lot of what we're focused on is the degree to which currently existing efforts could illustrate some of what I think much more profound shifts in the landscape in a longer term can execute. And there I think some of the MDEpiNet programs will come back to programs that have been developed in orthopedics and cardiovascular and grow. But I see this as complementary. And what I love about the sort of structure of the planning board document, is I take this as three kind of portfolio buckets, where some faster successes that show there's actually a very attractive business model that the data can be higher quality, the safety information can be more robust, because safety concerns are really the barrier to innovation, and the speed and cost of doing a trial can be far slower. The first registry based randomized trial I have been involved with was a trial on women, and it was just a trial of whether we went through the wrist or the leg in doing a cath. This was a public health study. It wasn't a device trial other than it was an interventional study. We used a registry based model. It was a prospective randomized trial. But the site coordinators who quickly appreciated that two-thirds of the work that they would traditionally need to do was already being done by the registry electronically populating those case report forms, this is the only study in 30 years of doing clinical research where we were ahead of our enrollment curve before we had activated 50 percent of our sites. This is a different way of

doing business.

So I think there are some smaller bites, some quicker successes that could complement the bigger movement and again, going fast and going far, I think to me is at least the vision of what pursing the national system looks like. And there, I think MDEpiNet's and its construct is a good place to keep that balance.

MR. DANIEL: Great, thank you. I would like to go ahead and open up to the audience for any questions. If you do have questions, raise your hand and we've got a microphone in the audience, so Dale.

SPEAKER: So I wanted to just compare contrast some things we heard in maybe the first panel and in this panel, and then ask a question. In the first panel there was a lot of emphasis by multiple people about the need to be agile, the need to recognize that technology is changing very fast, that what we can do today may not be -- we can't even imagine what we'll be able to do tomorrow. And we shouldn't build ourselves into obsolescence. In this panel what I'm hearing is we've made a quarter of a billion dollar investment in multiple systems. We have to leverage those systems, which, by the way, the board agreed on. But are we looking to really, if you will, house ourselves in these big investments or do we think in two or three years we can do something similar, not for a quarter of a billion dollars, but do we have an X prize where we can do it for five million? Do we have infrastructures in place? And how do we make sure we keep this inter-mediating these big investments and we get much more agile with innovation? So my question is, where does a quarter of a billion dollars go? By the way, I build systems. I know where it could go (laughter), but I'm interested in where did it go, where will it go and where does a quarter billion dollars go in five or ten years?

MR. DANIEL: Joe?

MR. SELBY: So thanks for the question. Probably the most immediate challenge and the one that's occupied an inordinate amount of our time, given this investment, is for the first time really capturing data from the electronic health record and standardizing it, transforming it and so that across 11 delivery systems, ultimately, hopefully many more, many millions of people, we

will have standardized clinical data to match the relatively standardized claims data that we've had for a long time. I think the reason this should endure and be worth it, is because this is not a single study. This is not a single purpose. This is not solely for devices nor drug safety nor CER. It ultimately is building a tissue if you will across the country that can be latched onto for any number of kinds of studies -- pre-approval, post-approval, surveillance, safety, and CER. So I think if you didn't have an investment like this, you'd be doing that every time you set up some other system. You could find a five million dollar system that could connect people but could it gather all the other data that this infrastructure is set up to collect?

SPEAKER: (inaudible)

MR. SELBY: Yeah, well, you just said the magic words. Yes. Yes.

MR. DANIEL: Start.

MR. SELBY: I certainly, in PCORI, its Board of Governor who is sitting there, Dr. Kuntz, does not intend to continue plowing that kind of infrastructure money into PCORnet over time. These are largely startup costs and they are largely the costs of number one, getting the electronic health record data into standardized fashion, number two, creating a culture of collaboration and a culture that allows not only the continued ongoing work on the data infrastructure and the collaboration, but also the capacity to change and to adapt new technologies that come along. The third big part of the investment is involving patients, involving clinicians and involving systems leaders, so I think those are enduring foundational elements that one needs if you're going -- you know, technology is kind of beside the point when certain systems are saying, this data is not going to be shared. So an infrastructure and a culture, a network that has the key players involved, I think, can adapt the technologies as they come along. But we do think that research use is what's going to sustain a large bulk of a network like this long term, not continued quarter of a billion dollar investments every five years.

MR. KRUCOFF: So I hear a little different spin on the question, and I hope I'm not missing the question, but it certainly, in a universe where the only standard is progressively accelerated change, this is cultural, this is technical, and certainly from a health care point of view,

hopefully it's also therapeutic accelerated change. I said very briefly before, but I'll just repeat it because I think it's at the heart of at least my view of the question. We have to create in parallel with the system, in a learning health system, an environment, a culture, that supports that system, through the ability to have ongoing dialog about what is changing, and how do we approach that change. So we heard very clearly, a patient perspective is, collect the data you really need, okay? Don't collect a lot of what if kind of data. Get the data you really need. On the other hand, as we all know all too well, with real innovation and medical devices, what we also get are surprises. So how do we deal with the surprise and it's challenge to the system that isn't collecting or might not be collecting or when do we start thinking about collecting, and where is the dialog with the patients who are the source of these data, about that balance of the data that we really need that we know we need today -- I don't want to digress into the know we don't know and what we don't know we don't know and, but that's actually the dynamic with medical device innovation, and with data collection tools. You know, is it really EHR based technology that's going to need to be the future or is it iPhone based technology with patients reporting? So I think the key is, even in the larger farther reach of this national system, we have, to be successful, we have got to create a culture that goes with the system to continue to engage dialog about what's changing, what's new, what's on the horizon and to what degree is what we have built sufficient or potentially insufficient and how do we go about that shift, again, as partners, real partners? And that to me is an eco-system oriented environment and it doesn't come easily. We need to concentrate on it. It's got to be an active a creation as the system itself. Okay?

MR. DANIEL: Sure, sure, this is a great question Dale, by the way.

MR. PLATT: The systems that we're building for PCORnet and for Sentinel are future ready in the sense that they will accommodate ICD10, SnowMed, RXNorm Loink, when systems begin to use them. We're trying to build a system that can answer questions for FDA or for PCORI or for society now, we got to deal with the information that systems are currently collecting and it's remarkably diverse, so some say, when you get out of dirty claims data into EHR data then things will be better and I assure you, things will be worse. And partly that's because

electronic health records are infinitely customizable. That's a feature when vendors market them to clinical systems, and it is a bug when you're trying to build a system that can integrate across organizations. Sentinel does work with EHR data. Just as a guess, how many different units of measure are there in just in the Sentinel data for glycosylated hemoglobin? You're right -- 32. (laughter) Now none of these 32 is a problem for a clinician. So it serves the clinical purpose fine. But if you're actually trying to do analysis across that data, you have to make a substantial investment in making the data fit for purpose. And so when you ask, where does all that money go, a lot of it goes for Sentinel, millions of dollars a year goes into quality checking data that was perfectly good for its original purpose, but unless you do the quality checking, you won't realize that quarter two of 2012 has just disappeared someplace, or that there was a change in the way, in the number of diagnoses that are captured in the enterprise data warehouse and if you go from five diagnoses to seven diagnoses, it changes all of your predictive modeling. So the money goes to a lot of things that -- when you're talking at the level of panel one, you don't have to think about. If you're doing it foxhole by foxhole, it turns into an expensive arduous procedure and I agree with you, you don't want to try to standardize all the data. You just have to be attentive to the data that's of most interest. So the future, as I say, the future will be terrific. But working now is expensive and time consuming because a lot of people have to be attentive to make the data suitable for the questions that are being asked.

MS. MS. BOCCHINO: I could prolong this, but let me make just two brief comments. As you all know how plans pay a lot of money to PCORI, was part of the mandate, INACA, and so they want to make sure that that money is being appropriately used, and used for value. They will go to a certain point for an infrastructure to be built but after that, they're not going to continue. There's going to be this loud noise that Joe knows he's going to hear at some time, that this is not about infrastructure building. This is about doing the research that we need to have to give us the information on gaps. But the infrastructure is needed and so there's some tolerance right now for that. But just to echo what, you know, Rich and others have said, EHR, I've been puzzled by this, they can't talk to each other. We have created silos of EHRs and it is so

frustrating. In claims, if you try to put claims together, I will tell you, it is your worst nightmare, because of the way physicians code, because of the differentiation and benefit packages that either employers select or consumers select, and you don't know a lot of time, is it not ordered because it's in the benefit package or not in the benefit package, or was it not ordered, was it missed? Was it a missed opportunity? We've got a long way to go to standardize data. And I think these both infrastructure pieces on Sentinel and PCORnet are hopefully going to get us there, that we invest in them and build off of them as opposed to just creating new infrastructures.

MR. DANIEL: So Sally, last word on this question.

MS. OKUN: Oh thank you. I just really want to call for collaboration. I feel like we have an opportunity to go on this parallel complementary path, where innovators such as ourselves can innovate and we can be agile and we can test out new models and methods, but we can also learn from the structure and the attention that's being paid to the national infrastructure that's being put together and I also would echo that we have also spent 10 years building our infrastructure and have built a lot of it on some of the traditional structures, so we have ICD, we have SnowMed, we have Link. All of our data is coded to all of this. So the opportunity for us to collaborate and be on parallel paths and learn from each other in this learning health system is just unprecedented. And I think the opportunity, especially in the device world, really represents something where we can bring a whole new level of information and possibly uncover some surprises you wouldn't expect along the way, because of the novel way that patients tell us about their experiences.

MR. DANIEL: Great, thank you. Any other questions from the audience? Yes. Up front.

SPEAKER: Yeah. I consider this project in a sense, trust, and the quality, accountability of data is the first condition that you want to make meaningful sense, not just getting the money from government, because the government maintains almost frivolous purchase of frivolous everything from land to money or resources or appropriation. So if you want the government to give you money, just to make it work, I'm thinking just make it a project, but not

really making it meaningful. So the government, you have to fix it first and especially for medical institution, to make this a transaction. Everything is wrong way, then you are not going to make it work, because the data, it will not be correct. The data will not be correct and then the patients or the nurses will not be correct, and it just happened, several decades ago, until now, still the same thing. It's not just the medical industry, but also almost every government agency. They all have a fraudulent maintenance of fraudulent data and fraudulent sale of data, so you just have to fix that system first and it's very easy to fix the system. It's just people reluctant to do it. Like its government agency or maybe FDA, maybe Congressional staff, they have internet, they have incumbent block and things like that, but that will not really take part of the incumbents. And that will not allow people to see the incumbents, and they will observe the incumbent, and they will even -- something that your email account. So I really mean for suggestion but the people will not be there. So that's what I say. If you want to make it meaningful, let's fix the real system, not the way you're national system. What I mean is the system of current society living.

MR. DANIEL: Great, thanks. Good comment. So I do think that what our approach here is, some collaboration with government at the table, but also the private sector, that really do have the expertise and experiences with building systems like this and we can, one thing that I did hear from everyone on the panel was that collaboration is key, both from the private sector and the public sector. Just to summarize also, the other things that really did come out of this discussion were, let's start with the pilot. These are feasible pilots that can begin to address some principles for moving further, just start doing something now because we can and we have the capability of beginning to build the system. Also a theme that was pretty interesting is, Sally, having patients, you know, your point about treating a patient like a data partner is really an important point and the theme of participation in such a system. And you know, I would like to end with what I think is the quote of the day, which is a paraphrase of Mitch's quote, which is, collaboration will get us going further, and that's a common theme throughout this panel as well as other panels. So thank you for that. And I'd like to thank all of our panelists today. Thank you.

MR. MCCLELLAN: All right, while they're moving down, I don't have much to add

after Greg's excellent summary and after the great comments from this last panel, as well as everyone else today. I do want to thank all of our panelists for their time and effort in this discussion. These are people who have been working hard on issues related to better evidence to promote better health for a long time, and have found ways to make those efforts work well with some of these new opportunities around post-market medical device surveillance. So we have before us, as a result of that, a lot of opportunities to build on the momentum that you've heard about today, to get to more effective use of medical devices, more efficient regulatory processes, and much more valuable innovation in medical devices, through to the development of the medical device surveillance system, and Greg just paraphrased Mitch, which I think the goal here is definitely not to go alone. That's not going to work, but also to move forward quickly on overcoming the challenges and fulfilling some of these tremendous opportunities. You heard from the panelists, a lot of feedback already on this report. This is very important for moving forward effectively, for building on the momentum and opportunity here, for making sure that the ideas developed here fit into legislative processes, fit into a lot of activities going on throughout our health care system. There will be more opportunities for all of you here in the room and everybody who's joining us on the web, to contribute to this discussion. The FDA will be publishing a federal register notice shortly about the report with instructions on how to provide comments. I understand there's a two month comment period for this report. I encourage you to, if you have some further ideas, suggestions on how to move forward, to get those in and preferably in less than two months, not just discussion about the long term vision, but as you had heard many of the commenters today focus on, what are the next steps to get there, highlighting perhaps some of the very important obstacles and barriers to effective progress on post-market device surveillance, but also opportunities and ideas for promising directions on overcoming those barriers, not just the idea long time model that's an important part of the report, but also, ways in which pilots can create value, create opportunities to move towards that long term vision right now, so a lot of things that are, that could be part of your comments. The report is really just about starting this process but this is unquestionably not the end of the process. Maybe it's the end of

the beginning on efforts to pull together a truly national, effective, valuable and sustainable medical device surveillance system, but to get there, it is going to take continued collaboration and we're going to continue to do all we can here at Brookings to facilitate that. I do want to thank the people on the staff here at Brookings that have made this event, the report and hopefully the further progress building on the report possible. It includes Greg Daniel, who you just saw, leading our work in this area, Pernaud Aurora, Saha Qutaraz Katerzi, Matt Longo and Joanna Klassman, I just want to say a special thanks to Heather Colvin. This was a short time frame for the report. I can't tell you how many conversations I had with her, and emails I had with her while she was worried about family getting into town for the holidays, or picking up kids on the weekend, but still prioritize this along with all of those other activities. It's been a great team to work with and just a reflection of the commitment to the ideas and the great potential of this effort. It's a real privilege to work with them, with FDA and with all of you on this very important topic of medical device surveillance. So thank you all for attending, thank you in advance for continuing contributions to achieving the goals that we've laid out here today and we look forward to making that real progress as soon as possible. Enjoy the rest of the afternoon. Thank you very much.

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Expires: November 30, 2016