Washington Prescription Drug Price and Purchasing Summit
September 22, 2016

Donna Sullivan: So, good morning and welcome to the Healthcare Authority's second Summit on Prescription Drug Price and Purchasing Strategies. I am Donna Sullivan. I am the chief pharmacy officer with the Health Care Authority. I just wanted to go over some logistics before we get started. First of all, the restrooms are out the doors and to the right at the end of the hall. We have refreshments in the back, and there are some also out in the foyer. Today's meeting is going to be recorded. So, when we do have participation from the audience, we do ask for you to wait for the roaming microphone to get to you, so you can ask your question, and we can get that recorded, so that we can make sure that we put that information into the lake of information that we're collecting here.

Also, I'm not sure if we have any legislators here attending. There were a couple that had registered. Do we have any legislators? If so, could you please stand up, and we'll introduce you? OK. So, maybe they'll be coming later.

So, next I wanted to just go ahead and review the agenda. We're here today really to talk about value-based purchasing and really explore the cost of prescription drugs and how the Health Care Authority and other purchasers within the state can actually start managing the high cost of prescription drugs and put more value into the products that we are purchasing. So, first we'll have a recap of the June summit from Dr. Dan Lessler. Next, Laura Zaichkin will give a description of the State Health Care Authority's view on value based purchasing. That will be followed by a panel discussion that is moderated by Sean Sullivan with five panelists from industry, as well as purchasers and PBMs. We'll have a short break, and then we'll wrap up the day with a presentation from Jane Beyer on the SMART-D Initiative that is going on at OHSU. So, again, thank you for coming, and Dan, I'll hand it over to you.

Daniel Lessler: Great. Well, my name is Daniel Lessler. I'm the chief medical officer at the Health Care Authority, and I want to welcome all of you to today's conversation, the second in the summit series, as we are calling it.

To provide just a bit of context here, what I wanted to is briefly review some of the conversation from the first summit that was a couple, a couple of months ago, and place the conversation we're going to have today in the context of value based purchasing and, as Donna said, we really want to do a deep dive on alternative payment models for pharmaceutical purchasing and especially risk sharing agreements, because that was an area that really surfaced as a potential area of opportunity for purchasers at our first summit, and we're fortunate, as Donna has mentioned. We've got a terrific panel and facilitator, and we're looking forward to engaging that panel and actually then having time to engage all of you in discussion.

So, really, our goal in these two convenings is really to understand what is happening in the industry, what's happening with drug prices, and what sorts of strategies can we, at the Health Care Authority, undertake to really address the high cost of pharmaceuticals by driving toward value, and we're going to have some more discussion in terms of framing the pharmacy piece more broadly in the context of that the agencies work toward promoting value based purchasing. I think today, it's really, I think, partly about learning, well largely about learning and educating ourselves so that we really have a deeper understanding of what's happening and what kinds of alternatives we have to pursue that really make sense for us, as an agency. So, this is the last... really the agenda and speakers from the last session we had a couple months ago and for people who are interested, actually all of the material is online. So, if you go to the Health Care Authority's website, all the presentations are available for downloading, and as you can see, we really had a great group of people from various parts of the industry, healthcare policy, and academics, to engage this conversation. My job in the next 15 minutes is to summarize eight hours of conversation and everything that's in this syllabus, and again, that's available to you online at the Health Care Authority website.

So, first, and really all of this is by way of summary in some sense, just background, set some context here. The net spending on drugs in the United States between 2013 and 2015 increased 20%, and it sort of depends on which data you look at and so forth and how you create the

metric, but roughly prescription drugs now comprise about 17% of total healthcare costs and per capita spending in the U.S. on drugs exceeds that of any other Western industrialized country.

One of the things we really sort of began to focus on, and we'll have more conversation about today, is the extent to which specialty drugs are driving that increase in prescription drug costs. So, with specialty drugs, and I know there are sort of different levels of understanding and background here. As I read this literature, it's very interesting to me, because there really is no widely accepted definition of specialty drugs. I think initially, and this was always my way of thinking about them, when people would talk about specialty drugs, I would think about the biologics or drugs that are derived from living cells and difficult to administer and complex to maintain and so forth. For example, the antiinflammatories, such as Humira for rheumatoid arthritis, but really over time, the definition of specialty drugs has really expanded. Now, for example, CMS really uses a definition that's driven by cost. So, Medicare has defined specialty drugs as drugs costing more than, more than $600 a month. So, there is sort of this great variation. I think, essentially, the idea here is specialty drugs tend to be new drugs to market that are very expensive and often are biologics but not necessarily.

So, this just gives folks an idea of the relative spend on pharmaceuticals, and you can see here the trend for specialty pharmacy is really quite high at almost 36%. So, that's why there is a lot of focus on that group of pharmaceuticals.

So, a lot of people are obviously struggling with this. We've got a, you know, I think, a great mix of folks here from provider groups to Medicaid plans to commercial plans and so forth. I think from where I sit at the Health Care Authority with responsibility that the agency has for Medicaid, obviously, the cost of pharmaceuticals has been a huge issue for Medicaid nationally, and folks, I'm sure, have heard about some of the debates around hepatitis C medications and their costs, and the National Association of Medicaid Directors has actually been grappling with this trying to think through, well, what kinds of strategies are possible here, and they have, they have actually outlined those that you see here, and I won't read them all, except for the last one, because

that's really where we're going to do the deeper dive today of allow innovative payment arrangements. For example, allow states to enter into outcome based contracts with manufacturers where payment is made per successful course of treatment rather than per pill. That's one example of risk based contracting. There are other examples, as well, but just to point out that this idea is of interest not just to commercial payers and purchasers but to public payers and especially Medicaid, as well, and we'll have a chance with Jane Beyer here from OHSU to talk a little bit more about that Medicaid piece later in the morning. At our last convening, one of the folks who spoke was Bill Ely, who is the VP for Actuarial Service at Kaiser Permanente Northwest, and this is a quote taken directly from his slide, and really I think is part of why we are all here today. He makes the point, "The current market for drugs in the U.S. is broken. It's time for a new drug pricing model that rewards needed biomedical innovation at prices patients can afford." So, I think that's the problem that we're seeking to solve for, at least to some extent, in today's conversation.

So, in that context, payers, Health Care Authority included, are really looking for ways to address costs and find value, and I think that the important point here is the ways in which we've usually gone about this, ways that are very familiar to people in this room, tiered formularies, drug rebates, these kinds of approaches are less and less effective, or at least appear to be, and they are really not available, oftentimes, for specialty pharmaceuticals where there are not close therapeutic alternatives. So, that's the context and I think the tools that we've had just really are not, I mean, we continue to use them. We need to continue to use them, but they're not getting us as far as we need to go.

So, we're looking for new approaches, and at the last convening and again, if people go and pull off some of this information from the website, it's really terrific. There were a number of different ideas that were discussed, two of which were value based formulary. So, the idea of really using cost effective analysis to determine value and then using that definition of value for a particular pharmaceutical as a way of putting drugs, in particular, in copayment tiers. Now, that's an option typically for commercial payers and, again, as you'll see, we're trying to address both sort of these ideas across the commercial sector but also for public

payers. That's not an option for public payers or for Medicaid. So, we also talked and looked at alternative purchasing models and so called performance based risk sharing agreements, or PBRS is the term that is used.

So, performance based risk contracting, really, is very consistent with other healthcare purchasing trends, in terms of this idea of paying for value, and I think importantly, it offers the opportunity to align incentives, but while it appears to be on the surface a viable option, there is a lot of devil in the details. First of all, it really would apply to selected products and there are lots of complexities in terms of implementing this in a way that you actually to that value equation, and I'm hoping that today we can dive in to some of those complexities and have that conversation.

So, today, as I say, is about doing that deep dive. We recognize that to the extent that these kinds of risk bearing agreements for pharmaceuticals have been implemented, they really have only been implemented in the commercial sector and then only to a very limited degree, and I think someone is going to comment a little bit about that, and we have an opportunity today, as well, to explore this approach for Medicaid. So, that's what we're planning to do today.

So, again, I want to welcome everybody. I think you for taking time out of the day. I'm looking forward to a really good conversation. What I want to do now is tee up the next conversation and let's see. I'll introduce our next speaker, and it's really a pleasure to introduce Laura Zaichkin who is the deputy chief policy officer at the Health Care Authority. I've worked really close with Laura over the last few years, and I'm really grateful to have had that opportunity. Laura really has been at the cutting edge of leading the agency's work related to healthier Washington and a big part of that, as people may know, is about implementing paying for value strategies. So, what Laura is going to do is provide sort of the bigger framework in terms of the value based purchasing strategy of the Health Care Authority going forward and then tie that to the pharmacy piece that we're discussing today. So, it's really a pleasure to introduce Laura Zaichkin, Laura.

Laura Zaichkin: Great. You never know how short you are until you get up in front of one of these podiums. So, as Dan said, I'm Laura K. Zaichkin. I'm the deputy chief policy officer for the Health Care Authority. I'm hoping that what I can do today is frame up our paying for value approach so that we can continue to have a big picture view for the remainder of the morning, as we dive into the weeds on this really important topic of pharmacy.

So, just a little bit about the Health Care Authority. The Health Care Authority is unique, because unlike other major purchasers in this state, we wear many hats. We convene stakeholders around important initiatives. We make, create, and implement policy with many of our partners outside of this room and in this room, and most importantly, in the context of paying for value, we're the largest purchaser in the State of Washington. Health Care Authority purchases healthcare for over 2.2 million Medicaid or Apple Health clients and public employees and their families. So, we cover one in three non-Medicare eligible residents in Washington State. We spend $10 billion annually, and we want to make sure that we are spending those dollars in the most effective way in order to ensure health and healthcare and affordability for the people of Washington State. We do have differences in our Apple Health and our public employee benefits programs; however, it is really important to note that we do have significant provider network overlap. So, regardless of the program, patients are getting care in the same places. So, it's really important that we are aligning our strategies, as much as we can, because the impact of clinical policies is maximized because of this network overlap. We have internal wellness strategies with the state. So, we have a wellness assessment strategy in place where participation and followup plan is linked to financial incentives.

Some of our purchasing decisions are guided by our state's sort of blueprint for achieving the triple aim of better health, better care, and lower costs, and some of our strategies are driven by executive order or by the legislature. So, for example, we have a purchasing mandate made by the legislature that was passed in 2014. They issued a mandate to Health Care Authority to increase the use of value-based contracting, alternative quality contracting, and other payment incentives that promote quality, efficiency, cost savings, and health improvement for

those who we serve under Medicaid and the public employee benefits program.

I mentioned healthier Washington. Healthier Washington is the State's plan for help systems transformation. Paying for value is a huge part of this, because as we know, incentives drive behavior, and we want to ensure that we're putting the right incentives in place in order to drive the most high quality effective care, and also creating a healthy system where people live, work, and play. So, healthier Washington is a combination of a four-year $65 million dollar federal grant, and we are nearly halfway through that grant at this point. Also another potential implementation mechanism is the 1115 Medicaid Transformation Waiver, which we are hoping to hear about any day now, and then as I mentioned, the 2014 legislation, particularly House Bill 2572 and Senate Bill 6312 that really changed the way that we shape our Medicaid and our public employee benefits program, and also how we're, how we're paying for that.

Healthier Washington includes three strategies. We're really aiming to pay for value, ensure whole person care, and build healthier communities. We have cross-cutting components that we're working on, that impact the entire health system in Washington State, not just the healthcare delivery system. So, you may hear about accountable communities of health. We have nine of those in our regions throughout the state, and those play a part in really ensuring the triple aim in healthcare delivery and costs and just sort of a general population health in Washington State. We're investing heavily in analytics and interoperability supports under healthier Washington. We have an aligned set of common measures in this state that we employ in our contracts. We also are providing practice transformation support to our clinical providers under healthier Washington, and we, as part of healthier Washington, as well, we're the first state in the nation to certify patient decision aids in order to drive shared decision making. So, l those are some components of healthier Washington that are all working together with the right incentives in place and paying for value strategy, as a foundation in order to drive health system transformation.

So, a refresher, what is paying for value? Traditional healthcare payments really are based around and reward the volume of services provided. We're trying to reward the value of services provided. So, we're tying healthcare reimbursement to financial performance, clinical quality, and patient experience, as we embark on our paying for value journey. We are incentivizing patient centered evidence based and whole person care. That's of importance to us. We want our members to receive the right care at the right time in the right setting, and also it's important to remember that volume based reimbursement can drive over utilization and more care does not necessarily mean better care. So, we need to keep this in mind of the… the quality patient experience, cost, while also balancing the overutilization and underutilization.

So, payment drives delivery system transformation. It drives the transformation that we want to see in our delivery system when we think about our paying for value strategy and our healthier Washington initiative overall. There are clear and powerful contrasts between the fee for service system, which really is the status quo. It's a volume based system, and there is a big difference between that and a transformed value based system of healthcare reimbursement. Fee for service leads to fragmented clinical and financial approaches to care. A value based system creates integrated systems that pay for and deliver whole person care. Fee for service lacks coordinated care while coordination is central to value based payment purchasing and delivery. There is a sense that fee for service leaves our members unengaged and left out of their own healthcare decisions, while we're aiming for a value based system that engages members and empowers them to take a proactive role in their health and also, as we've discussed in the utilization comments on the last slide, fee for service creates a necessary variation in care that lacks clinical or financial accountability and transparency. We are really looking to standardize performance measurement and build transparency, as a foundational piece of our clinical and financial accountability.

So, what are our specific goals? How will we do it? By 2021, in partnership with purchasers, providers, and payers, Washington State aims to leverage its purchasing power to move 90% of its healthcare market from fee for service to value based payments. We are looking to

test, improve, and bring to scale some of the shared savings and cost of care models and also, we're aiming to implement Medicaid payment and delivery models that support full integration of physical and behavioral healthcare, which is a key component to value based payment and purchasing.

So, before I talk about our specific approaches, I really just want to make an important link between payment reform and delivery system reforms. Our approach employs a strategy that leverages the financial incentives and drives high quality, high value care.

So, we are implementing three strategies to accomplish our value based purchasing goals. We are looking to purchase high value healthcare, and we are doing that in our Medicaid and our PEBB programs now. We have, within the Health Care Authority, we're pushing forward for payment redesign models with clinical and financial risk, starting with Medicaid and PEBB. So, one major program that we've been putting a lot of work behind over the last several years is our accountable care program for PEBB members. We implemented this in 2016, and we're expanding it to nine counties in 2017. So, we're currently partnering with the Puget Sound High Value Network and the U.W. Medicine Accountable Care Network.

In addition to our innovations in PEBB, we also, or with the accountable care program, in particular, we also launched a total joint replacement centers of excellence program for PEBB members, and in 2017, VM will be our partner in that.

So, we're also looking to align with federal value based purchasing. The federal goal of 50% Medicare clients in alternative payment models by 2018 is very much in alignment with our goals of 90% by 2021, and we have adopted a lot of what the federal government has put forward under their... or will put forward under their quality payment program, and their healthcare payment learning and action network effort that's been going on over the last couple of years. We are really looking to align in order to help accelerate the payment models and the value based payment approach that we have put forward in Washington State.

I do want to mention our value based roadmap. We released this earlier this year and it outlines our strategies to fundamentally change the way that healthcare is delivered by leveraging our role as a purchaser. The purpose and goals of our value based roadmap are to reward delivery of patient centered high value care and increased quality improvement, reward Medicaid and PEBB health plans, and health systems for performance to, again, align our reform approaches with what the federal government is doing to drive standardization based on evidence, increase longterm financial sustainability of state healthcare programs, and continually strive for that triple aim of better health, better care, and lower costs, and I would even add that quadruple aim of provider experience and provider satisfaction, as well.

So, it will be continually updated over time. This is an iterative strategy. We have VBP milestones from now until the 90% of state financed healthcare being purchased under a value based system in 2021, and you can see some of those milestones along the way, including 2019. We're looking at 80%, which has been our commitment to CMS, thusfar, and we will be rolling out different or evolved strategies over the years in order to build upon the work that we've already done in integrated Medicaid purchasing, in our accountable care program, and other value based approaches.

So, as I said, but I do want to put a finer point on, Washington's goals do fit with the national movement to really actively move away from the fee for service system and towards value based payments. CMS aims to see 50% of Medicare payments linked to quality by 2018, and in addition to moving 90% of state financed healthcare into value based payments by 2021, we are looking to move 50% of the commercial market to VBP. So, as we think about scaling and spreading, we are thinking about our role, and other large purchaser's roles, in moving along this continuum with us.

This is the continuum we're following, and it's in alignment with the Medicare goals. So, we have adopted the CMS alternative payment model, or alternative payment framework so that we're all speaking the same language to the market. We want to send the same signals to the delivery system in order to make sure that we are aligning and not

creating any more confusion or kind of work or unnecessary work for our partners.

So, earlier this year, Medicare launched the healthcare payment learning and action network, we call it LAN, to help advance the work being done across sectors to increase that adoption of VBP. The LAN does consist of private payers, providers, employers, state purchasers, consumers, and others to accelerate this transition. So, what's being done at the state level is being done in parallel at the national level, as well. So, you can see the alternative, the APM payment framework here, and it provides some common definitions for us all to work from. There are four categories shown here that range from fee for service payments with no link to quality to category 4 or population based payments.

There are a lot of different types of alternative payment models, but I want to really stress here that at least at this point, the federal government is not prescribing any specific model, like, bundles or capitation, but we are all aiming to work along this continuum.

The way that we align with this, and our definition of value based payment, is in this category of 2C through 4B. So, fee for service is not part of what we consider VBP, and we really consider 2C through 4B to be true value based payments. Something that I do want to note and is on our radar, however, is that when final rules come out from Medicare this year, we do anticipate that their definition and what they will be considering alternative payment models will be entirely in categories three and four, but they recognize, and the state recognizes, that 2C really is a nice starting place and is very achievable.

So, just to kind of talk specifically about how this links with what we're talking about today, pharmacy is part of our strategy around total cost of care, and it's part of our VBP strategy. So, using our accountable care program, for example, we consider our accountable care program, and this is our partnership with U.W. and the Puget Sound High Value Network, and we launched that as a refresher this year, and we are spreading it. We are looking at the ACP model in payment model, that LAN framework, 4B. It's an APM with upside and downside risks for a defined population, and our two networks are responsible for cost and

quality. So, our costs include medical and prescription costs, and our quality improvement model includes measures that tie to pharmacy measures, as well.

So, just to leave us all with what we're attempting to achieve, as we move to paying for value, we are, the State is transforming the way it purchases healthcare. We're aligning with Medicare and with national models, as much as possible, in order to move away from fee for service to this value based model, and at the end of the day, this is about the people who we all serve. We are doing this in order to not only ensure affordability, but also to make sure that we're improving health and improving the quality and effectiveness of healthcare for Washingtonians. So, I think I'll stop there.

D.C. Dugdale: Thanks, Laura, for your presentation. Actually, a simple question.

Daniel Lessler: If you could introduce yourself when asking a question.

D.C. Dugdale: D.C. Dugdale, I'm the medical director for Care Management Population Health at U.W. Medicine. So, I'm deeply into the accountable care partnership for PEBB employees. Laura, when you say that 90% of state financed healthcare and 50% of commercial healthcare will be value based, so where does the PEBB contract fit there? Is that considered state financed or commercial?

Laura Zaichkin: Yes. It's considered, the PEBB contract fits within our state financed model.

D.C. Dugdale: So, the goal there is to bring payers that are in the pure commercial market along on the value based road?

Laura Zaichkin: Yes.

D.C. Dugdale: Great. OK. That's what I thought. Thanks.

Daniel Lessler: Any other questions?

Dan Kent: Dan Kent, chief medical officer United's Community Plan, Medicaid Plan. Can you say a few words about global tracking outcome measures? We're talking about value based care and healthier Washington. So, some global measure of health for the state ought to be going up, and the cost curve out to be being bent or maybe even flattened? I'm particularly interested in the global outcome measures beyond all the details of all the initiatives. How does it sum up? How do we ultimately tell ourselves, we're making progress?

Laura Zaichkin: Yeah. So, we have a, as I mentioned, a core set. I think it's still 52, statewide common measures that we're using to inform our healthcare purchasing, and those are seen as cross-cutting measures that are continuing to evolve and also track throughout this effort. I would say a lot of those include quality measures that are extremely important to look at, and we're also looking at the per capita trend in spending. So, I would say that thinking about the package of quality measures with overall spend and cost is important.

Daniel Lessler: Are there other questions?

Laura Zaichkin: We have one up front.

Kathy Brown: Hi, Kathy Brown from Premera. Great presentation, thank you. When I hear the 90% of state financed healthcare will be value based by 2021 or 50% of commercial. Wow, that seemed really, really ambitious. So, and I like it, but two questions. When you say that... when you talk about value based care is that anything from the 2C? So, if you're giving rewards for performance that puts them in the 90%?

Laura Zaichkin: Yes. That is how...

Kathy Brown: OK.

Laura Zaichkin: ...we define VBP is that 2C through...

Kathy Brown: OK.

Laura Zaichkin: ...4.

Kathy Brown: So, it's not a sort of writ large people will be at a value based... will be taking risk, I guess, is my question.

Laura Zaichkin: No. We defined VBP as anywhere along that continuum, and like I said, I think that the environment around that may shift a bit when Medicare really truly defines what they consider to be VBP.

Kathy Brown: Yeah. And then how do we compare... how does Washington compare to other states in their trajectory and what they want to accomplish?

Laura Zaichkin: I am told from our national partners who work with us on healthier Washington, that as far as an aligned strategy that's really leveraging all pieces of the system and is aligning also with what's happening at the national level, that we're pretty far along. As far as specific comparisons to Oregon or Minnesota, I don't have that information, but I think everyone is pretty early on in this. We see pockets across the nation and across the state where people are doing really great work, and it's about, nationally, it's really about building upon those bright spots and what's working to achieve that full tripling.

Daniel Lessler: Any other questions? Alright. Thank you.

Laura Zaichkin: Thank you, so much.

Donna Sullivan: So, first of all, before we go on to the next speaker, I did want to recognize Senator Carlyle that has joined us over on the side. Thank you for coming. So, I just wanted to let you know that he is here and give him a shout out. I'd like to introduce now Sean Sullivan and to steal Sean's quote from the other day, there is no relationship between the two of us in recorded history to the extent that we are aware of that, even though we do share the same last name. So, Sean is a professor and dean of the University of Washington School of Pharmacy, and he is internationally known for his work in health economics and outcomes research. Here you go.

Sean Sullivan: Thanks Donna. Good morning, everybody. It's kind of dangerous to give a University professor an extra 15 minutes. I'm going to be parsimonious

so we can get to the panel, because I think that's where the fun and the meat will be. I'm going to just set this up a little bit and then introduce the panelists, have them come up. We've got some structured questions. They are in your packets. They are at the back of my presentation. We'll start with those structured questions, and then we'll evolve the conversation to include questions from the audience. So, you'll see me weave that in sort of towards the middle part of our time. So, that's the plan for the next hour or so. Does that sound about right?

OK. Alright. So, it feels like this to a lot of people, and of course, that's concerning to all of us. It's concerning to us as healthcare providers, as manufacturers, as payers of healthcare, but it's also concerning to us as human beings and those who may either take care of young ones or take care of your older parents. And so, the question today is, what can we do in a world where we desire innovation, we want the newest and greatest treatments, to be able to afford them in the future. So, I'm going to start with a story, and this is a great story of scientific innovation that led to the development of this drug back in 1953, pyrimethamine. Spectacular innovation at the time. It now sits on the WHO's essential medicines list. It won a Nobel Prize for the people who worked out the pathways to get to this medication. It is indicated for the treatment and prevention of malaria, something I think we can all agree is a problem around the world, but it also have a very... it has another indication in the U.S. and a few other countries for an infection associated with HIV. There is no patent. Intellectual property rights for this product are gone from a patent protection point of view, and in the U.S., there's a single supplier.

You can find this product for pennies in most of the rest of the world, and here are some examples of what it costs. GSK used to be the sole provider of this product to the United States, but in 2010, they sold the rights to market the drug to CorePharma. CorePharma looked at the market, and it's pretty small in the United States. There's not a malaria in the United States, and of course the market was largely for the HIV positive population, and they were supplying the drug at $13 per tablet and generating about $10,000,000 in sales. For a pharmaceutical company, even a small one like CorePharma, that's not a very big market, but given the fact that the cost to produce this thing was so small, their profit margin was quite good on this product, but they decided to get out

of this business, and they sold it to this guy. This is Martin Shkreli who, I think, is behind bars now, but I'm not exactly sure. He's the CEO, or was the CEO of Turing Pharmaceutical. They bought the product and raised the price from $13 to $750 per tablet, and he went on a ton of talk shows. You probably saw him, and I can tell you the big major international pharmaceutical companies were not happy with this guy. It caused a lot of consternation and put them under a microscope, because he decided to do this, raise the price from $13 to $750, and when you asked him, and there's lots of sort of public video about this. When he was asked, what was the justification for this? The response was, well we're taking all those resources, and we're going to plow them back into innovation, which in his case, and for this company, was patently untrue. It went to pay salaries.

And now the new kid on the block. Last night, if you watched... I don't know if you watched any of the hearings, but the CEO for Mylan was grilled and said, I believe, that they only make $50 per vial, or per pack. I can't remember if it was vial or pack. It doesn't matter, right, but the public sees these things, and they want to know what we're doing as institutions, both the producers, the innovators, and the buyers who are spending our tax dollars. They want to know what we're doing about this.

The U.S. Market is massive, right? It's more than half of the global market on a sales volume perspective. It's huge, but when you begin to look at the distribution of those expenses, you see that about 1% of prescriptions account for 25% of our sales. We have a very robust generics market, but even that market is changing, as evidenced by pyrimethamine that became a sort of branded generic. The market is full of very innovative companies, large multinational companies who understand and know, which I think we all do, that it is very risky and very expensive to develop a new product. Anyone here not think that's the case? Anyone want to go out and start a drug company tomorrow? It's a very risky business, although plenty of people do with wonderful ideas, some of that coming out of the University of Washington, some of it coming out of Fred Hutch. I mean, we've got a very active research space here in our metropolitan area that is creating, we hope, new treatments, but we recognize that it is expensive, and there are high

failure rates, even at the very end of the development process. So, we've created, in this country, an industrial policy that rewards these companies if and when they're successful, and what we've done to encourage that through favorable tax positions, etc., is we've given them a patent, and we've given them a very long patent, and that patent grants a period of exclusivity and, in many cases, a monopoly to sell that product. We, in the United States, are frankly the last free pricing market in the world, and there are consequences of that, and we can talk about that if you'd like, and we have no federal sector price negotiation. Both of the political candidates running for national office this year have indicated their interest in starting a conversation about federal price negotiation. They are trying to find ways to deal with this problem.

The spending growth is, as Dan showed a statistic over the last few years, this is annual data from IMS that many, many people quote, and whether you look at gross receipts, whether you look at list prices or net prices, the bottom line is, the trend keeps going in the positive direction.

The list price is, just to get some terminology, are those that are set by the manufacturer, the marketer, the distributor. The net are the acquisition prices, or those that result as a consequence of negotiations, and in markets where we have no central price negotiation, like, the U.S., and little competition, whether that competition is through the competition afforded by the labeled indication or the therapeutic alternative, manufacturers offer very few discounts. It's what we saw when Sovaldi was launched, as an example. Very few discounts, and in the United States, those anticipated discounts are already baked into the list price at the time of launch, and also, unlike other countries, and frankly unlike many other products, prices don't fall the longer the products are on the market. Prices rise.

The entry prices are high, particularly in the biologics space, particularly in the cancer space, because as a country, we value life extension, but we've not asked the hard questions yet, how much are we willing to pay for life extension, six weeks, eight weeks, twelve weeks, a year? And when those products are on the market, we tend to take... the companies tend to take price increases, and they do it with various levels of justifications. I'm not disparaging the industry. I'm stating the reality.

This is what happens, and this is what folk, like the Health Care Authority, like the private sector insurance companies, this is what they face. This is what they look at every day and when it reaches certain thresholds, then the public sees it, too, because it's in the news.

So, let's get to the real question. What can be done to try to deal with this? Well, we've tried all kinds of things, and here's a list of things that we've tried over the years. Now, if any of these things worked well, those trends I showed you from IMS wouldn't be nearly what they are. They don't work very well, and we know that. We all know that, but as Dan said in his opening remarks, we still have to do them.

What are the emerging options? Well, there are some emerging options that people are messing around with around limiting access to reps and samples and adding clinical decision support to e-prescribing tools, things that sort of really target utilization, restricting buy and bill practices of providers, a whole host of things, value frameworks, reducing the patent exclusivity period to negate monopoly positions. This is an interesting one, when it is in the public's interest, because it is a public health problem, hepatitis C, what about buying the patent directly from the manufacturer and then distributing it at very low cost? These are things that people talk about, including pointy headed academics like me. We talk about these things. We think about these things. Dramatically reforming the FDA process would potentially make a huge difference. All that time spent in the regulatory mechanism costs money. The cost of clinical trials is huge, but what about some other ideas? And these are some other ideas that folk are finally talking about, and the one in want to talk about to introduce the panel, is innovative contracting agreements, and here are some examples of innovative contracting agreements.

Price volume agreements, agreeing on volumes for certain target markets and then rebates above those agreed volumes, right? That essentially implements differential pricing. Outcomes based pricing models. We're going to talk about those a lot today. Paying for outcome, and risk based pricing models. Paying differential prices for different at-risk populations. These are things that are being experimented with around the globe, and in some cases now finding their way into the U.S. market. Are these

kinds of agreements, do they have utility for Washington State Health Care Authority? Do they have traction? They have appeal. That's why we're here, but they also have potential barriers, and that's why I'm going to introduce the panel to talk about now.

So, let me take a few moments and introduce the heavyweights, actually, that we have on the panel, and ask them to come up, uh, one at a time. So, first, I thought we'd start with a two-time University of Washington graduate, and that's Kathy Brown. She is the Director of Pharmacy at Premera Blue Cross. Kathy? Please, come up and sit wherever you choose. Jason Dohm, he's the Vice President for Clinical Account Management at Express Scripts, Jason. Robert Judge, he is the Director of Pharmacy Services at Moda Health. Louis Nguyen, he's the Manager of Pharmacy Health Plan and Delivery System Operations for Group Health, and finally, but not least, Newell McElwee, who is Associate Vice President for Core, which is the Center for Observational Real World Evidence at Merck Research Labs, and I can tell you that Newell is heavily involved in thinking about these kinds of contracts from the Merck perspective. So, let's give our panel a nice welcome.

OK. So, while I'm going to be giving a lapel mic here, and while I do that, I want to just start us off with the first question. So, you just heard the presentations by a number of folks. Healthier Washington has a goal of increasing the use of innovative contracting models and value based purchasing methods as part of its health system transformations. That's the background. That's what we're trying to get at. So, what kinds of pharmaceutical innovative contracting models could play a role in the kinds of value based purchasing arrangements that you heard talked about this morning? Kathy, can we start with you and see what you might think to start this panel off?

Kathy Brown: Can people hear me OK? OK. So, at Premera, we actually do have ACL full risk and shared savings models, but we're new to the game. I mean, everyone is really. So, we've been starting those models, and I have to say, I feel like maybe I'm not the most qualified person in the room, but I don't know. Maybe I am, in that we're... do we have interest in these kind of models? Absolutely. Have we used any of these models yet? Not quite yet. I think the biggest piece is that why there is interest is just the

whole idea of a close alignment between value and outcomes is something that we're interested in. Obviously, as we've gone in on the commercial side with the ACO's, one of the concerns from the provider community is, they have very little experience in managing risk. So, they have a lot, I would say, on the pharmacy side, that to a provider group that we've worked with, one of their biggest concerns is drugs, and specifically specialty drugs. In fact, to the point where they want to carve out drugs, and we're kind of going back to the table saying, well, no. We can't carve out drugs. OK, can we just carve out expensive drugs? Well, no. So, I think that when I think about some of these more alternative pricing models, I think it's a way to work with the ACO so that it gives them tools to manage the risk. So, well the models aren't up there anymore. So, when you think about the one where...

Sean Sullivan: I'll put them back up.

Kathy Brown: ...oh, thank you. So, the first one, the financial utilization model, that gives them... that would say when we're working with an ACO that the first, in this case, is 10% I think. In this case, it's 10%, but you actually agree on, you know, this is the... you'll pay full boat for this, and you'll get money rebated back as more patients come in. I think one of the concerns we have from an ACO perspective is, well we don't know how many patients we're going to get. There's those kind of issues, and while we have a stop loss with the ACO, most of the time, each individual drug, or each individual patient, doesn't hit the stop loss. So, I think that's one area that we're seeing interest in.

Then, the second one is on the outcomes based pricing models. So, for example, a drug like Entresto, which is for heart failure, the idea would be if you don't see a reduction in Emergency Room use and in hospitalization for heart failure patients, we will rebate money back. That has a lot of appeal in an ACO model where they're managing cost and quality, because they're basically saying, OK. Then, that gives them tools to manage some of the risk. It gives them some more predictability into the drug pricing. So, I think that's probably one of the biggest pieces.

Then, the only other thing I would say then let other panelists talk would be that one of the things, we're going to talk about barriers and barriers

to these models. One barrier to the model... there's a bunch of administrative barriers to risk sharing agreements, or some of these kind of value based contracting arrangements, but I would argue that there is a lot of administrative barriers to the current model that we use. The current insurance company list of things that we do to manage costs or manage risk has their own administrative hurdles, whether it's quantity limits, whether that's putting step therapy in. So, I would argue that we're already spending money on that administrative side. So, I think that I would argue that going into some of these pieces would be more helpful than not.

Sean Sullivan: We're going to come back to barriers, too, and talk about that very specifically. Robert, your perspective here on the utility of these kinds of agreements.

Robert Judge: Sure. So, the goal is really worthy, and I think we all kind of nod our head in that direction and say that's where we need to get to. Because of this focus on combining quality and risk, it seems to present itself really well for risk based, outcomes based agreements. Because that model kind of supports what we're trying to get done with the Affordable Care Act and the ACP models that are out there. So, that would be the first way that I would look at it. It's also probably the hardest thing to solve, because it requires kind of a continuity of the whole healthcare delivery stream. It's not just providers and payers, but it's pharmacists. It's the pharmaceutical companies all partnering together to deliver that, but it's also the one that potentially promises the greatest benefit or delivering better outcomes and high quality control costs, but I will just say as kind of an editorial, the best outcomes based models really don't add a lot of value if costs are increasing. So, we saw this slide that shows 212% cost increases. You're not going to see a corresponding impact negating through an outcomes based model. So, it works great. There is little data that says whether the proof is in the pudding and whether that proves itself out, but the promise is there. It's very attractive and it makes sense to do in kind of trying to integrate the healthcare delivery model. So, I would put my head around outcomes based models.

Sean Sullivan: Let me ask you, Newell. I mean, you're an individual who spent most of your career in the pharmaceutical industry, and you're now, maybe you

can tell the group about this, but you're now sort of charged with thinking more deeply about these kinds of agreements from a Merck perspective. What kinds of innovative contracting models do you think are going to work in this kind of an environment, the environment that was painted earlier?

Newell McElwee: Thanks Sean. So, let me start by saying I really appreciate the presentations by Dan and Laura, and just to go back to Laura's slide that showed the evolution of these contracting models, which I call the Patrick Conway model. I think to date, we've been stuck mostly on 2C, or maybe even above 2C for pharmaceutical contracting. It's been very simple. It's been one-sided risk. It's been only commercial plans, and it's been basically giving rebates for your drug not performing or whatever. I think that when you look at CMS as a whole, the move from volume to value is much further ahead for providers than it is for pharmaceutical companies. So, most of the demonstration projects from CMMI are for provider based programs and not pharmaceuticals. We could probably learn a lot from that, but I think the trajectory and the movement in pharmaceuticals may take a little longer, and I agree with Kathy, we are very early in the game. I'm not even sure the game has started yet.

Sean Sullivan: You don't have any agreements you want to tell us about that are working?

Newell McElwee: Well, so Merck has been doing this for quite some time. Probably seven years ago, there was an agreement with Cigna that was in the public domain, made the front page of the New York Times where in diabetes patients, if the population A1c was lowered to certain target levels, they got additional rebates. It was not even tied to our drug. So, they could achieve that entirely with the use of insulin if they wanted. So, not achieve through our drug, so a very simple approach. More recently, we've moved to contracts that are linked to, for example, in diabetes patients, certain American Diabetes Association Clinical Practice Guideline Metrics for appropriate use of our drugs that are linked to our drugs, but these are just very simple one-sided risk contracts that are not along the continuum that Laura described.

Sean Sullivan: Louis, you're at Group Health, which is a very different model than most of the other health plan purchasers around the state and certainly around the country. How are you all thinking about these innovative contracting models, and do you have some examples you can share, or do you have some words of wisdom as we begin to think about these more practically?

Louis Nguyen: Thank you, Sean. As many of you know, Group Health is at the twilight zone in transitioning to become Kaiser, once that becomes official. So, there is a number of initiatives and discussion that are either being put on hold or kind of waiting to see which direction we're going forward, but in that respect, we are definitely at the very early stage of experimenting with these types of contracts. It is an extremely difficult situation for payer, like ourselves, and others in the room. I think the tension in this is that being able to find a contract that is mutually acceptable to both parties, both from the pharmaceutical perspective and the payer perspective. This is extremely difficult. Barring all of the administrative areas we would talk about, and the utility of such a contract is, at this time to us, extremely appealing in many of the therapeutic categories. We can see many of the contracted networks in our field are demanding value based outcome being a payer perspective. At the same time, this is clearer on the medical services rather than on the pharmaceutical side, as a pharmacist having the responsibility over drug prices. This is new ground for us. So, I don't have a lot of wisdom to offer up front, but a lot of thought that we can explore further.

Sean Sullivan: Great. So, Jason, you sat in the middle.

Jason Dohm: Yes. I see that.

Sean Sullivan: Figuratively and literally, I guess. So, talk about the PBM role in these contracts and what you think of in terms of facilitating these contracts, or what barriers might there be from your unique perspective?

Jason Dohm: Are we still on the ACO topic?

Sean Sullivan: Well, we can be there, too.

Jason Dohm: I mean, from the ACO perspective, there are really three places where the PBM sees its role today, and I'll say today, because this is evolving, obviously, very quickly. As of today, our main objective is to ensure that physicians and the ACO's have access to excessive amounts of data. That's very laser targeted and so it's identifying patients who have gaps in care, gaps in adherence who aren't taking certain therapies, combining both medical and pharmacy data and leveraging those tools. It is also leveraging a lot of predictive modeling, which I know a lot of health plans do today, but PBMs are starting to take more time to focus on leveraging predictive models to predict future high cost claimants, high cost patients, potential patients for fraud, waste, and abuse. So, that's really, I'd say, bucket number one. Bucket number two is to focus on breaking down some of the barriers in terms of the challenges, I would say, that we create for ACOs today with regard to PA's and step therapies and formulary exclusions. Clearly, if they're taking the risk, then how do we then remove some of that risk to then open up the doors a little bit more to break down some of those roadblocks, if you will, and with that, then as a third bucket, is the having sometimes a pharmacist tied to the ACO's with some of our client arrangements, so that there are physician detailing type staff available to discuss various drug therapies in very specific patients, etc. So, that's, as of today, I think, from a contracting perspective, we really are, at least from a drug contracting perspective, we aren't far along there yet. Now, from a retail pharmacy network perspective for sure, but that's really not, I think, what this venue is focused on.

Sean Sullivan: Right. Go ahead, Robert.

Robert Judge: You know, I was just kind of thinking through the models out there and getting to specifics. There is really kind of three contracting models that I can think of. There is a product base, which is kind of the world in which we live today in the pharmacy space. There's a population kind of model. There is a performance based model, which is the outcomes based. So, in the product environment, it's really a one-way risk model that would say you're guaranteeing some level of rebate based upon a product, and then there's some element of performance. It's a way to kind of minimize the risk and get some experience in how something could work. Another would be a population model, which says I have a defined

population, and I'm going to stratify my rebate. So, I'm going to subset my population out and maybe do a rebate on one side that's a set rebate amount and another would be based upon some performance metric for that population. Then, the third is, I'm really going to try to some threshold amount, which is an upside and downside risk, which is kind of what was defined in the model there. And that's probably the most complex one, because it requires agreement on methodology, agreement on the data that's going to be collected and measured, but those are three models that, I think, would make sense.

Sean Sullivan: Before I move on to the next question, I want to point out that on your tables, there are some notecards. I recognize that some people might not want to raise their hand and ask a question publically, but if you'd like to ask a question that you want the panel to address, feel free to grab a notecard, write it down, and then in about five minutes, Leta is going to go around, and we'll grab those cards from you, and I will read the questions here. Is that OK? Alright.

So, let's come back to these agreements for a moment. A lot of these agreements work under the assumption that if you make an investment up front in the use of a pharmaceutical, that investment results in some improved outcomes downstream that have cost savings associated with them. That's sort of the framework under which most of these agreements are nested. Does that framework fit with your business models and the way that you think about managing healthcare costs? Because I think that's really important. If the industry comes to the table with an agreement that's sort of nested in this framework, and yet your business model does not support thinking that way, there is a disconnect, and I think Louis, you sort of pointed this out a little bit, and I want to work on this a little bit with the panel. So, Kathy, can you?

Kathy Brown: Yeah. I think that's a real point of debate. I mean, it's a real point of discussion, certainly at Premera. We're a business. I'm a pharmacist nested in a business and while we talk... it even comes up in something like adherence, in adherence modeling, but certainly when we talk about outcomes based contracting and the outcome that we're looking for, think about statins, and we have a commercial... if we think about the commercial population particularly, the average length of time somebody

is at Premera is five years on the commercial side, one to two years on the exchange side. So, yeah, there's a lot of debate when we talk about... this is just sort of theoretical, talk about starting a statin in a 48-year-old, and the risk or the benefit to that statin shows up in the morbidity mortality when they're in their 70's. Sure, when we've done the modeling and when our company has done the modeling, there isn't a return, not in the time that we would have them at Premera. So, that is absolutely something that gets debated there. Now, you could say that a lot of people Premera and come back. The State of Washington is somewhat stable, but it still goes to say that a lot of the benefit is when they hit Medicare. So, that's something that we debate a lot.

Newell McElwee: I would add that we debate, as well. There are a lot of performance based contract we were pitched with, right? All sorts of different agreements, and the challenge we are faced with, candidly, is the ROI relative to a traditional type of an arrangement. So, if you're going down path A and let's just say that performance based agreements, I mean, clearly, there are, I think, and we'll talk about this when we get to some of the other barriers, but with that price, many of our contracts were up against best price. So, the pool of dollars is a finite pool of dollars, if you are on the manufacturer side. So, clearly we find it traditionally more successful just to negotiate a deeper rate on the rebate, as opposed to going through the level of effort of the outcomes based metrics and tracking the data and things like that. So, at least at this point, now that may change with certain disease states, and I think that's the challenge we all face is, we have to be very laser targeted with regard to which disease states we would address with these types of outcomes based agreements, and I've got a lot of other thoughts, as well, but I'll wait until question two.

Kathy Brown: I guess I would add to that, that there is a lot more interest in these agreements, at least to get started. It's a lot easier at Premera to talk about agreements that pay off in 12 to 18 months or something like that, in one to two years, and I think that does a couple of things. It gives us some easier... I think we have to look for agreements that give us better short-term win, so we can build the capabilities, and then we can talk about what it looks like in the long-term.

Sean Sullivan: So, I'll just come to you Newell, just because, you know, you come from the other side of the framework, which is we're innovating products that have long-term health outcomes, we hope, and we would like to see these products used because of what we believe to be solid evidence around long-term outcomes. How do we get risk agreements when the business models that we're talking, you know, folk that we're talking to, their business models don't align with that.

Newell McElwee: Yeah, this has been a real challenge, and we hear this all the time. My first job in the industry, I led the OTC switch for Nicorette and Nicoderm, and we couldn't get anyone to pay for those products, even though smoking cessation is one of the most cost-effective things that you can do, because initially, the cost would go up, and the costs didn't start going down until about year three or four. That's a real challenge. I think one thing I'm hopeful about is that ACO's, I believe, have a longer time horizon, because while patients may change health plans, they don't change doctors so often. So, that helps us a lot.

Sean Sullivan: Right. Louis?

Louis Nguyen: To start off, I would agree with Kathy in terms of let's begin with experimenting with or exploring the possibilities within these value based contracts. That's the starting point. Many of us have not had real experience or longstanding experience setting up these contracts. Pharmacy benefit is certainly the first used and most used benefit in our design. So, it's become an incredible important question for us to address the costs involved in our expenses. So, in my opinion, the time horizon that a health plan needs to consider in providing benefit or even structuring the formulary is something that is different between payers. For Group Health, we have a general ten years time horizon for our populations, as we also own the delivery system. So, we have the payer side, respective, as well as the physician treatment, and patients don't typically change for that.

Sean Sullivan: ROI calculations. You mentioned this, Jason, right? You're thinking about return on investment calculations. How do you all sort of, when you start thinking about buying pharmaceuticals, where does your mind go in terms of return on investment, because these are big investments in

many ways, and how do you think about return? Whoever wants to go first? I can pick on someone.

Jason Dohm: No, I'll go first. So, from an academic perspective, you sit there and say, well let's see if we can get to an ROI on a product, and it's really complex, because you really don't know that if you have a patient who is persistent or compliant with a medication, when the payoff for that medication is going to be, especially if you have a turn in your plan. If you're looking at the exchange marketplace where members will change annually, it's one ROI. If you look at a Part-D population, it's another ROI. If you look at a commercial population, you know, they're all very different. So, after kind of staring at that for a while, you say, well, I can't get there. So, let's look at the right pharmaceutical practice, and is it the right thing to do? A great example is when we had the new hepatitis C treatments come out, a cure. How many times do we get that? And it was really hard to say, well, let's treat everybody with a hepatitis C diagnosis, because it will bankrupt you. So, you have to make some cuts on how you do it. And is that a ROI? No. It's trying to figure out the practice good pharmacy therapy with the dollars that you have available, and that's kind of how far, I think, we go as an industry.

Sean Sullivan: Anyone else want to deal with the ROI question?

Newell McElwee: I'll tackle... there's so many things running through my mind that are tied to question two, but I'll hit this one, as well.

Sean Sullivan: Sure.

Newell McElwee: From an ROI perspective, clearly, it's class by class specific. I mean, hepatitis C was a good example where we really... there was a lot of activity. Obviously, Dr. Miller made a lot of noise and really tried to push the entire country to decrease the cost of that medication, but also open up access. So, there's a tremendous amount of discussion internally with regard to the Medovir scoring, which patients should and should not receive therapy and ultimately it came down to some very difficult discussions and some difficult negotiations, but where we ended up landing, was we would open up access beyond Medovir three and four, because of the discounts provided, which at the end of the day, we felt

was the best path to take, especially considering all of the economic factors with regard to the net cost of the drug, also looking at the PA approval and denial rates, not only up front but on appeal. So, a lot of people that... I had many, many conversations with this around some employers. The challenge is, too, on the commercial side, some employers, airlines, hotel chains, etc., retailers, had a tremendous adverse effect with regard to this patient population. So, they were really hit hard. So, I spent a lot of time getting bites out of my rear end on this topic, and we had to go through the analysis. A lot of folks did not think through the appeals. So, most appeals are done from external third party and a lot of the patients who were denied therapy up front would end up getting approved through an appeal. So, that had to be a big part of the factor, as well. So, I'll stop going on and on, but there is... it's very case specific with hepatitis C, which is a big one, and PCS [inaudible] once the outcomes trials are published next will be another analysis. We'll probably be doing the same thing for the NASH indication once we see that for that particular product, as well. So, we are... I think the marketplace is evolving. Clearly, the costs of a medication, you're basically gift wrapping somebody a brand new car from... a very nice car, $100,000 or so for a new drug, and a lot of people tell me on the payer side. It's, like, you know, if you wanted to go get a mortgage for a house, think of the things you have to go through to get a mortgage for $100,000 or $200,000, whereas to get a medication, you go to the doctor's office, get a prescription, call in, do a PA, boom. You just got a $200,000 drug. So, clearly, there is a level of intensity within our shop of requiring more documentation, putting a great level of scrutiny on the entire process, and I will stop there.

Sean Sullivan: No. That's fine. That's great.

Kathryn Brown: And I think that links to the ACO conversation we just had was, you know, that the thinking of administrative burden, what we have today and the scrutiny on the whole process if we went to more of a value based arrangement, more of an ACO based arrangement with upside and downside risk, you know? Could that mitigate some of that? Would the intensity be where it belongs maybe on the [inaudible]?

Sean Sullivan: Louis, you wanted to respond to that?

Louis Nguyen: Yeah, definitely on the top of ROI, this is pretty close to my heart, and I mean, in our organization, it really, and I think many of you experienced this too is, you ask the chief medical officer what the ROI would be, that's a whole different answer than what the administrator, the CEO ROI would be, although there are some commonalities there. As for me, ROI in this respect, especially in the value based contract, is that many of the contracts are set up at the single drug entity in that, and part of it is they look at the ROI on more of a portfolio of drug and risk exposure that we have. Overall, in terms of our drug span down to the category of drugs, and the ROI in this, there is part of it that is difficult in the value based contract, the predictability of the nature and design of the value based contract. The time value that is often not talked about in measuring outcomes and defining when that outcome is, is becoming realized over time. It has some bearing on what other trade off system would use that money that you would have upfront and come back into your system for your business. So, that's where I define ROI in terms of all of these things. Certainly, I mean, there are other tools out there, such as the ICER value framework that would allow payer and other interests to look at what the value downstream would be in terms of outcomes and evidence based, but at the same time I think the overall ROI is something that, to me, is better looked at as a portfolio risk reduction overall.

Sean Sullivan: Great. Robert Judge wanted to make a final comment.

Robert Judge: Well, I think slowly, and sometimes my thoughts, oh I didn't think about this. So, I'm listening to the conversation and I'm thinking, wow, to determine ROI. That sounds like a pain in the butt. It'll never happen, and it's kind of a downer, but in this topic that we're discussing, which is really a directional statement about where we need to go as a kind of a society and certainly as an industry. I think there's reasons to be more positive in terms of our outlook, and it comes down to kind of three elements. Sure, as we become more comfortable with what value based agreements are and how they work with providers, then I think we can get, we can start developing models for determining ROI's. As CMS works with hospitals and providers to have them really develop and demonstrate really good risk bearing models, that's going to inform the whole process. Then, finally, for pharmaceutical companies, as they gain

experience with which health insurers know what they're doing, and who are the guys to work with, because it takes all of them to work together to pull out these kind of outcomes based or risk sharing agreements. So, directionally, I'm more optimistic than I am in terms of saying how do I figure out an ROI on a product today.

Sean Sullivan: Great. So, what I'm going to do now is, I'm going to ask Dan if he and his team have any questions for the panel, and that's a signal that we're going to open this up to a broader conversation with the audience. So, I have some questions that have been collected. If you missed handing them off to Leta, just raise your hand, and we'll come get them. There's a couple there. Dan, do you and your team have any questions?

Daniel Lessler: Actually, are you going to get into some of the nitty gritty of these agreements and the complexities?

Sean Sullivan: Yep.

Daniel Lessler: OK. Well, I just want to go back to ROI and actually, Sean, to sort of pick up on some of your presentation and actually, you know, this conversation has been around for a long time, and folks might be familiar with Victor Fuchs' book called *Who Shall Live*, and you can pick that book up today, and all you need to do is add zeroes to the cost estimates, and everything else is pretty much the same, but with respect to ROI, sort of the bigger picture as I... and I want to come back to hepatitis C, because I've lived that for three and a half years now. Is there a price above which people would have just said no? I mean, what... we talk about ROI, it was $100,000 out the door initially. It's come down. If we were $150,000 would we have said no? If we were $250,000, and just recognizing, and if anybody has any thoughts on where that number came from and why wasn't it higher? How high would we go?

Newell McElwee: Well, I'm not sure where the price came from, but the industry can help. I have my guesses, for sure, but would we have paid? Good question. I think the higher the cost would have necessitated more restrictions. I think we would have seen greater restrictions down to, you know, the Medovir 3/4 probably would have been the final resting place, perhaps. It's tough to say. That is the challenge is the... I think our biggest

challenge we face is the tolerance for what is the next ceiling to break through and what will the market bear is what you hear a lot. And I think the market continues to bear until somebody raises a flag and says enough is enough with regard to X. I think we are all going to continue to spiral. The thing I've been reserving to say, though, is that the thing that we're... I would say we talked a little bit, but before there was a slide that said what we've been doing so far hasn't been working. I, not to totally disagree with you, but I do disagree with you to a certain extent. A lot of my clients that I work with have 85 and 90% generic fill rates and have had fairly single digit trends in pharmacy for many, many years other than some spikes here and there along the way, and 2014 was definitely an anomaly with regard to hepatitis C and compounds, which, unfortunately, were a big nuisance for many of us, but what's happening, I think, right now is history for those of us who have been in the business for a long time. History is just repeating itself. So, it's... these are the same discussions we were having in the 80s when all of the SSRIs and the HMGs and everything else were in the market, and we were like, oh my God, how are we going to afford this stuff. The thing is is that, history will repeat itself, and competition, which Express Scripts and PBMs and health plans love, will prevail. Competition, competition, competition. We love allow similars. We love... the beautiful thing about the human body is that there is only so much stuff that can go wrong with us. It's true. I mean, there... or you die. I mean, and so there are a finite number of disease states and then the manufacturers will continue to create new solutions within those disease states. Many of the top specialty categories today have five to six alternatives and each year, we renegotiate our agreements, and each year we achieve a couple standard deviations greater than we did the previous year. So, I would say that's a big factor is competition. What I would, I think a lot of us need to think about is, how do we either pump more products out of the FDA faster so we can create competition sooner, or do we delay care for the first year or two until more competition enters the market and the price goes down and then we tackle the hepatitis C and the other disease states.

Sean Sullivan: So, let me just respond, am I saying yes, many of your customers have had single digit growth rates, but those single digit growth rates have been in the high single digits, and they've been several fold over just regular price increases across the economy. That math is pretty simple.

That math says we're at 3 trillion dollars in this country, and when you have organizations or institutions like state healthcare purchasers that simply can't go back to the population and ask for more tax money, it means now that funding a massive amount of Sovaldi for hepatitis C patients doesn't come from a pool of money that Dan's just been sitting on and say, I'm just going to save this until something like Sovaldi comes along. It comes from other uses. We have to pull it away from education or pull it away from any other number of investments that the State has to make. So, I would fundamentally disagree that we're not repeating history. We've reached a world where our budget constraints are finally at a point where healthcare costs are taking resources away from other things. I want to put that out for this conversation, because we have to start thinking about innovative approaches to funding what, in some cases, are incredible innovation. Let's be straight up. Sovaldi was a game changer from a disease point of view. It's a cure, and that's amazing, but we nest that with a whole host of other price increases on other products and marginal innovations that come with huge prices, and now in a budget constrained environment, we are having to pull resources from other uses. That's the problem today, and that wasn't the problem 20 years ago, as much as it is today. So, that's just a little response back on, but that's OK. That's what this is about. We're here to have a good conversation. So, let me open the floor up and see if anyone wants to raise your hand and ask a question in public. You are more than welcome to do that. OK. We'll start with you.

Stephanie Yamamoto: Stephanie Yamamoto with Johnson and Johnson. Just a question. I really appreciate everybody's comments, but in the ROI discussion and the hepatitis C discussion, I was wondering, where is the patient in all of this? Where do you guys feel like they fit in the ROI discussion, in the value discussion, interesting thoughts?

Louis Nguyen: I was going to touch on this based on Dan's question earlier, as to how high should the price go and what's an acceptable level this would be.

Sean Sullivan: No, let me just be clear. Dan wasn't asking how high the price should go. It was a theoretical question, at what point do we just say we can't?

Louis Nguyen: Right.

Sean Sullivan: We just can't write those checks.

Louis Nguyen: Absolutely, an important correction there. Thank you, Sean. So, when I observe... the other important indicator in what we measure in terms of ROI is the patient pay amount. What we have observed over the years is, it continues to go up as we create these additional tiers in our system and formulary, which does translate to increased patient paid on this. I think part of this is, in order to absorb the cost, at least on the commercial side, we have to allocate the pie and take resources from others, but at the same time, some of that translates down to the premium that our members ultimately would have to bear some of that. Outside of the revenue cycle, once we have signed up the 12-month revenue cycle and the rate making with our premium, we are locked into that, and the next opportunity is only occurring at the next budget talk. So, I think, in addressing this, I think the question then is for a lot of... just like many other products out there, I think the consumer would, at some point, be the main driving force to address how drug prices affect their financial budget at the daily level. At some point, our consumer may not be able to afford the most affordable health plan out there and they would be the first to say that, look, as prescription drug costs continue to increase and that translates down to the premium, I think this would become a more important force, as there will be more patient advocacy groups paying attention to this kind of discussion.

Kathryn Brown: I guess I would add, it's a great question. Sometimes, I think when we talk we do get a little theoretical on ROIs and it becomes numbers on a page instead of trying to solve a real customer problem, you know? I pay too much. I don't get what I need. Sometimes, I get what I don't need. My experience isn't what I want it to be, and one of the concerns that I have is, when we talk about all these arrangements, and what I've seen in the last couple years at Premera is drug prices flying up and rebates flying up. Everything that comes back, every discount that comes back, innovative ideas all come back in the form of a rebate, and that guy standing at Walgreens and getting Sovaldi or Harvoni prescription, you know, they're seeing full freight. So, I wonder... I really feel like, as we... I really feel like that's something we need to talk about and talk about how that patient standing at the Walgreens counter, especially

somebody paying full freight, I mean, they're the ones that are hit the hardest, but even ones that insurance covers a lot, you know? They're not... it just adds to the opacity or the lack of transparency that the industry, frankly, deserves some of the rap it gets for. So, I think that's the other patient concern I'd bring in.

Jason Dohm: So, the patient is in the equation. Absolutely, they're in the equation. They actually are the consumer of the product, but if you think about, I'm going to take it theoretical again, we don't have a market, right? We have manufacturers' set price. They distribute the products. They sell them. They distribute it to a pharmacy who buys the product. The pharmacy buys the product, and they dispense it to a patient. The person who makes the decision to buy that product is actually the provider, the prescriber. They prescribe the product. They don't pay for the product. They don't use the product. Pharma, or insurers, pay for the product. They don't select the product. They don't negotiate with the manufacturer for the product. They do it through intermediaries like their PBM friends. So, it's not like a normal market. We've got all these artifices that we've created to kind of work around it, and so as insurers when we say, geez, they get patients to insure a level of compliance with medications, skin in the game counts. So, there is a copay element, but as drug costs have gone up, the portion that a patient pays of the overall cost of drugs has gone down, but it reaches a point where the patients can't pay, and then the whole thing starts to unravel. The good thing, though, even in this weird market, we have pharmaceutical companies who have patient assistance programs, at least for high cost drugs. In our company, every patient who gets a high cost drug goes and apply for a PAP, patient assistance program, to offset their costs. So, patients pay a dramatically less amount of the cost of the drug, because of how pharma has been working with payers and the pharmacy companies to kind of figure out how to bring some normalcy in a really abnormal market.

Sean Sullivan: Pass that down to Newell there, and then we're going to get to another audience question. Newell, you have a quick response?

Newell McElwee: Just a very quick comment and observation and that is that outside the United States, patients are increasingly a part of the health technology assessment process, and they are at the table. So, for example, our

formulary process, they would be at the table for the formulary process. We have not been very good at that in the United States, but if you want to see a really good process, look to the north to your neighbors to the north. Go to CADTH.ORG. CADTH is the health technology assessment for Canada. Look at their process. ICER, who many of you know about, is just starting. I sit on the ICER advisory board. ICER is just starting to include patients in their process. So, I think we will increasingly see patients involved in the decision making process.

Sean Sullivan: Thank you for clarifying that. You had your hand up. Would you like to ask a question? Yes.

Victor Collymore: I'm Victor Collymore, chief medical officer Community Health Plan. Sort of two questions. Regardless of new contractual relationships in terms of outcomes, one of the questions I actually wrote down is, I don't understand what precludes pharma from doing scenario planning relating to those prices, anticipating what the outcomes will be, and therefore, readjusting their price per unit to reflect the likely rebates they would have to pay on outcomes. To me, this is ultimately, we may be kidding ourselves here. So, that was the first question, your opinion about that. The second would be, I simplistically look at my costs by saying, the price per unit and the volume. It's been estimated there is 30% waste in terms of overall utilization. So, isn't that a more fertile area to look at, as opposed to necessarily just the price per unit.

Sean Sullivan: Newell, can you take a shot at the first question? Do you want a refresher? Do you want a summary or you got it?

Newell McElwee: I think I got it. Let me assure you, that there's a lot of scenario planning going on. I go back to the quote that Dan had in his slide from the chief actuary, and that is, the entire system, I think, is broken. So, I'm not sure that more scenario planning is the right answer for the future. That's just my own personal opinion. I think we need to stop selling pills and start selling what our pills do, but that's just my own opinion.

Victor Collymore: [inaudible] contractual relationship based upon outcome, will your price really be reduced on a unit basis?

Newell McElwee: I don't know the answer to that question. So, I'm on the R&D side, not the commercial contracting side. So, I really don't know the specific answer to your question, sorry.

Charissa Fotinos: My name is Charissa Fotinos, and I'm from the Health Care Authority, and one of the things that... it's not been said but it's sort of implied is that tacitly that all the drugs that we prescribe as providers and that patients take work, and that's sort of a fallacy I would say. I think we talk about transparency, but one of the things that seems to me that would help greatly is that if at some level, and it really can't be ours because we're so far down the chain, but either at the PBM level, the plan level, that in order to pay for a drug we demanded full transparency from the manufacturer, and that's including individual patient level data, as opposed to the first look how good this drug is. We have 200 people and they all survived, and then ten years down the road we see, oh, yeah, but 1000 died. So, I think part of it is, if we're going to talk about this as a market and a consumer driven process, I'm not going to buy something unless I know it works, or I see a good review. We sort of have people trust that I write this for you, and it's going to cure you, or on TV I saw, I forget the drug, you'll live longer if you have horrible cancer and take this. Will you? So, I think one of the things that we could do across the board is to be a little bit more demanding about show us the proof that what you're selling us works, and if you can't show us that, then we have a different discussion related to performance and value, or even things to consider, such as NM(1) trials. You want to try a $300,000 drug for my patient. If it works, I'll pay you. If it doesn't, maybe we won't. So, I think there are a lot of, I think transparency is a huge issue that one of you touched on that we are very, very far from.

Sean Sullivan: It's a great point, and, in fact, the idea of a personalized response to a medication, make sure it works, if you will, is really embedded in the concept of these agreements. Let's pay for it when it works. Let's not pay for it when it doesn't work. So, what about that? I mean, are we willing to go there, and what are some of the barriers to actually making an agreement like that? Look, I've got a biomarker test. I can give the patient one or two cycles of the treatment. I can go in and make a test and determine if it works for them, and then we'll pay for it if it works. We won't pay for it if it doesn't. Comment, Newell?

Newell McElwee: So, I think in theory that's moving over to column three in Laura's old chart. I think in theory it should work. There are a lot of nuances and things to be worked out, because the population studied in clinical trials may not necessarily be your population. So, making inferences from that population to the patient that you have in your office with the door shut is really hard to do.

Female: [inaudible]

Newell McElwee: Right.

Sean Sullivan: But let me challenge you on this and push you a little bit, right, because you say, in theory this could work.

Newell McElwee: Yeah.

Sean Sullivan: I can tell you, and you know this, you go outside of the boundaries of our country, there are agreements like the ones I described that are working right now. There are dozens of them in Italy, dozens of them in Australia, dozens of them in the U.K., which are based exactly on the model that we'll test drive the product. If it works, we'll figure out what that means, we then pay, and if it doesn't we don't. So, it's not theoretical outside the U.S., it's real. So, can it work here?

Newell McElwee: So, Sean, you know that we purchase your database. We know all of what goes on outside of the United States, and most of those agreements are price volume agreements, dose cap agreements, price cap agreements, very few are outcome based agreements, and then when you get to actually trying to make it work in the U.S., and let's just take for example a Medicaid population. So, how many of you are familiar with the Wisconsin County Ranking System? Anyone use the, yeah? So, what they've done from the School of Public Health is create this county ranking system to rank your health within the county. Only 20% of patient outcomes are due to clinical care. So, I would ask you about... so, are we able to include social determinates of health. If we have a patient outcome that is survival for a new oncology product, would it be important to know if the patient was homeless? I would say yes. So,

until we can start getting all of those kinds of data to be able to make predictions on a particular patient, as to what their outcome is going to be and what all the covariates are going to be, it's going to be very difficult to get there.

Kathryn Brown: I guess what I would argue, though, is you're setting a price, you know, hepatitis C is an example. We're setting this very expensive price with the determinate that it works. So, we're setting this really expensive price saying, yeah. It's going to work. It's going to cure hepatitis C, or it's going to decrease your morbidity from X, and we're setting the price at a value base, and I think that seems to be a change in my years as a pharmacist. When I was a first a pharmacist, drug prices were set more on an ingredient plus or there was actually some basis for it. Now, the basis seems to be set on value. I mean, I sat through the Gilead conversations about how many less liver transplants there would be, and they had this whole nice algorithm, and that's why we set the price so high. So, they're basically saying to me, I've set the price this high because it works. So, I think to your point, that's why the value based agreements make sense. OK, you're setting this high price, and I'm paying this high price, because you're telling me it works. So, when it doesn't, you should be able to give me money back. So, I mean, from a philosophical statement.

Newell McElwee: I don't disagree with you philosophically.

Kathryn Brown: You're just saying a barrier is... I get it.

Newell McElwee: The first one of these that was done was done in the U.K. with the National Health Service for a cancer drug and just as a reminder, what the news media can do with this. The headlines in the London Newspapers were, sorry your grandmother died. Here's a refund. So, that's the kind of... so, I think there are implications for how you do it, but there are also external implications for how it's perceived by the media and society, in general.

Kathryn Brown: Yeah, and you're pointing out an important barrier, which is, you know, you've got to have a metrics to agree on, metrics that are easy to measure. I think those are some barriers you brought up.

Sean Sullivan: Other? Donna?

Donna Sullivan: So, this is Donna Sullivan. I'm with the Health Care Authority. I've seen other questions and one of the things that I know that is important in these types of arrangements is adherence to medications or insuring that prescribers are limiting these medications to the appropriate population. So, my question is, is whose responsibility should it be to ensure patients are adherent and that prescribers are prescribing in the appropriate population. Drug companies have a whole army of representatives calling on doctors. It would be interesting to see, instead of them marketing their product to prescribe it for everyone but to be put at risk for the prescribers using it in those that are not the appropriate person to be put on that medication.

Male: Yeah, well said. It gets back to your waste question before, as well. So, I think this is a large opportunity that's untapped today. So, I will touch on the adherence, well, I'll touch on waste and then adherence, but try to guess how many prior authorization takes per month that are strictly clinical PA's? Anyone have any quick guesses at top of mind? 500,000 PA's per month. So, as you can imagine, that's a large internal fixed cost burden for us, but also a tremendous savings for our clients, but yet it's not yet totally optimized, and what I mean by that is, there are a lot of prior authorization approvals that are approved where, you know, today a lot of our PA's are question and answer, and we're taking the doctor's word for it. What we've been doing with a lot of these recent therapies and hepatitis C, oncology, now with inflammatory conditions, is truly asking for the documentation, because we find it mission critical, and it's really moved the needle. The challenge we face, though, is we can't blanketly require documentation for 500,000 PA's a month, because we would paralyze the healthcare system. So, we're investing heavily, and I think, a lot of us in the industry are investing heavily in electronic PA's capturing documentation that way, but that is a significant opportunity, as I would argue, is how do you capture some of that information on the prescription, as it's being transmitted into our system so we get all of that stuff up front. So, that's something, perhaps, for us to discuss and figure out, but adherence is still a big challenge, and I think that's where we've been able to strike some interesting arrangements with the

manufacturers is trying to focus on quality of care for people who are getting the prescription, keeping them on it. We've been doing a lot of programs lately with early discontinuation reimbursements back to our payers, and I think you will start to see that really expanding across our book as another opportunity.

Bruce Smith: Hi, Bruce Smith from Regence/Blue Shield. We're talking about drug pricing and purchasing today, and we've heard a couple of times about how things are different in other parts of the world, as far as the contractual details, and, in fact, on some of the earlier slides the actual prices. We know with Sovaldi and Harvoni, it's essentially half the price in Vancouver, B.C., as it is in Vancouver, Washington. If my Subaru, my next Subaru was half the price in Vancouver, I'd probably get up there to buy it rather than buy it here. I know we can't import drugs because of our current laws, but we certainly, patients can certainly go up to Canada and pick up their drugs and bring them back. That's legal, if they want. What would, I mean, if we had access to the pricing that's available a few hours north of here, or in other areas of the world, it would at least rollback the dramatic price increases we've seen in this country in the last few years. It might not help the rate of climb from thereon, but at least we'd pull it back aways. We can't do that right now, but in the words of lean thinking, I don't know how to do that yet. What it would take to operationalize or institutionalize, I mean, if the Health Care Authority could cut their drug prices in half, because it's not just Sovaldi and Harvoni that's cheaper in B.C. Many, many drugs are cheaper, some very dramatically, because of the way they contract. Would there be a way for us, as a state, as the Health Care Authority, through the corrections office, for example, they are spending a fortune on Sovaldi and Harvoni. How about if they buy it from the Costco in White Rock, B.C.? Would that help? Can we do that? Do we know how to do that?

Sean Sullivan: Does anybody want to respond?

Louis Nguyen: I'll try to respond to this, as I've lived in B.C. for many years, and part of it really was the government, British Columbia, actually has a mandate on manufacturers to cap their pricing and also even at the pharmacy level where most of the pharmacy operations make their revenue from a dispensing fee rather than applying another markup to the drug

acquisition costs. So, part of this answer is really going to come from our legislature and the mandate to regulate pricing within the regulatory confines.

Male: That question reminds me of the same conversation in the early part of the last decade when everyone was going up to Canada to buy brand drugs, and it's a panacea. It's an attempt at a panacea. I don't think that's the way to approach this. We live in a fragmented market, right? We've got... because we are America, and this is how we do it, we've got companies that are in business to make a profit or to serve shareholders or their board of directors if they're a nonprofit, but the fragmentation is, we've got manufacturers who produce the drugs. We've got PBMs who facilitate the fulfillment of those drugs through their arrangements, and we've got insurers who pay the drugs, and for us to even start getting progress on this, it was mentioned about transparency. Transparency is just not a pharma issue. We all compete and we compete very, very hard, and we don't share information. So, until we get to a level of transparency in the marketplace, like what they do in the U.K. or in Australia, this is a tough go. Having said that, if you're going to try to do some alternative pricing strategies out there, there are some things that have come up in terms of what's required. It was mentioned about... Newell mentioned the fact, what if you have somebody who is disadvantaged or is homeless or loses a job or has some social issues, where's the care provider, caretaker in this? So, you've got to have stakeholders involved. That's not only just the provider and the pharmacist, but it's the whole community of caretakers or stakeholders that need to be involved in these types of models. There were talks about metrics. Do we buy into a metric that was used to approve the product from FDA, or do we come across some other metric that an insurer can gather, or the PBM gathers on our behalf, and that we could all break bread on? If you don't have a common set of metrics, you're never going to get there. A lot of this is data gathering and Health Care Authority talked about how they're investing in that data gathering. If you don't have IT tools to help you kind of gather data and slice the data and interpret the data, you're not going to get there. So, there's key metrics or elements that you need to pull together that really fix the core problem, as opposed to saying, well let's go there to fix our problem,

because it's a structural issue. It's an integration issue, and it's a transparency issue.

Sean Sullivan: I want to, before I turn to you, Jason, I want us to spend the last five minutes, because that's about what we have left, talking about barriers, because Dan and his team are really thinking about experimenting with some of these agreements, and I think Charissa's comments are what motivate that in part. We should be paying for things that work and perhaps not paying for things that don't work. There are barriers. Kathy, you mentioned some administrative barriers. Some of you have mentioned some other barriers along the way. I want to explore what those barriers are. Best price is one. I think someone mentioned that here, and how those barriers might be overcome. I liked your response, Kathy, when you talked about administrative barriers that we already have administration in the system. Maybe, this is trading one administrative barrier for another, and it's not as bad as we think it is, if I'm putting words in your mouth, but what are some of those barriers, and I ask the audience to think about this, too, and maybe raise your hand and offer these barriers up, because if they're going to try this, they're going to experiment here, what are the things they need to be thinking? Dan's got his pen out. He's writing. So, what are the barriers, and what do they need to be thinking?

Jason Dohm: Best price is an obvious one for us. We definitely know that we're up against the best price ceiling for many, many products. So, to do reimbursement for the full cost of the drug trips a new best price, which is an issue. So, we need a new definition of best price. The other thing, I think, is we need to find a way for a little bit touching [inaudible] before of really high cost patients. So, if you're a payer in this room, I can tell all of you how many hemophiliacs do you have, and you'll say I have five, I have three, and I have seven. We have got to find a way for those really high cost patients to perhaps a broad, or something needs to be done where there are some discount opportunities available for those million dollar patients, or those two million dollar. I've got some payers that have 2.5 million dollar hereditary angioedema folks in their population. So, that's another piece, as well.

Sean Sullivan: Great. Others? Barriers from the audience, too? Anybody? Go ahead, Newell?

Newell McElwee: So, best price is one, but I think in many ways, that's one of the easiest ones for us to deal with, because it's CMS, and we've had many conversations with CMS and they can issue waivers and various other ways to deal with it. Legal barriers that involve other federal agencies are more difficult for us to deal with. So, for example, if we wanted to do an outcomes based contract and use an outcome that was not in our label, the FDA would consider that off label promotion. So, that is one barrier that is substantial for us. There's another barrier for kickback, which is basically OIG. So, if we have a contract and it's with a federal program, and there is a federal incentive that if you hit a certain quality metric you get additional payments by the government. Our lawyers think that that is a kickback risk. So, those are probably the three legal barriers that we have to deal with. There is a logistical barrier that I think Kathy mentioned that we hear from every single payer, and that is that we have to make these simple and I heard... we had one payer just last week said, this is kind of like going into a grocery store and someone asking you to fill out a 30 minute survey to get a 25% discount on the bananas. So, just a lot of work for... I mean, they perceive it's a lot of work for not very much return, and even the ones that we've been involved with, the teams on both sides, after the second and third year, people start asking questions like, wouldn't it just be easier just to give a discount. So, I think we have to really address this logistical issue of making it easy for people to do.

Sean Sullivan: Yep, very good.

Louis Nguyen: So, and I was just going to add on to the logistical issue versus the instant gratification of upfront rebates and discounts and things like that. I mean, we live in a culture where a lot of things just have to happen fast and a certain way. In many organizations, the 12-month revenue cycle and budget. That makes a very difficult conversation to enter an agreement that fits both sides, in terms of longer time horizon. So, I think that is certainly one barrier in terms of the time value of money, as many of the organizations are looking at their budget and allocating

accordingly, as to what the 12-month cycle would be. There is time value and trade off in other investment to the delivery system.

Sean Sullivan: Thank you. Anybody in the audience.

Donna Sullivan: So, this is Donna again. So, one of the challenges, I think, that we face as a public purchaser, is the expertise to one, mine our data to determine whether or not the outcome was actually achieved, and then, you know, just having that expertise to pull the data and then to do the data analytics, and what is the expectation from the manufacturer side on who is responsible for mining the data, making sure that the outcomes are met, making sure that all of the agreements, as far as compliance and adherence were met, and what can payers do, or what can manufacturers do to assist the payers that don't have that expertise in house to enter into these types of agreements?

Sean Sullivan: So, it's a capacity for actually analyzing the terms of the agreement. That's a barrier for sure.

Kathryn Brown: Yeah, and there's a difference between what can be mined out of claims data versus what has to be on the provider's side and care data, and I think that's a real barrier. I mean, starting with things that you can get out of claims data, like reduced hospitalization, reduced morbidity, you know, those kind of things, and even that's a challenge, I'm hearing, because someone has to still mine the claims data and get it in a way that you can use it. So, definitely, that's a barrier. I know at Premera, we're spending a lot and Express Scripts even more, about being able to be much better at mining data in both care, as well as coverage data. We're also making strides, although it's still emerging, with health information exchange. So, how can we actually have that provider data, as well as just our payer data and mine that in a way where we can see outcomes, but definitely, that's a big challenge.

Male: I think the question is a lot more complex, right, because you can't necessarily assign a particular outcome to the result of the medication, and that brings all sorts of attributes that you have to consider that today, in the healthcare industry we don't really have. So, you can make

some guesses or some assumptions, but I think I would caution against saying the correlation does not depict the causation.

Sean Sullivan: Alright. Well, we're coming up on the break time. First, let's thank for the panel for their engagement here. I did receive all the cards. I went through them, and I think we hit most of the points that were asked by the cards, certainly not all of them, but most of the points. If there is something that you wrote down on your card that you didn't think we got to and you want to ask the panelists directly, that'd be great. Feel free to come up at the break and do that. With that, Dan, I'm going to turn this back to you.

Daniel Lessler: So, well I also want to thank the panel, but I especially want to thank Sean for a really great facilitation of a very provocative conversation. So, we have built in here about a 15-minute break, and then we're going to come back and do a deeper dive on this approach to value based pharmaceutical purchasing in Medicaid. So, this would also be a good time, if folks have questions for the panelists, to maybe catch them, and we will reconvene, why don't we say about 25 after the hour. Thanks.

And let's grab the coffee and please have a seat. Alright. We're going to get... it's a talkative crowd. Everyone, please take a seat and we'll get started. Maybe we could just let folks who are outside talking know that we're getting reconvened here. Thanks a lot. OK.

So, I think a great conversation with a much deeper dive into the value based purchasing piece broadly for pharmaceuticals, and along the way, mention has been made about Medicaid and certainly the Health Care Authority purchases on behalf of Medicaid in this state, about 1.8 million people, and pharmacy costs are an issue. So, what we're interested in doing now is looking specifically at the potential opportunities for this kind of value based pharmaceutical purchasing in Medicaid, and we're fortunate today to have with us a person who is really working at the leading edge of trying to understand what is possible. Janey Beyer is currently the program officer with the Milbank Memorial Fund and the Oregon Health Sciences University Center for Evidence Based Policy. In that role, she supports state legislators and executive branch agencies in their efforts to develop and implement evidence based informed health

and social services policy to improve health outcomes, and certainly pharmacy is one of those. So, Jane is well known to many here, as she worked in Washington State government for many years, and I think particularly relevant to the conversation about Medicaid, amongst her many senior leadership roles in state government is that from 1995 through 1998, Jane served as the Washington State Medicaid Director. So, with that, we're going to hear from Jane and sort of put this in a Medicaid context. Thanks.

Jane Beyer: Thank you, Dan, and thanks to everybody for having me here. I really appreciate it. It's always good to have an excuse to be in my home state, even though I work in Portland technically and zip around the country, and I'm glad you guys all had a chance to get your ootsies out during the break. That's good. So, I'm going to try to go pretty quickly. Somebody should tell me when I have five minutes left, and it's... I'm going to be doing a lot of legal speak and a lot of Medicaid speak. I've been a Medicaid wonk for more years that I want to admit. So, I'm going to try to keep it at a high enough level that it doesn't get too wonky, but that's always a risk when I'm talking.

So, first, what I wanted to do today was, and I think we'll go through this pretty quickly, because I'm assuming we have a pretty sophisticated crowd, but just talk a bit about the constraints that the federal Medicaid drug rebate program lovingly called the MDRP, which is embodied in section 1927 of the Federal Social Security Act, what the provisions of that are, but more importantly to talk to you about the SMART-D project and the work that we've been doing to try to identify, as I call it, ways to thread the needle inside of or alongside of the MDRP to give states more room around alternative payment models for alternative prescription drugs.

This slide, basically, sets up, again, what the goals of the program are, strengthen the ability of Medicaid programs, to manage prescription drugs through alternative payment, and then also just work with a group of states. Right now, we're working with about a dozen states, and others as well, to give Medicaid leaders an opportunity to contribute to what's going on in the national debate, and I would say, especially given today's discussion, to think about ways and provide opportunities for

state Medicaid programs to bring prescription drugs into their value based purchasing work. What I'm going to say is what SMART-D is not. SMART-D is not about changing the drug launch price. That is another whole debate. We know that it's going on at the federal level, but it is not about modifying launch price, modifying list price. I also want to say, and I think this morning's discussion was great, because there was discussion generally about the barriers to implementing APMs and value based purchasing methodologies, and now we're also going to talk about some of the complexities of the federal Medicaid statute and working within it to try to accomplish objectives. So, what I would say is, it's not simple for the states that we're working with. It's a lot of complexity. It's working with manufacturers, managed care organizations, given that so many of the states rely heavily upon managed care entities for their Medicaid programs. It's PBNs. It's providers and really, really importantly, it's working with the federal government with the centers for Medicaid and Medicare services, but on the other hand, it's not unlike other initiatives that state Medicaid agencies take on. If you think about Healthier Washington and you think about the overall goal of moving the system more towards value based purchasing, the list of entities that I read out are the same entities that the state Medicaid programs are working with now to try to develop any kind of value based purchasing strategy. We all know that Medicaid programs are the incubators of innovation.

So, just to give you a sense of where we are with respect to the product, we hit a big milestone about a couple of weeks ago, and we completed phase one of our project, which was, I think, consisted of two main things. It was a lot of in-depth research that I'll describe to you in a bit, that is now publically available, wholly available on a website that we've launched. It's www.smart-d.org, and I've got it at the end of my slides, and we also spent phase one developing a group of states that we're working with. As I indicated, it's about a dozen states, to just start engaging with those states and to learn more about how they currently manage their prescription drugs through their Medicaid programs. We reached out and had discussions with Medicaid MCOs. We had discussions with PBMs. We're in discussions with consumer advocacy groups just to really get that base level of research done. We're now launching into phase two, disseminate, and I actually think of it as much

more than disseminate. We are going to be working with those dozen or so states that we're working with. We're starting to do readiness assessments to those states to sort of say, OK. Where are we now if we wanted to engage in an endeavor like this? What do we need to do next? We will be providing with the funding that we have, this project is funded with a grant from the Arnold Foundation. So, we have capacity, our team plus consultants, to provide technical assistance to states. So, that technical assistance could be economic analysis. It could be helping them develop state plan amendments or waiver applications. It could be helping them think through some of the data challenges that were discussed this morning. We are also working really hard with the pharmacists and doctors on our team to develop some examples of APMs that we think are most appropriate for the folks that Medicaid serves and then link those up with the legal pathways that we're going to be talking about. Finally, we are, at this point, really trying to reach out to pharma companies to get a sense of whether there are companies that we can work with and do some matchmaking between pharma companies and the states that we're working with, and I'm happy to talk to any of the pharma reps who are here after my talk to begin those discussions. We've already had a couple of companies reach out to us, which is really encouraging.

So, this is my puzzle that I put together with the help of people who know way more about how to do fun graphic stuff than I do, but when we thought about how to approach this, we said, how do we fit this project into the puzzle of what is and what are state Medicaid programs. So, in phase one, we knew that we needed to, looking at the orange, we knew that we needed to try to go do some economic analysis, look at the drugs that are coming along the pipeline to give state Medicaid programs an assessment of what drugs, what classes, what disease states were likely to be those high cost specialty drugs that were going to drive expenditures into the future. On the green puzzle piece, we did a lot of work with states to really get a sense of the baseline of what they're currently doing now to control Medicaid prescription drug utilization, to do better about getting the right medications to the right Medicaid clients, and also to think about cost considerations. On the yellow, this is what I'm going to be talking about today, more focused, which is the legal analysis and the legal options that we think states might have to do

some of this work. The blue, akin to what I think what Sean was talking about earlier we've done, we've worked with consultants, done a lot of research about the APMs that are being currently used overseas and in the United States, and in grey really, really trying to think for the states that we're working with about where their broader sort of health system transformation thinking was and how something like this could fit in. I was actually the evil person who contributed the questions that related to how could we fit value based purchasing for prescription drugs into ACO like models to try to think about where there are opportunities to align that kind of work, and when I think about Washington State and about the fact that through House Bill 2572 there has been consensus around the performance measures that should be used to measure performance in the healthcare delivery system in Washington State, I think about synergies. Are there ways to link up prescription drug APMs to the quality measures that multiple payers are thinking about using in their contracting. So, for example, when we have all the challenges around data, if we're already collecting data to look at those quality metrics that are being incorporated into purchasing, can we use that data to help inform prescription drug VPNs for value based purchasing in the same kinds of disease states in clinical areas that are a focus of the performance measures. So, it's really important. So, what fits into that to complete the puzzle, is the work that we're doing in the SMART-D project.

Just some real overview. We worked with Bill von Oehsen and his team of associates at Powers Pyles Sutter & Verville to develop the legal analysis that I'm going to be talking about, and again, the goal is to understand the current federal and state legal framework that we're working in, look at options both inside and outside of the MDRP for use of APMs. The states that we're working with have a variety of models, some of them are still fee-for-service only states. Others are doing managed care contracting. Again, referring to what I just said earlier, support overall state value based payment initiatives, and also looking at value based payment not exclusively from the perspective of an agreement with a manufacturer, but also opportunities to work with pharmacies and other providers to bring those kinds of value based ideas into prescription drugs. I'll offer example ACO models.

Just one thing I wanted to point out, when we were writing this report, everybody loves all this terminology. When we were writing this report, we were really struggling, can there be a difference between an alternative payment model and value based purchasing. When it comes to prescription drugs, I think there can be. If we look at value based purchasing, sort of thinking of value based purchasing as you are purchasing link to clinical quality measures. So, clearly, there are APMs that we can think of as value based purchasing, but there are ways to use, and you'll see it when I go through the pathways, there are ways to use APMs that could be independent of, or not exactly what we would call value based purchasing. I keep struggling with it. It's almost like I'm thinking about a Venn diagram, and you've got two circles, one of them is APM, one of them is value based purchasing, and they do overlap to a certain extent, but they don't always.

So, just in terms of federal way and current federal way, I think most of us know in the Medicaid prescription drug rebate program, there is a statutory rebate that varies depending upon whether it's a brand, a generic, and also how quickly a manufacturer has been raising their list price, if it's above CPI, there is an adjustment. The rebates are drug specific. They are not indication specific, which is a question that comes up when we're looking at how, through Medicaid, and you'll see when I reference it, how through Medicaid we can think about indication based work. We know that under Medicaid, states cannot used closed formularies generally under the MDRP; however, preferred drug lists are authorized. There are prescription limits on terms of number of prescriptions, etc., that are throughout the Medicaid statute, and then with respect to Medicaid, outside of the MDRP, we know that there are for fee-for-service drugs, recent regulations that came out related to using actual acquisition costs and regulating dispensing fees, and that patient cost-sharing is subject to specific limits.

Other federal issues that I'm going to address quickly, which I'll address at the very end of my presentation, which have been raised by Newell, is off label promotion, anti-kickback, and concerns about multiple discounts. Then, we've got relevant state law. So, in a number of states, not Washington, there are any willing provider statues for pharmacy. In many states, there are exclusions of specific drug classes from preferred

drug lists. If I'm remembering correctly, in Washington, it's atypical antipsychotics, I think HIV AIDS drugs. I think hepatitis C drugs. So, they are in state law, and it varies from state to state, as a lot of the pharma folks in the room know. And then we have states that have undertaken, either via regulation of managed care organizations or PBMs, rules around business practices for those entities that could impact prescription drugs. Really, what this is about, what I take away from all of this is, when you've worked with one state, you've worked with one state. So, as we work with those states, we'll be diving in on all of these questions for each particular state that we work with.

So, when we sat down with Bill von Oehsen and his team to do our work, we said, let's be in a world where we're not modifying federal law. We're not worrying about congress, and what we are doing is looking for opportunities within existing law for states to pursue opportunities around prescription drug alternative payment or value based purchasing. The first one, and we're calling them pathways, the first one is supplemental rebates. Many of you think of supplemental rebates as OK, I'm negotiating with the state to get… I have competing drugs in a drug class, I want to get preferred drug status. So, it's all about how much of an additional supplemental rebate the manufacturer is willing to offer to get their drug preferred status on a preferred drug list. However, the research that we have done and fortunately it was affirmed by CMS very recently when they sent out a notice that the link to is here, is supplemental rebates don't have to be that traditional model of it's just an additional ingredient cost discount. They can be indication based. There is more flexibility around using supplemental rebates. They can be population based. They can be dose based. It's in the context of a supplemental rebate, and most importantly, supplemental rebates are not part of the best price determination. So, people look first to supplemental rebates around opportunities for creativity.

As we've mentioned before, supplemental rebates, because we collect drug information, we don't collect indication for which the drug is used, in terms of risks, we still need to figure out a way to get the data about the indication for which a drug was used if we're going to use supplemental rebate pathway. We, in negotiating, you have the issue with Medicaid of closed formulary versus preferred drug list, and they are

still subject to the other restrictions around patient cost-sharing etc., etc., that applied to the Medicaid program.

The second pathway that we identified is managed care contracting. Managed care contracting is unique in two respects. Since so many states outsource and include prescription drugs in their Medicaid MCO purchasing, for example, Washington State, one of the ideas that we explored when we were doing our research was, could the MCO act as, in essence, an agent of the state to be working with manufacturers on creative purchasing arrangements and value based purchasing arrangements. So, that's the kind of concept behind that. The other benefit is, remember I talked about the fact that there are federal rules that say states have to use actual acquisition costs for Medicaid drug purchasing, that does not apply to drugs purchased through managed care. So, managed care organizations have a bit more flexibility around thinking about not just supplemental rebates but also how they pay pharmacies and other providers to provide their services. So, we think here there are opportunities for creative and innovative managed care organizations to do work on value based purchasing for this pathway. In terms of the risks, the biggest risk is, we have managed care organizations that are contracting with pharmacy benefits managers, and this changes up the nature of that relationship potentially, because if the MCO and the PBM are negotiating on behalf of the state, that's different than whatever the financial arrangement might be between a PBM and a managed care organization. We are having discussions with CMS now around these legal pathways, and one of the ideas that we are testing with CMS is this concept of, if the managed care organization is negotiating a supplemental rebate on behalf of the state, can that protect those rebates from impacting best price. Again, it's with the Medicaid program, I think one of the interests is taking advantage of that supplemental rebate not effecting best price, as much as possible. We would, of course, and I think for all of these, we, of course, need to be thinking all the time about what state law is relevant that might impact it, and I'll talk a little bit again at the end about off-label promotion and anti-kickback.

The third pathway that we identified is there is actually an exception in federal law that excludes from the Medicaid drug rebate program,

managed care organization arrangements with 340B provider entities. Are folks familiar with what 340B is in the room, or do I need to… OK. Yeah. Does anybody want me to explain with 340B is? Yes? OK. So, 340B is a program under federal law that grants certain types of entities, rural health clinics, federally qualified health centers, hemophilia treatment facilities or treatment providers, with the opportunity to purchase drugs, oh and critical access hospitals and disproportionate share hospitals, that gives them an opportunity to purchase drugs at a pretty low price, and in this case, because it's outside of the MDRP, rebates can be adjustable. They can be indication specific with all the variable things that we talked about earlier, dosage, populations, etc., etc. Again, here is another opportunity, 340B pricing is not included in best price determination. So, there is flexibility for MCOs to enter into arrangements with 340B hospitals or with FQ8 federal community clinics, or rural health clinics, without having to worry about the best price determination calculation. Because 340B prices are already below the statutory Medicaid rebate, we don't have to have states taking the risk, and I'll talk to you about that a little bit later, of uh-oh, if I do this and I'm giving up my guaranteed statutory rebate, do I want to take that risk, because 340B pricing is already so low. In a situation like this, because it's outside of the Medicaid drug rebate program, there could be opportunities for closed formularies, and again, we think this can fit really well with establishing sort of a center of excellence or a whole person care kind of approach. Earlier, somebody asked a question about where is the patient in the hepatitis C discussion, and having been not just a former Medicaid director but a former behavioral health commissioner here in Washington State, to me, when I think about some of the folks who are on Medicaid who have co-occurring mental illness and substance use disorders who acquired hepatitis C because of IV drug use, to me, that patient is not about giving somebody a pill. It is about much more than giving them a pill. It's about access to mental health treatment. It's about access to substance use disorder treatment. It's about care coordination. So, we think this pathway provides opportunities for really some creative work and partnerships to pair some of those high cost specialty drug treatments with really whole person strategies.

Risks, this is a big one, you need the cooperation of the 340B entity. So, where, for example, a clinic is benefit from the spread between the price

that they paid for the drug and the price that they are paid by Medicaid or whatever, it's really a discussion about are there opportunities to do shared savings models so that if we're willing to invest in a whole person model, and we can reduce the use of the drug, or we can get a better drug, how can we share the benefits. Again, because this is with managed care organizations, state would be navigating it through their managed care contract. The same issues again that I'll talk about later.

So, another exemption from the MDRP is hospital dispensed covered outpatient drugs. Hospitals, there is an opportunity, which we are not aware of having been used before, that CMS has not issued guidance on to date. If a hospital is essentially willing to bill the state Medicaid program at whatever their acquisition cost is for the drug, there are arrangements that can be done outside of the Medicaid drug rebate program, which could open up opportunities. For example, with some states that are experimenting with episodes of care bundled payments with hospitals, there might be opportunities to more effectively bring prescription drugs into those kinds of arrangements. Probably the easiest linkage is with 340B hospitals, because we know sort of they're getting the good 340B prices.

In terms of risks, just like on the third pathway, you need the cooperation of the managed care organization and the 340B entity here. It's a cooperation with hospitals to have those discussions about the difference between the price they pay and the spread that they're used to getting. The pathway five, this one technically physician administered drugs are not considered covered outpatient drugs under the federal Medicaid drug rebate program, and this one, the biggest... it is an opportunity to work with physicians, again, on disease specifics. So, for example, to work with oncologists, to think about whether there are creative purchasing ideas that can be done around oncology drugs. Again, because this is outside of the MDRP, you can use a closed formulary. You can have indication specific rebates, and again, you can link it up with sort of, like, for example, an episode of care model. The biggest risk of this one is that many states, this is actually contrary to the direction that a number of states have taken. Many states, in order to gain more control over what's going on with prescription drug utilization in their Medicaid program, are bringing physician administered drugs sort of over

to the pharmacy part of their shop rather than keeping it in the medical part of their shop. So, we're being very, very up front about this pathway being sort of contrary to where states have been moving recently, and the other really big risk for the state in this one, is that the state is giving up a guaranteed statutory rebate in exchange for the potential of something like this yielding better costs for them.

Pathway six, this one is relatively simple, I think. There is a provision in federal law, when states have their Medicaid programs, there is an opportunity to develop what's called an alternative benefit package for certain groups of Medicaid clients. The most obvious group is the newly eligible population, the folks up to 138% of poverty that the Medicaid expansion states have taken the opportunity to... or for the states who have taken the opportunity to expand Medicaid. Under this alternative benefit package, there is the ability to use a closed formulary. So, for a specific group of Medicaid clients, a state can have a closed formulary.

The risks associated with this, most states that have done Medicaid expansion have said, I don't want to do a separate benefit package. It's too complicated. I'm just, like, Washington State. Washington State has said the Medicaid benefit package that applies to our standard eligible population, the folks we normally serve, we're applying to the newly eligible folks as well, but some states have not. Then, the other one is... this is Medicaid wonkism, and I'm not even going to get into it, because I don't want to completely overwhelm you.

The last pathway that we identified is in a section 1115 waiver. The federal government does have authority to waive provisions of the federal Social Security act for state Medicaid demonstration programs, and there is the authority to waive provisions of section 1927. So, for example, as we've been having the discussion here this morning, best price came up a lot. If a state wanted to pursue a multipayer approach to value based purchasing for prescription drugs, one way to think about not having best price being an impediment would be to ask CMS to grant the entities participating in that multipayer arrangement an exemption from the best price calculation for purposes of the arrangements that were going to be going on under the demonstration. In addition, some people have thought about an 1115 waiver in the context of just moving

purchasing of certain prescription drugs just outside of the way they're normally purchased. So, an example would be Massachusetts, for example, recently enacted legislation setting up a trust fund that allows municipalities to buy naloxone so that they can give it to first responders, to police officers, so that out on the street, they can get it to people quickly. So, one thought is, could there be a similar strategy that involves Medicaid, as well, for something like naloxone where you have such a clear public health imperative. Other people have talked about under federal law, there's the vaccine for children's program, which is a whole separate system for purchasing vaccine, and in Washington State, Washington State formed the Washington Vaccine Association to keep alive a universal purchase concept for childhood vaccine. Is it worth thinking about whether that kind of a model should be thought about for other drugs where there is a really significant public health imperative, like buprenorphine for medication assisted treatment? Some people have talked about it for hepatitis C, as well.

The risks associated with an 1115 waver are, you're negotiating with the federal government, and there is a requirement for federal budget neutrality. So, it would be a long involved discussion, but I can say that we've had two discussions with... the SMART-D team has had two discussions with CMS to date, and both of them have gone really, really well, because CMS is facing the same struggle that every state is. What can we do about high cost prescription drugs. So, we have an open dialogue going back and forth. We're exploring all of these pathways, and it is really good to see that there is an openness to having those discussions.

So, really quickly, I want to talk just a minute about anti-back, about off label promotion. So, we have done some work on the federal anti-kickback statute. I will have to caveat this by saying that just like their specificity around working with a particular state, any state that we work with on any kind of an APN arrangement for prescription drugs, we will look at through the lens of the anti-kickback statute and off label promotion, but what I can say is, the anti-kickback statute essentially says that a drug manufacturer or any other Medicaid or any other healthcare entity cannot, with intent, offer anything of value, including payments, to increase the use of that service by federal healthcare programs,

Medicaid, Medicare. There are ten explicit statutory exemptions, and Congress also gave the office of the Inspector General the opportunity to define safe harbors. There are 25 safe harbors currently. Most significantly, there is a statutory exemption, and there is a safe harbor that relates to discounts or reductions in price. So, that's the one that we would be looking at the most carefully.

If you don't mean a specific exclusion or a safe harbor, there are standards that OIG has laid out to drug manufacturers, in terms of thinking about these things. To date, HHS, as I indicated, has not issued any regulatory guidance on this specifically or any advisory opinions, but when we looked at the case law around anti-kickback and the advisory opinions that have put out, two things seem to be most notable around protecting or reducing the risk, the anti-kickback risk. Number one, in these cases, a manufacturer is negotiating directly with a state rather than a commercial entity, and most importantly, since these are state planned amendments or waivers or whatever, CMS is going to be involved. CMS is going to be looking at it. So, if CMS approves, and we're doing innovative things, we're assuming that they are going to be seeking input and insights from the office of the Inspector General.

With respect to off-label promotion, off-label promotion, it's a form of mis-branding. In essence, many of us have seen litigation and settlements over the course of the years. If a manufacturer is marketing or promoting the use of a drug for off-label purposes and those drugs are billed to Medicaid, the manufacturer can face false claims and prosecution. So, with respect to any of these arrangements, we're going to be asking, do any of these arrangements involved off label use of a medication, and we're going to be thinking, does it violate federal law. When we think about how to limit the risk, the concepts that we came up with is, of course, manufacturer truthfulness. Is there an arm's length discussion that is going on between the state and the manufacturer about what they know about the off-label use? Is there independent clinical data that we can use that references the use of that drug for the off-label purpose, and again, we're assuming CMS review and approval of any of these kinds of arrangements. There is actually some recent federal case law around off-label promotion and first amendment rights where there have been favorable decisions for manufacturers around the

opportunity to discuss off-label uses of drugs, but I definitely will not get into that now.

So, I think I went over what we're going to be doing in phase two, in terms of working directly with the states. Here is the SMART-D website. Here is contact information for me and for Bill von Oehsen if you have followup questions, and as I indicated at the outset, if there are any pharma folks here who want to have a discussion, I am more than happy to have it. Thanks so much.

Donna Sullivan: So, Jane. This is Donna. I have a question for you. On your slide in, I guess, past number five about physician-administered drugs, I'm curious as how those were defined, because state Medicaid plans are required to submit physician administered drugs to CMS to collect federal rebates. So, I'm curious as to how they were defined to be exempt from the Medicaid drug rebate program. From our standpoint, they are actually included in that Medicaid drug rebate program.

Jane Beyer: So, when we looked at the definition of covered outpatient drug in the federal statute, we felt that there was... that physician administered drugs could arguably not be within that definition.

Donna Sullivan: And this is, from our position as a state, CMS has given us guidance that yes, they are included in that definition.

Jane Beyer: OK. So, that will be part of the discussion that we're having with CMS around these. I mean, in all, I would say of all the pathways, I think this is the most challenging one for the states, because it means forgoing a potential statutory rebate, and that's a significant risk.

Daniel Lessler: Other questions, or if people prefer to write them on an index card, that's OK. Very good.

Male: This is fairly long-range thinking. [inaudible]. Off-label, usually there is something going on, there's some goodness to the drug or off-label wouldn't be happening. So, considering MCO or state getting together with the industry to do the study, to prove out the benefits that are in

the off-label space to find out if the drug is truly effective for this new use, and then get the labeling updated. How long would that take?

Jane Beyer: Oh, I do not know the answer to that question.

Donna Sullivan: I don't know the answer to that, but the other conundrum that we fall into is that studies are done and published that clearly show a medication is useful where it does not have an official FDA labeled indication. The product is near its patent life. It will never get its label updated, and therefore, Medicaid programs have a difficult time actually encouraging use of that less costly, equally effective product off-label compared to the brand new drug that just came on board with that particular indication. So, that would be another conversation with CMS around what is the compendia that we use for medically accepted indications.

Jane Beyer: Yes. Excellent input.

Daniel Lessler: Newell has a comment over here Jane.

Newell McElwee: So, at least at Merck, we think about trying to generate evidence and actually get approved indications, but a lot of the concern about off-label promotion at this space is not what you think it is. It's not looking for a new indication or a new... so, it's not taking a cancer drug and saying we want to use it for toenail fungus, right? It's a situation where in your label you have data from phase three trials with FDA approved endpoints that are done under good clinical practices, and the question you're trying to apply for a contract involves how your drug is going to perform in the real world, not under those circumstances for the same targeted patients, right, and then if you throw in total costs, we never studied total costs in phase three. So, those are the kind of nuances around off label concerns that we have.

Jane Beyer: OK. That's good information.

Daniel Lessler: Other questions or comments here? OK. Well, Jane, thank you, very much. That's a great discussion of some really complex ideas. So, at this point, we're close to wrapping up. What we would like to do, and I think, do we have a form for folks to? So, on the tables is just a form with

I think three questions, which would be really helpful. We did this at our first summit and got incredibly insightful, helpful input. So, we really just want to get your ideas, essentially, about how we, at Health Care Authority, might be able to take some of the ideas we've been talking about here and potentially put them into practice. So, what we'd like to ask you to do is just take five minutes here and give us your thoughts. These are anonymous. We're going to collect these and, as I say, it's very helpful input that we've received in the past. So, we'll just take a few minutes here.

So, as we finish up here, and people are writing and I really appreciate your ideas, I know that people want to, as they finish up, leave. I want to just again thank the speakers today, our panel participants for a really engaging, provocative conversation that I think puts some great ideas on the table. I know some real fodder for us to take back to Health Care Authority, and I hope likewise for wherever you work in this industry, some ideas for you to take back. It takes a lot of work to put something like this together, and I just really want to recognize the folks that have done that work beginning with Leta Evaskus and all the planning and herding the cats and making sure we all got our presentations in and talked to each other. Ray Handley who has been extraordinarily helpful just in terms of conceptualizing and thinking through what this would look like. Judy Hull who also somewhere I think outside my assistant who keeps us on track, and of course Donna Sullivan who is my colleague in crime on the pharmacy end at the Health Care Authority. So, I just want to give them a special thanks, and then thank all of you for taking time to come and participate in the conversation today. Thank you. If you didn't, there are parking validations and you should have gotten a parking validation. If you don't, you can stop at the desk on the way out and again, feel free to take your time in finishing up your comments, and we'll be collecting those and again, thank you, all.