



Value-Based Pricing for Prescription Drugs: Opportunities and Challenges

**Alliance for Health Reform
CVS Health**

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Sarah Dash: Good afternoon, everybody. Welcome. I am Sarah Dash. I'm co-CEO of the Alliance for Health Reform and, since this is the first briefing I'm moderating in my new role, I want to recognize my partner in crime and other co-CEO who is Marilyn Serafini, and I also want to wish the best to Ed Howard who, as many of you know, led the Alliance for nearly 25 years before he retired last month.

So, just as a reminder, to those of you who might be new to us today, the Alliance for Health Reform is a nonpartisan, nonprofit organization that is aimed at health policy education. We don't lobby on any issues, although it is our hope that by opening discussing the tough issues in a balanced way, we will do some good in helping policy makers and others move towards a higher quality, more affordable healthcare system.

Today has been a busy day already. I know that it is Emancipation Day in the district and hopefully your taxes are done already because we are about to buckle down and get to a really interesting and tough issue, and that is drug prices. And I also want to thank CVS Health for their support of this important conversation.

So you can join the conversation on Twitter using the hashtag drug prices, and we're here today with a really fabulous panel to talk about what value might mean when it comes to prescription medicines, how that value is assessed, and how it fits in with overall healthcare payment and delivery. And we know that on Monday of this week, the Alliance started off with a briefing on delivery system reform and what we know about alternative payment models and so forth, so perhaps it's fitting that we're ending the week talking about how prescription medicines might fit into that conversation.

So within these so-called value frameworks, or value models, have been garnering a lot of attention and today we're going to hear about the data and considerations that go into the value equation, what might be missing, and where we go from here.

With that said, I'd like to move to introducing our panel for today's discussion and I really encourage you to read their full biographies in your packets, as well as the background materials which are really informative. I'm going to go from my right to my left. First, we will have Steven Pearson, who is founder and president of the Institute for Clinical and Economic Review, also known as ICER, and he's going to tell us about their value framework. And next, we'll have Leigh Purvis who is director of health services research at AARP, and she'll address the role of consumers and patients in developing value frameworks. To my left, to your right, Dr. Bobby DuBois, who is chief science officer and executive vice president of the National Pharmaceutical Council, and he's going to discuss some of the tradeoffs posed by value frameworks in the context of prescription drug prices. And then, finally, Dr. William Shrank, who is chief scientific officer and chief medical officer for Provider Innovation and Analytics at CVS Health, and he'll talk about value from the perspective of healthcare payment and delivery.

So without further ado, we will get to the panel and we'll start with Steve, if we can load his slides. You feel like you're so far away from me.

Steven Pearson: Thanks, everybody, and good afternoon. It's a real pleasure to be here, thanks for inviting me.

This seems like the topic du jour. It's obviously headlines and it's in the papers and you've been hearing a lot about it, but it's obviously just a small part of a larger conversation about healthcare costs, about access, about quality. Sometimes I feel like this is the only slide that I would need to put into a talk

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about value-based pricing of anything. It makes a point that this has real implications for us as a country. This is actually data from Massachusetts alone, but I feel fairly confident that it's mirrored in other states, as well. What you see here are – it's a 10-year snapshot of what has happened to state spending on healthcare versus everything else. And this is a little bit old now, it's 2001 to 2011, but just to capture this briefly, this left-hand bar, here, shows that in that time, state spending on healthcare went up by 59% and basically, to make room for that, 20% overall had to come out of everything from public health, mental health, education, infrastructure and housing, human services, local aid, public safety. So this is the reality that states face, even more critically in many ways in the federal government, but it's a testament to the fact that we are continuing in an era in which we are outspending in health compared to other societal needs. And there's a real tension between how we think about the value that we get from our healthcare spending and, again, these other societal values and things that we could be spending our money on.

When we think about the pricing for drugs, in particular, there are different conceptual ways to think about what a quote/unquote fair price is. And there are going to be a lot of quotation marks in this slide because they all are open to interpretation. One is, well, why are we even talking about fair prices? The market determines what the price is and we have decided we're a capitalist country and we believe in the free market, so therefore, the free market supply and demand should basically determine what the price is and any other attempt to decide what's fair is somehow misguided. I'm not going to go into the depths of the economic or philosophical pros and cons to this, but just to recognize that it's certainly a very strongly held view of many Americans that this is the way the pricing happens. It's not something that's manufactured out of Washington or anywhere else.

Second, you'll hear a lot of discussion about the idea of pricing should, in some way, reflect the cost of what it takes to develop and to produce these drugs plus, obviously, some reasonable profit; that we should know what it costs to make a drug and all of the failures that go along with drugs that don't make it to market and then wrap that up, say that you get a certain profit on top of that and that's the way a fair price should be looked at. And, again, you'll hear a lot of policy makers expound the idea that this is the way we should be thinking about reasonable, fair prices.

The way that my Institute and most countries around the world think about this is to really focus on the quote/unquote value. The added value that new drugs, let's say, would bring to patients and to health systems. And that's the approach that I'm going to briefly talk about now because a lot of the value frameworks are focusing on this idea of how do we capture the added value that drugs bring and think about that in a coherent way?

We have a value assessment framework that looks at everything from the specific effects on the clinical outcomes—that's the risk and the benefits for patients. It looks at the context of whether we've had drugs for this condition before, whether there are additional benefits for patients, families and others. At the end of the day, we have found it helpful to frame what we call a value-based price benchmark using two anchors. One is to think about the long term cost effectiveness. I know that the term cost effectiveness is one of those technical terms that everybody thinks they know exactly what they mean by it. It's tricky. Because to say something is cost effective is not, in health economics at least, mean that it's saving you money in the long term, it just means that it's giving you some benefit and the extra price or cost you have to pay for that is in proportion—in some kind of reasonable proportion so that we're willing to get a lot of benefit and spend a lot of money. If we're only going to get a little benefit overall then we shouldn't spend a lot of money. It should be somehow scaled to that. So the technique that health economists use is called cost effectiveness analysis and the metric that is used is the cost per quality adjusted life year. That's a way of measuring how much longer a drug might enable patients to

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live, taking into consideration the side effects, the quality of life that a drug might give. Some drugs might only improve quality and not life, others life but not quality, but you have to look at both. And again, economists and others have figured that the range in the U.S. generally is somewhere the 100 to 150 thousand dollars per quality it's called. And, as an Institute, we like using a range because it leaves open the real idea that there are these other considerations that society, that payers, and others may want to look at so that there's not one single number, one line in the same. It's a range that we want to think about.

So that's the long term look. We think about the long term effects. Maybe a drug prevents heart attacks 20 years downstream. That's good. We want to capture that. Maybe it prevents hospitalizations, so you look long term. That's not the only piece that states and payers and patients need to think about. So we also look at what we call the potential short term budget impact and this is a way of trying to basically estimate how much the budgets will be hit by the uptake of a new drug unless we manage it very aggressively, let's say by, you know, either making it tough for patients to get to or other approaches. The way that we do this is very transparent. It's a calculation based on looking to see whether the cost impact potentially of a new drug will lead, we think, to a growth in healthcare costs that are outstripping, continuing to outstrip, our national economy. So the basic assumption, and this is based on some state legislation—Massachusetts and a part of Maryland—its health economy is actually explicitly pegged to the state GDP growth, and if the costs go up higher than that, there's actually some mechanism for something to happen to try to bring those costs back into line with growth in the overall economy. So we, then, have an approach to doing the math and I'm conscious of the time, so I'm going to go kind of quickly through this, but you have, I'm sure, those materials—we basically look over a 5-year time period and, doing the math, we think that the reasonable standard to set an alarm bell at which we would be worried about the potential short term budget impact, is around 904 million per year for a new drug.

How do we go from this to the actual prices? I'll just give you a couple of examples. We've looked at several different drugs. One is called PCSK9 inhibitor drugs. These help to reduce cholesterol for patients who have very high cholesterol problems. The list price—there are two companies that make these drugs that came out—the average list price was \$14,350. That's not the actual price because everybody goes out and negotiates. But what we did is we said, "Well, at what price would it seem to be a reasonable value based on its long term cost effectiveness and the potential short term budget impact?" According to our analyses, looking even at the long term, you would need about a 50% discount from the list price to get into the kind of reasonable value range. But one concern, though, is that even if you did that, this is a drug that could be used for millions and millions of Americans with high cholesterol, and so we estimated that if you don't want to ring that alarm bell of worrying about the short term potential budget impact, you'd have to have a price as low as \$2,177. And basically, anything over that—oh, that's really cute. You like that? A new attempt to make the point that this is an alarm bell. If the price is over that, it doesn't mean that that's the right price it's just the price at which beyond that we have to think hard about where savings might come elsewhere, what else we might do to help manage the uptake of a drug so that it doesn't contribute to a very rapid increase in our growth.

I will go very quickly through an example to show that it's not always the case that drugs come into the U.S. market at prices not in alignment with value. A drug called Entresto for congestive heart failure, the list price was \$4,560. If you look long term our analyses suggested that that could support a price of two to three times higher and still be a reasonable value. The company, however, chose to price it lower and, in fact, if you're even thinking about our alarm bell, you would only need about a 9% discount, and that's well within the range of what most negotiators, the plans that pharmacy benefit managers would be able to achieve.

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Because of the time I'm just going to skip this slide because what I just wanted to mention was that we're entering an era in policy where people are more and more aware that value frameworks like ours are being used, the information is in the public domain. The question is how can it be used? What can we do to align our system with value? And so, one way to think of this is what would we do if a drug's price does meet the benchmark? Well, you could do basically good things for it. Give it carrots, so make it included in the formulary, you know, especially the exchange formularies. Try to say that it should be a first tier drug with very low co-pays out of pocket for patients because, again, remember, we are getting a good value at this price. That's the general feeling. Defunct gold card means that doctors don't have to go through a lot of hoops to get the drug approved. And then the bottom four bullets are actually things that would take some action at the federal level, do things through Part B, the 34B discount program—I'm going to leave some of these for further conversation at the end.

So with carrots, we would need sticks so that the price doesn't somehow come into some range that we consider aligned with value. Then, again, all the bad things would happen. We would make it difficult for patients to get it, might even exclude it from formularies. We might have patients try something else that's cheaper first and have to fail it before getting it, and maybe we would only reimburse up to some value-based price instead of giving all of it.

With that, I'm just going to say moving forward, one of the things that's very hard in any kind of season in Washington, especially an election season, is to view this as anything but black versus white. You know, good and evil. What I like to point out is that this really is an important policy problem because it is attention inherent in any healthcare system, this tension between profits and access and innovation. And, of course, profits supporting future innovation are a good thing but, at the same time, I really do feel that prices that can be scaled to align with value, we don't need to feel that they're going to kill innovation, kill the drug industry, drive businesses overseas, whatever you might hear in the kind of heated political rhetoric. There is attention there but it's not all or nothing. And ultimately, we have to really work to keep the patient at the center of this conversation and we all try to do that. It's really important. To me, the patient means not just the person across the table from a doctor in the room, it's the patient tomorrow, it's the patient's community, if the patient lives in a community and remember, again, we've got other needs for resources—education, environment, public health—so we have to think about all of this as a balance when we think about the patient and what their best interests are. Thank you.

Sarah Dash: For those of you who are standing, I think there's still a few empty seats up front, so if you feel like you prefer to sit come on up.

Leigh Purvis: Hi. Thank you for having me here today. My name is Leigh Purvis, and I am part of AARP's Public Policy Institute where I am responsible for covering prescription drug issues. Kind of as a level set here, I have a feeling I would lose my employee badge if I did not take a moment to discuss why we're tackling this incredibly complicated topic in the first place.

I think everyone in this room is aware that Americans use a lot of prescription drugs. Nearly 60% of American adults are using one or more and 15% are taking five or more. These numbers are actually low compared to the population that AARP represents. Among older adults, nearly two-thirds are taking three or more on a regular basis. Americans also tend to have a fair number of chronic conditions, about half of adults have at least one chronic condition and 25% have two plus. Among AARP members, more than two-thirds have two or more chronic conditions. So when we're talking

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about prescription drugs we aren't talking about a one-time cost. We are talking about something that our members are facing every day, every year, for the rest of their lives.

This is not news, I think, to anyone in this room, but prescription drug prices are pretty much out of control. They are high, they are growing. We are seeing launch prices entering the market that exceed \$100,000 a year. Some of them get as high as \$400,000 a year. And, unfortunately, that's just the beginning. High launch prices are one thing. What happens after those products are on the market is another. We are seeing price growth trends of around 10% for a lot of prescription drugs so, as incredibly expensive as they seem when they first come on the market, they are only going to get more so every year that they're available. We also are seeing an increased focus on products that can command very high prices. There are a lot of, for example, orphan drugs which are used to treat conditions that don't affect many people, and manufacturers are able to charge incredibly high prices because they need to make their money back. We also are seeing a lot of interest in specialty drugs. Those are also the drugs you typically see with these incredibly high prices. And a lot of the drugs that are in the pipeline right now are those specialty drugs, so what we're seeing right now really is kind of the tip of the iceberg. There are a lot more of these products coming and they're going to cost us a lot of money.

So what does all of that mean to AARP and, quite frankly, to everyone in this room? We really are approaching a tipping point where we simply cannot afford the trends associated with prescription drugs. We literally, as Steve alluded to, do not have the money to continue spending the way we have been spending. And if there's one thing I hope all of you go home with today, it's the fact that this is not something that only affects people who take prescription drugs. Every single person in this room who has health coverage and pays taxes is already paying for these products and that is something that everyone needs to keep in mind. It affects you. You are seeing it in your healthcare premiums, you are seeing it in your taxes. The PCSK9 inhibitors that Steve alluded to are incredibly expensive anti cholesterol drugs and there's research indicating that everyone within an insurance pool will see their premiums increase by over \$120 per year from those products alone, and the price associated with those products is relatively low--\$10,000 to \$15,000. So, again, this is something that you will see. You are paying for it, and it is something that should be important to you.

More to the discussion today and, quite frankly, why we're talking about this in the first place: how do consumers get involved in value-based pricing? I think it's pretty evident that it is very difficult for Americans to agree on pretty much anything these days and that will translate to defining value as well. It is going to be very difficult for us to have an incredibly diverse population agree on what value means to them. You also have to be mindful that someone who is sick is going to have a very different perception of value than someone who is healthy. You cannot rely on cost alone. There are other things that are very important to patients, things like survival, symptom reduction, or even the ability to go to church on Sunday. That said, cost is a factor. Just because something is valuable does not mean that it's affordable and that is something that we need to keep in mind. Even the most valuable product, if it costs too much for us to be able to pay for it we're not getting a whole lot out of that. Something else to be mindful of is that something that sounds good on paper may not necessarily be something that we agree with once it's personal. One thing I always like to point out, and it's actually related to research for one of my fellow panelists, is that Americans generally think that generics are great, but those numbers drop substantially when they talk about using generics themselves. So there is a little bit of a disconnect between what people may say they want and what they actually want.

I also feel like I should mention that Americans like very expensive things. That is going to make this more challenging. There is actually research indicating that patients respond better to expensive

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placebos than they do to placebos that they think are less expensive. So there is some inherent bias within our system that makes us like expensive things.

Now, that said, given it's complicated, there are some general guidelines that should definitely be taken into consideration as we work toward developing a definition of value. One is that we need to have some sort of agreement. Value is not limited to prescription drugs alone. We are trying to get to value across the healthcare system and we do need a definition that can be applied broadly. There also needs to be an incredible amount of public comment. Like I said, Americans are a diverse group. They need to have their say. We need to have beneficiaries, providers, insurers, researchers—everyone needs to be in the room as this definition is developed. Also, it goes without saying, but I will say it, everything that is determined to be valuable, it needs to be based on evidence. We need objective evidence and, unfortunately, that is something that is a little bit lacking within our healthcare system right now, particularly when it comes to prescription drugs. But we do need that evidence. We need to be able to prove to people that there's a rationale to what's being done.

Well, that said, given the activities of the past month or so, there is some question as to whether or not this is all just lip service. Are we really ready to move to value? We have seen an incredibly vehement response to CMS's efforts to reform reimbursement under Medicare Part B. This is an indication that, yes, everyone likes to talk about value but maybe there's a little bit more wiggle room in terms of actual implementation and it does kind of go back to the generics example that I provided previously.

All of that said, why are we doing this? Because we have to. The costs associated with prescription drugs are simply unsustainable. We cannot afford to continue spending the way that we have. We have billions of dollars at stake for taxpayer funded programs like Medicare and Medicaid and we have to be mindful that those programs need to be sustained for the people who need them. Unfortunately, also when we speak of tipping points, we also are talking about the fact that we are reaching a point where people simply cannot afford the prescription drugs that they need to get and stay healthy and that obviously is a huge concern for us and should be a concern for everyone. Thank you.

Sarah Dash: Thanks, Leigh. So, Bobby DuBois. And, just a reminder, you can Tweet along if you like to, hashtag drug prices. Thanks.

Robert DuBois: Well, thank you all for being here, as well, because this is an incredibly important dialog, but it's a dialog that is just beginning and a lot of back and forth needs to occur.

At the end of the day we need to figure out what is value and how do you measure value. It is not going to be determined quickly or easily, as you've heard from the two previous speakers, but people, like Steve and others, who have developed frameworks have brought this dialog to the fore, and that is really, really important. And so this is something we all need to participate in. But you guys are in policy, making policy, advising roles. So, as you begin to think about what legislation to write, or what regs to put together, I want to leave you with five take home messages.

The first is the value equation looks simple. It's what benefit do you get for what cost. Measuring it, defining it, enshrining it in legislation—it's a big deal. Okay? First thing. Second, the frameworks that I had on a previous slide, and what Steve shared, and others are working on, have a lot to teach us, but improvements are needed. And improvements are needed before we think about how we roll this into the private sector decision making, or the public sector decision making. That's the second. The third is, when you develop a framework what's important is, does it line up with what our goals are, or what we call guiding practices? So, I'll talk a little bit about that, but they should, of course. Fourth, we have

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many exchanges, many different levels within exchanges, many competitors within each of the meta levels within the exchanges. Hundreds of options. To think that we will end up with a nationally determined weighted standard isn't in keeping with that broad set of choices that we have, so keep that in mind. And the last, in spite of what you just experienced, which is a free lunch, in reality, there is going to be a careful tension and balance, as Steve raised earlier, between today's access and future and continued innovation. So those are the five things I hope to leave you with.

God is in the details with a lot of different things. So it seems like a very simple equation but what do you put into the benefits and what do you put into the costs? So, if you're thinking about cardiovascular disease, well, how many heart attacks are saved, how many years of life, etcetera, etc. But do you include the ability to return to work? Do you include pain control? Do you include can you play golf? Is that part of the value equation or not? That's a tough question. We have to wrestle with that. What do you put into the cost equation? Well, what's the cost of the drug, what are the costs of the hospitalizations? That's all pretty straightforward. But what about a new drug or a new device that means that your spouse doesn't have to take care of you as much as they used to? Well, is that part of the "cost" savings? Productivity, or care giver burden. So, these things are very complicated and we need to sort through this and it's going to take a little bit of time to figure some of these out. So the equation's simple, the reality of a lot of it isn't.

Oh, that yellow color is awful. [Laughter.] Yeah. Well. Anyhow, what it says, if you could actually read it, is for frameworks today we've got the 1.0 version. Okay? And they've taught us many lessons. There's a half a dozen of different frameworks, they take different approaches, they focus on different audiences, they take into account different types of evidence, they measure cost in different ways. We've learned a lot. But there are improvements. We need to be able to understand well how did this calculation come about, and can I duplicate it, and what if I put in my own numbers in the model, what would it look like? So there are lots of things. Do you have stakeholders throughout the process? What type of validation or vetting has there been? So, ultimately, and this one you can hopefully read, there's going to be a 2.0 version and a 3.0 version and a 4.0 version, but we're not there yet. So how do we get there?

Our group has put together a set of guiding practices, principles in essence. We're not putting together a framework, but we're saying if you do develop a framework, there's a set of things to think about that might weigh into your framework, and we've got some copies of the actual guiding practices and some other work, I think, out in the front if you're interested.

So this is a subset of the guiding practices. So, as you're developing a framework, or as you're thinking about using a framework in a commercial environment or a governmental environment there are things to think about. How is the framework put together? Were lots of stakeholders involved or not? What type of evidence did you include? Just randomized controlled trials? What about real world experiences? Again, how did you measure the cost? How did you measure the benefits? And there are some best practices to think about when you look at a framework and say: is this ready for prime time? And these, we hope, will help guide the evolution of these frameworks. And they're all evolving. They're not done yet.

The fourth, and I alluded to this earlier, is the concept of couldn't we have a nationally determined framework with a specific set of weights? Which would mean we all agree upon the relative importance of a drug or a device that helps old people live longer versus young people that might prevent certain disabilities in some populations and not in others. How important is it to have a new development that gives people hope, meaning yes, on average maybe I won't live that much longer but 10% of the people

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are cured; how important is that? Are we going to have a single nationally determined quality or value number? And our feeling is, my feeling is, it's got to vary. It's got to vary by the population, by the clinical condition, by the region and it needs to be something that's very transparent on the exchange menu but is not likely, from my standpoint, to be desirable to have one Washington determined determination of value. So that's the fourth point.

And, the no free lunch issue. So, 90% of people just about are on generic drugs today. Well, what if we magically decided 100% should be on generic drugs because we're going to throw away all the patents or make the patents very, very short, or we're going to force prices to be at a certain level. There is a tradeoff between how much access is available that we might force, through legislation or regulations today versus, as Steve mentioned, the need to continue innovation. Now, it all sounds very hypothetical and people say, well, you know, there's always profit so we can take a little bit away and people will be fine and the companies will be fine, but think about the health exchanges. We've read news report after news report about the community insurance plans going out of business. They will no longer provide insurance coverage for certain individuals. United Healthcare is pulling away from certain markets and why is that? It's a business. If there's no profit they don't want to maintain in that business. So there is a tradeoff, so do keep that in mind as you think about policies and whether some of these value frameworks are ready to move forward in those ways.

So these are the take home messages. It's in your slide, I won't read it again, but what I would like to do is leave you with just food for thought: this came out yesterday by IMS. You may have run across it. It basically is what's the spending trend been and you often hear the numbers, well, spending on drugs has gone up by 10%, 12%, 15%, 17%. They did something that's quite unique. Everybody looks at the list prices and the growth of the list prices. They actually said let's look at the actual net prices when you get rid of the discounts and the rebates and the other things—the real, in essence, cost of these things. And what they found is that the aggregate spending increase was about 8%. Now you'd say, well, that's an awful lot of increase. But then, if you ask the question how much of the growth in drug spending was due to, well, more people are getting drugs through the ACA. Or, people who used to be on generic drugs but now there's more effective drugs that happen to be brands, okay, so those are more expensive versus the thing that the media only focus on, which is price increases. In reality, if you strip away all those pieces of the puzzle the actual price increases for brand drugs was less than 3%, not hugely different than inflation, so just something to think about when you read the headlines. You've really got to peel apart is this the list price, is this the real prices that are really being paid for? And it may look like a big number but that may be a lot more patients are being treated, or now we have treatments that we didn't have. The policy implications are really different than if we doubled the price, we tripled the price. Because when you average it all out, that number that was growing was actually a modest number. So, I leave that with you and happy to talk about any of these in the Q&A.

Sarah Dash: Thanks, Bobby. Will Shrank.

William Shrank: Well, thank you for the opportunity to be here and I'm glad to have a chance to speak after Bobby because we have some specific numbers to address, some of the topics that Bobby brought up.

So, first, the goal of this discussion is to speak about what are the sources of increasing drug costs in the U.S. and what we can do about them. And it's true. The reason we're all here is because something's changed recently in terms of drug costs. We had seen prescription drug costs sort of plugging away in 2% or even to 0% growth for a bunch of years and then, in 2014 there was a really dramatic increase.

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This is the latest National Health Expenditure data, and this caused a lot of folks to tend to pay attention to this issue of rising drug costs.

So we took a really close look at our own data at Caremark where we have a clear vision into what the sources of the prices are and how we negotiate them. And we found, like everyone else, in 2014 a double digit increase in trend. But the key drivers of trend for us were inflation. Brand inflation, specialty brand inflation, and that represents year over year increases in price in medications that were available during the previous and then, the subsequent year. We saw modest generic inflation, modest increases in overall utilization and in 2014, there was really an interesting phenomenon around Hepatitis C that led to a meaningful increase in spending. And, at the end, you'll see the black column is our efforts, the PBM management strategies to reduce overall drug spend. I'll talk a little bit more about that on the next slide.

So what did it look like in 2015? So, 2014 prices was the beginning point. Again, we saw substantial brand inflation and, again, substantial—not as big—specialty brand inflation that was the main contributor to increased trend, modest generic inflation and modest increases in utilization. Again, our PBM management did much to ameliorate some of those increases, so overall, the trend after rebates, after discounts was 5%, substantially less than the 12% we had seen the year before.

I'm going to talk a little bit about what those PBM management strategies are. First, intelligent purchasing so we leverage our scale to negotiate with pharmaceutical manufacturers. In that setting, competition is critical. We're far more effective at negotiating prices in settings where there are multiple medications within a class that are similar efficacy. An example here is Hepatitis C, so in 2014 it was a massive driver of trend and towards the end of 2014 new medications became available on the marketplace. In 2015, we negotiated with all those manufacturers and identified an exclusive strategy with Gilead, the maker of Harvoni, and Harvoni had an exclusive deal on our formulary. We negotiated a price that was significantly less than what the United Kingdom's national health system negotiated and, because Medicaid benefits from the lowest price in the commercial marketplace, Medicaid price, for Harvoni, just shortly after we inked our deal, reduced by approximately 50%. We use versatile cost management strategies, which is really a focus on sort of the clinical nuanced approach to try to make sure that we get the right patient on the right drugs. We have a deep clinical bench. We leverage the most recent evidence. We work closely with the specialty guideline developers to make sure that for every class we have a clinically sound, clinical algorithm that establishes the rationale for who should and shouldn't get which medication at what point. It is a clinically evidence-based approach.

And then, we use that to develop our formularies and we have a variety of formularies we make available to our clients. They range in how selective they are, but if you move towards the most selective formularies, you see we've demonstrated empirical published evidence that more selective formularies, one we call the value formulary, our clients, our payers experience a 20 million dollar savings per 100,000 members per year, higher generic use, and we also find better long term adherence because patients can adhere to medications that they can afford.

And lastly, we use real time data surveillance to try to identify those outliers where there are medications where the prices change rapidly. So a well-known example to everybody in this room: the Turing example, where a single medication for patients with HIV and AIDS increased in price from \$13 to \$750 essentially overnight. We identified that rapidly. We created a solution, a much lower cost solution that was clinically equally effective, and were able to switch patients to something that was much more affordable.

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So, here's another example, and Steve brought it up in an earlier discussion around PCSK9 inhibitors. It's a new class of medication that came out last year to treat high cholesterol. It treats the same condition as statins, which are as tried and true a class of medications as you'll ever see. The PCSK9's are indicated not for everybody with statins, but for those with specific genetic abnormalities—familial hypercholesterolemia, those who can't tolerate statins, and those who are suboptimal response to statins. And it's important to recognize that generic statins now cost somewhere between \$200 and \$400 a year for therapy and the PCSK9's, on the order of \$14,000 a year for therapy. And with 30 to 40 million Americans being treated for hypercholesterolemia, you can imagine what's at stake here. So we developed first a very sophisticated, evidence-based approach to help doctors identify just who was appropriate for this therapy. We educated doctors across the country and encouraged them to identify those patients that could be treated with statins alone, make sure that they were adherent to those statins, be clear about what is, in fact, statin intolerance, and be really crystal clear about who needs the PCSK9 inhibitors, at the same time there were two manufacturers that came out with medications in this class simultaneously. We negotiated with them both simultaneously. We came up with an exclusive deal with one of the manufacturers, negotiated deep discounts so at the same time, we were both reducing unnecessary costs and, at the same time, trying to make sure patients got exactly the right medication as indicated for them.

And last, this is really only half the story and I would argue the bigger half of the story is not cost but when we think about value it's about making sure that patients who start on essential medications are treated with essential medications and they follow their recommendations. Non-adherence to essential medications is essentially an epidemic in this country. Fifty percent of patients, most chronic conditions, often do not adhere to their therapy and it leads to massive morbidity, mortality, and excess costs. We, at CVS, have embarked on a really robust effort to try to develop a broad array of services to try to meet patients where they are, to understand their very personal challenges associated with medications, ranging from simplifying therapy, reminders, better engagement, better education, aligning financial incentives, using health information technology, improving access by allowing patients to purchase their medications at retail or at mail at the same price, but ultimately this is a hard nut to crack—fixing the adherence problem. And we all, everyone on this stage and everyone in this room, is perfectly aligned on this topic. We all want our patients who are started on essential medications to take them so there is a real opportunity for collaboration here.

But, this is just sort of more context to think about the efforts along that continuum, to identify who needs to take the medication, how do you make sure that medication is as affordable as possible, and, once you start, how do you make sure that patient takes the medication? Thank you.

Sarah Dash: Great. Thanks so much to all of our panelists for this discussion. So, we're now at the question and answer portion of this briefing. So, you should all have a green card in your packet. If you have a question and you'd like to write it on that, please do so. There are also mics on that aisle and that aisle if you'd like to stand and ask a question. Let me, while you're doing that, let me throw out a question for the panel. So, as several of you pointed out, patients have different preferences. People have different ways of defining value and Will, as you indicated, there are clinical differences in people. Some people might really benefit from a PCSK9, maybe based on their genetics or other factors, others might not, and there's, of course, a lot of excitement about personalized medicine, or precision medicine, so just to go a little futuristic here, as we're talking about these value frameworks, how do we account for this enormous variability while still coming up with some kind of a framework that can be used in a more standardized way? So, I'll let you all decide who wants to take the first stab at that.

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Robert DuBois: I can take a first whack at it. I think there's two pieces to separate out. The ability to do personalized medicine, based upon characteristics of a patient, age characteristics, severity of disease, diagnostic testing, gene profiles, some patients will benefit more than others, and therefore, the value proposition might look quite different. That is an easily solvable problem. The frameworks can take that into account, okay? And Steve has done that when he looked at the patients that have cholesterol problems and there were categories that were familial-related that have more intensity and then others. So, that part doesn't worry me. The one that does worry me is that how do you sort of maintain a flexibility that patients are different, and what's important to patients differs. That piece I think is a more challenging one. Peter Bach of Memorial Sloan Kettering has a value framework that has little slider bars on it, and if you think having something for a rare disease is very important, you'd slide that up, and it reweighs everything. If you think it's not so important, you slide it back down. If you think the cost of bringing that drug through development was very important, you would slide that bar up or down. That's a very appealing approach to enable us to have some flexibility in how we think about it. So, clinically different than when we think about personal preferences and values.

Sarah Dash: Steve.

Steven Pearson: So this is a great question because it drives, again, to one of the core balancing acts or tensions, I guess. In any kind of insurance system, decisions are made, you know, on a policy basis for the care of populations, for broad memberships and yet, doctors and patients are one by one and they have to make decisions that are tailored in the best interest of the individual patient and that is tricky. On the other hand, insurance is a pooled group effort. We're not saying that someone can't have something; it's just that they can't use our group resources to pay for it, and you're quite familiar that insurance companies, for instance, currently don't pay for preferences like I want to have this treatment in Miami. I just want to travel down there and spend time there so you should pay for it. Or I want to have, you know, there are certain preferences that we would all say, yeah, that's not significant enough for insurance to pay for. That should be out of your own pocket if you want to. So, to try to build this in, though, I think it is possible to have transparently-looked-at-evidence that is sensitive to the distinctions among patients, but that can still be used to build insurance coverage policies and pricing that is better than the system that we have today. And, I will say that, in general, one strategy to combat any kind of value framework would be what I call diffusion. Diffusion will say we can't have one: we need multiple for all different regions, for all different purposes. And through diffusion, we end up with usually kind of nothing that gets real traction or use, if you will.

There are some value frameworks that are really tailored for individual patients and doctors. They're almost like shared decision making tools, and those are great. We're not talking about that. We're really talking more about the kind of broader population level policies around coverage and pricing that are very different. So, I think it's important not to let the diffusion argument, I think, obscure the fact that there is real progress to be made and we need to make it.

Sarah Dash: Okay. We have a few questions at the mic, so we'll start with you and then we'll go to you.

Kamit Burt [Phonetic]: Yes, My name is Kamit Burt. I'm with the *Pakistani Spectator* and my question is to Mr. William Shank. If you look, the marginal cost and marginal revenue curve of American pharmaceutical company, they're made pretty high, especially compared to what it costs in India or Pakistan. But let's say that those are third world countries and quality is not that good, but even compared to European intersection of these curves, American pharmaceutical curves are high. Now, I wish that you had a European gentleman from the same industry here on the stage. Normally they do

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propaganda: it's just greed from American pharmaceutical companies that keep, you know, these curve intersection high. And I don't want to bring the kind of quality factor, especially in India and Pakistan, a lot of people die because of these fake drugs. But there is a company like Abbott, very well-known companies, drugs they produce could be barred in India and Pakistan, both like maximum 10% of the cost what we buy drugs in the States. So, is that because consumers are willing to pay higher price in this country? That is the reason that drugs are very costly compared to those third world countries? Thanks.

Sarah Dash: So, that's a big question. I think we heard on the panel, you know, we heard from Leigh how drug prices are out of control and high and rising. We saw some numbers from Will, from CVS Health, some numbers, and then we heard from Bobby about, you know, some new data from IMS Health showing that maybe it isn't that bad. You know, I just – I think that's – it is definitely a really big question. I wonder if any of the panelists want to try to take a stab at that? No? Why don't we take your question and then see where we are.

Mike Miller: Thanks, Sarah. Mike Miller. I'm a physician. I've been doing health policy now for I think it's 27-28 years, mostly here in Washington and a lot of that's been around pharmaceutical innovation and access and I've got to confess, I'm a little confused. The title is about value-based pricing for prescription drugs but a lot of the content that was presented was about prices are high. Prices are too high. Prices are rising. Linn's comment about the Medicare drug model has been presented. The controversy around that is not around phase 2, which is value-based pricing, the controversy is around phase 1, the initial phase, which is around just jiggering on what prices are. That's not value-based pricing or addressing value-based anything. I think Patrick knows that.

My question is: the real controversy and challenge around value-based pricing for prescription drugs is there's a lot of times it's not unique to prescription drugs but there's a mismatch between who pays and who gets the value, or the value to whom—the value to patients? The value to the prescriber of the health system? The value to the payer? The value to society or government? There's a big challenge of that because of churning in and out of Medicaid or aging into Medicare or churning between insurance coverage. So, could people talk, on the panel, a little bit about how to think about—and Bobby's done a little bit, Steve's done a bit on this—how to think about how to approach value for those different stakeholder groups and build that into a reimbursement model. Thank you.

Robert DuBois: Yes, we've done research on this and we'll be going public pretty quickly about it. So, Harvoni, Sovaldi, the Hep C therapies brought to the fore this issue of their high expense up front and then you cure a disease and you save transplants and bad things from happening. And we asked the question: is that a unique example or are there lots of other diseases that are going to fit that same mold, because obviously, if United Healthcare pays to cure the Hep C, then Medicare saves the money. So we looked at a whole series of other prototypical diseases. One of the most interesting is a gene therapy for a kid, might be a million dollars. One insurance company is going to pay the bill—somebody's going to save a lot of money over time. What if you have a great treatment for Alzheimer's disease? Medicare Part D might pay for it, Medicaid, which currently pays for the nursing homes, would save the money. So there is a wedge between who pays and who receives. It's a very important issue. How do you solve it? There've been a number of proposals out there—I don't mean legislative. One is the concept that you don't pay the full amount up front for the million dollar gene therapy, you pay a certain amount a year, like a mortgage. That's one concept. Another is the concept of a bit coin, that as patients go from health plan to health plan, the new health plan would be responsible for paying for some of that cost so that the initial health plan didn't have to pay all the money. So there is work that's being done. Will's group has done some, we are expanding this, and there are some very interesting and

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intriguing solutions, but you're absolutely correct that, as we get into curative therapies, the price tag and the mismatch is going to be a huge issue we have to begin to address. But there are solutions that we can consider.

William Shrank: So, I'd like just to add on and agree entirely with what Bobby just said. You know, there's not a single model here. There's not going to be one simple, single way that we're going to create value-based pricing for medications and everyone's going to be perfectly satisfied. But we all do realize that these silos of medication and healthcare costs that are unrelated are – that's an unsustainable and fragmented way to think about health. And we have to think about drug costs in the context of the value that they bring to patients and there are going to be a host of approaches that we're going to try. We, at CVS, are testing a handful of things, or at least exploring a handful of things, as are many of our competitors and many of our colleagues. And we don't know yet what's going to work, and probably there's not going to be one model that jumps out. There're probably multiple models. But that's one of the things that are interesting about the Part B model that just came out. And the more we actually get out there and test new ways to align incentives for providers, for patients, measure outcomes better, really have a cleaner sense of what it is we're trying to accomplish, I am confident that these models are going to start coming into more focus.

Sarah Dash: So, can I just jump in with a question from a green card that I think follows on what you were just saying Will, and then I think Leigh had something to add and then we'll get to the folks at the mics again. But can you comment on the potential application of reference pricing? This is a question from the card, but more broadly, I think that to connect the dots a little, we've talked about how hard it is to come up with a value framework or an equation that everybody kind of agrees on and probably we'll never really agree on, but then there's the value-based payment piece of it, which is the Part B piece of it, which is the value-based insurance design that a lot of people are excited about. So, can you maybe comment on reference pricing and then, perhaps, if you'd like to comment more broadly on the application of some of these frameworks in terms of actual payment?

William Shrank: Well, on reference pricing, that's rather a simple approach, just to say that there's going to be a reference price within a class and we're not going to pay more. If Lisinopril is a highly effective generic ACE inhibitor, there's no reason to pay more for other ACE inhibitors, and if you choose to it comes out of the patient's pocket. But the value-based models that we're talking about sort of try to do something different. It's less around just focusing on reducing unnecessary costs. These value models are really trying to think across multiple domains. What do we avert by using a medication? Can we measure improvements in health outcomes and quality of life that are directly resulted from these medications? And, if certain medications deliver better results on those domains, then we think about them differently. So it's not just about cost. And I think, you know, the reference based pricing is much more of a simple blunt way of reducing unnecessary cost.

The future here, I think, the reason this room is crowded today, is that there's extraordinary potential in value-based models for prescription drugs. The newer, better medications, these newer or specialty medications, biologics, that are much more personalized, have the opportunity to meaningfully change the lives of patients, and the more we try to really understand how to measure value in them and how we want to pay for it and how we want to align incentives, how do we want to eliminate perverse incentives for doctors to prescribe things that are expensive just because they're expensive, but try to make sure that the alignment is really around the health outcomes of the patient—that's where we need to get to.

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Sarah Dash: Thanks. And Leigh, I think you had a comment, and if you could also comment, and this is also from a green card, about what about the value of these medications? I mean, at some point, isn't it wonderful that these diseases are being treated and, in some cases, cured? Thanks.

Leigh Purvis: First, I'd like to go back to the Part B proposal. Yes, phase 1 is more about reimbursement. But the reality is that CMS and MedPack and others have said that right now reimbursement for Part B drugs does not really provide any incentive for providers to take a look at the value of the drug to make sure they're using the lowest cost clinically effective product. And their stated intent is to try to incentivize the use of high value drugs, so while it is not as clear cut and as explicit as phase 2, there is a stated intent to move towards value there.

As far as value, in terms of innovation, again, AARP members use a lot of prescription drugs. They bring us a tremendous amount of value. They allow us to stay healthy, but we have a very strong interest, also, in maintaining that innovation but the problem is that right now that innovation is becoming unattainable for the people who need it, and that is the kind of tipping point that we are trying to avoid, quite frankly. We want to find a way to make sure that everyone has access to the drugs that they need, but we also want to make sure the drug manufacturers can innovate, and we have absolutely no interest in inhibiting innovation in any way. But, at the same time, we do have to be mindful that that innovation is utterly useless if people can't use it.

As far as how AARP views value, whether we have defined it, I think this is more of a, we'll know it when we see it. We have some very strict guidelines and ideas and policy about what needs to be in place as you're trying to define value, but again, we have a very diverse population. We want to make sure that everyone's opinions are included, but we are not going to come out and define it ourselves.

Sarah Dash: Yes, Steve.

Steven Pearson: So, just a brief word about reference pricing. The key, I think, in terms of thinking about the CMS Part B demonstration is to think that this is an opportunity for everybody to think really hard about where the opportunities lie to try different types of approaches to value-based pricing. And reference pricing is just one approach. Many health plans today don't reference price and, remember, here's the landscape where we're starting from. Let's say there's a drug that's being used for a problem in oncology. A new drug is developed that is no better, but remember, the FDA doesn't pay attention; that's not their job. They say it's better than nothing and so it is also available. It's no better. Now, I know that takes some analysis of the evidence and some discussion with patients with doctors. It's no better. The company in our country gets to name its price to Medicare without negotiation. Doctors will get paid more if they use the more expensive drug. What do you think happens? Equally effective, doctors get paid more for using a more expensive drug. It's not conscious but it happens and it's been shown to influence prescriber behavior.

So, these efforts to try experiments to deal with – to try to create a different approach, reference pricing is one. It may or may not work. In all areas it certainly wouldn't work. It's got to be targeted but there might be some places where, for instance, instead of step therapy where you would require a patient to try a less expensive drug and fail it first before getting another one, what if you reference priced both drugs to the same amount and let doctors and patients pick between the two? There might be some areas where that would make more sense, clinically and economically. So, that's why this is a really exciting time because CMS is open to comments on where, if to use these different tools—value-based pricing, reference pricing, etcetera. So, none of them are going to serve as a perfect solution for all

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different drugs, as Will said. There's going to be a lot of experimentation but I think it's time, as Leigh has pointed out, it's time to give some things a try.

Sarah Dash: Thank you. You've been very patient and then we'll go to you, sir.

Rala Banerjee [Phonetic]: Hi, thank you for your presentations today. My name is Raka Banerjee [Phonetic] and I'm from Held & Simpson Partners. And so, my question kind of touches upon our discussion from the last question. I know we've talked about the Medicare Part B model, and I was just wondering if you all had any ideas about possible frameworks we could use for Medicare Part D and I know the relationships between the pharmacies and Medicare is a lot more complicated through the Part D program, but I was wondering if you had any thoughts or possible directions for where that part of Medicare could move towards for value-based pricing. Thank you.

William Shrank: Well there is an existing CMMI model that's out in the field. It's called an MTM model: Medication, Therapy, Management model. And is the first to give Part D plans accountability for total medical expense. The idea is that Part D plans can get a prospective payment to support MTM activities to improve adherence and safe medication use with the goal of reducing total healthcare costs. And if they do so successfully and they reduce 2% or more of total healthcare costs, they share in the savings after netting out those prospective payments. They share in the savings in an interesting way. They don't get the money. That money comes back as premium support for their subsequent year, so the goal is to enhance enrollment in the highest quality plans.

So, this is a test that's underway in Part D, specifically to address this. I can say one thing we do at CVS Health, Silver Script is our Part D plan. It's now the largest Part D plan, and we work with ACO's and create a shared savings model with the ACO's on drug costs. So if we can work together and the ACO reduces unnecessary drug costs we share the savings with them because it increases our earnings. It's not something we've been able to expand greatly. It's something we're doing with four or five ACO's today. But there is great interest in figuring out how to create more accountability in Part D. The Part D plans have a great deal of levers and tools that they can use to promote not only lower cost medication use but also better health outcomes, better adherence, safer medication use, better transitions of care, and this is something that is of great interest to all Part D plans.

Speaker: Thank you for your presentation today. My question is actually sort of similar to hers. I was just wondering if any of you see any way that these value-based pricing frameworks that you're developing can be incorporated into proposals to give Medicare the ability to negotiate prices for Medicare Part D. Dr. Pearson, in particular, you mentioned this earlier. I was wondering if there's any way that you see, for example, your value-based pricing threshold, could that be some sort of negotiating target for Medicare Part D? I was just wondering if the panelists could expand on that. Thank you.

Steven Pearson: Yes, Medicare negotiation, always a chestnut. I think it has been usefully pointed out – one thing I think that most people would agree, even those who are vigorous advocates of Medicare negotiation, is that by itself it doesn't answer the question to what? To what end? Can Medicare walk away and say no, we're not going to cover at all this new drug if you don't price it within some range, or what? So, in my mind, that leads us to at least having some idea of where a value-based range would exist because without negotiation, again, it's not really clear what that means. Is a 25% discount a good one, a bad one? You just don't know. So, I am obviously dedicated to trying to work to learn how best to frame this information so that people can think about it transparently. But then you either have a system like virtually all other developed countries where the government does get involved and can

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walk away. Canada has done it recently, England does it routinely, Australia—where they can, on occasion, basically say we're not coming to an agreement here at a price that makes sense for us and so we're not going to cover you. Or, you try to use carrots and sticks and thereby create a business case so that for manufacturers, there is both a short and a long term benefit to price in alignment with value. To me, that's the potential win-win. So it's not like it's quite clear how that would work, but to talk about Medicare negotiation without understanding what the end game is I think is something that we still need a lot of policy development around.

Sarah Dash: Thanks. And, can I follow up on that question, Steve, by asking you a green card question here, which is that in your presentation you had mentioned new or increased use of market incentives as a policy prescription, and the questioner asks if you, in particular, could expand on that and then, Bobby, you had also mentioned competition, or was it Will? I think both of you mentioned competition as something important. So maybe we can spend a couple minutes talking about the market and market incentives.

Steven Pearson: Sure. Although every time you say it's a green card question I think is this an immigration meeting here? [Laughter.] We're not going to talk about that, right?

So this is where I actually think the government can learn both maybe from experiments at the states or certainly in the private market. I think that there are private health insurers and PBM's that are, like CVS, becoming very interested in innovation and experiment. Indication-specific pricing is something that they and express scripts and now others are starting to think about. That's, again, where you try to price differently for the same drug if it's used in different situations with very different effectiveness. Maybe there's a way to say we should be paying more for it when it's used and we get a lot of great benefits, and not so much in this other situation. How you actually do that is actually tricky, but it's something that's being talked about.

So when I think of market, again, I can't bring up my slide probably that quickly, but it gets back to the idea of carrots and sticks. And it might require a purchaser, let's say, to work with a health plan and say in the benefit design for my employees, that this health plan is going to administer, we will decide that in one area we will try it that if the price that we can negotiate comes into a value-based price benchmark, good things will happen. And I actually do know one case, now—Harvard Pilgrim Healthcare in Boston, on this drug, the next one – after this bouncing clock – that one down there – it had an initial kind of short term policy around Entresto, and following our report in meeting, they had an internal meeting in which they decided to loosen restrictions to this drug, saying that based on our report and their judgment of it, they felt that the drug did represent reasonable value and so they would now allow primary care doctors to prescribe it in addition to cardiologists. They would do some other things to relax the utilization management.

That's an example of a carrot. Now, if carrots are very sporadically used by very few payers, and I'm a manufacturer, it's not enough to get me to change the way I think about pricing. So there's going to be this kind of phase where there's going to be experimentation but will it have enough gravity, if you will, to attract enough payers and manufacturers to the table to work on different approaches to payment and to coverage? I think that's a real question. But there are ways to do it, to create carrots and sticks and even to apply the ones that we've got now that I think could be use to move us forward in this area. And we'd learn a lot from the experience.

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Sarah Dash: Great. Thanks. And John, before you ask your question, let me just remind the audience that you have a blue evaluation form in your packet and if you could just be mindful, before you leave, to please fill it out, and don't leave until it's over. Thank you.

John Rother: John Rother with the National Coalition on Healthcare. Will's data, I thought, was pretty illustrative in showing that the major driver in cost is the year to year cost increases, not so much the high initial prices yet most of the discussion about value focuses on setting the correct initial price. So, what can we say about the value equation as it applies to year to year price increases? Do other countries permit this and, under any kind of a value-based approach, would we permit or want some year to year inflation?

Robert DuBois: Let me come back to the slide that I shared. When you look at year to year increases it's very important, obviously, to look at net price and not list price. But there are three components to a growth. One is more people are being treated. Okay, now, would we say that's bad? Do we want to stop that? Probably not. Another is the actual price increases for that same drug, year over year, and yes, list prices have gone up a lot but the discounts have gone up even faster. And then the third piece of the puzzle, is the market basket. So we are moving from, perhaps, less effective therapies to more effective therapies and those more effective, newer agents may be more expensive than the generic agent.

So, I think it's very important to disentangle those three, and I'm not sure, in Will's data, because Will's data and our data were a bit different, or not our data, but what I cited for IMS, whether they separated out market basket changes versus year over year price increases for individual drugs, because the policy solutions are really, really different. If it's year over year increases in prices of individual drugs you might approach it in one way. If it's a mix, meaning we're moving to a higher, more expensive market basket for the same patient, then the types of things that Steve is doing might make very good sense.

John Rother: Can I give you just one example? Pfizer, early on this year, increased prices across the board for almost all of its products between 5% and 20%.

Robert DuBois: That's the list price. You then have to talk to Will and say what are the rebates and the discounts and the IMS data, look at the IMS data, please. It's the first group to actually net out the rebates and the discounts. So I think it's a very important piece of that puzzle, which often gets overlooked.

Sarah Dash: I think we'll have to have another briefing just on rebates and discounts and kind of the system we're starting from and maybe we can come back to that a little bit after these next couple of questions.

Steven Pearson: Can I just say one thing, though, in response to that, too? Again, thinking of the landscape as it's been created up till now, there's a reason that we had a Valeant and a Turing. The reason is because these smart people saw a business opportunity through the regulatory system that we've established whereby if you can manipulate your way through, or buy your way through, to own a drug without much competition you can charge whatever you want to in the United States. That has been the case, and smart people figured it out and took advantage and now, if you ask a lot of people what was the problem, remember even Turing – or not Turing, Shkreli, he said, the first thing he said was my main mistake was I didn't charge more for it. Ha-ha, right? But his point was, he could've done anything and now, from his perspective, probably and many "unfortunately" they've drawn a lot of attention, so it's going to be harder for that to happen. But the regulatory landscape still exists for that

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to be the case. So, in other countries, it's more regulated. Again, people hate that term but if you want to raise the prices on electricity by 50% or 100% you can't just do it. Health insurance plans, they can't do it. They have to go to a board and explain their reasoning.

So, I don't know what the right silver bullet is here. There's almost clearly not one but the basic regulatory backdrop through which we created the Valeant and Turing examples still exists today.

Sarah Dash: Thanks. You had a question.

Tiffany McCaslin: Thank you. I'm Tiffany McCaslin and I'm a policy analyst with the National Business Group on Health and my question is following up on the indications based payment models that were discussed previously, but I wanted to ask Dr. Shrank if he would maybe just chime in. One of the things that employers have heard with regard to this particular policy is that it would be very difficult to adjudicate from the claims standpoint, and I wondered if you could share any insight on that, and whether or not you guys have thought through any potential solutions to bringing that payment model to light.

William Shrank: You're right. In a typical small molecule, when claims are paid for typical small molecules we have very little clinical information, and that clinical information is essential to be able to make these sort of decisions about indication-specific prescribing. However, through our specialty business, it's a much different level of contact between our clinical team and the patient. So the clinical team gets to know that patient really well. They collect a great deal of information about their health, their social determinants of health, and specific aspects of their disease that allow us to be able to be much more precise about making these decisions and establishing appropriate eligibility criteria.

So, I think because we're talking about oncology meds and we're talking about the specialty part of our business, it does give us a lot more freedom, a lot more data, a lot more clinical data that we can work with try to really make sure we're getting it right.

Sarah Dash: Okay, go ahead.

Aimee Grace: Hi. Good afternoon and thank you all so much for your presentations. I'm Aimee from the Office of Senator Brian Schatz. My question is for Dr. Pearson. You mentioned that the patient is at the center when you're determining the ICER framework, and I'm just wondering if you could describe the extent to which the patient voice is incorporated into determining the pricing? So, for example, patients may have preferences to be treated in Miami that we may not need to consider as much, but, in terms of frequency of dosing, for example, that would allow a patient to go to church or the tolerability of certain side effects, those would be important things to take into account. I'm just wondering the degree to which that occurs in your framework. Thank you.

Steven Pearson: It's a good question. And, it's not simple, so in our framework we have—and we work with patient groups from the very beginning when we tried to help identify what are the real questions that we're trying to address—we want to make sure that we understand what the outcomes are that patients find important because sometimes those aren't measured in the clinical studies that are done, so we really want to be sensitive to a lot of these issues, and hear from them about how treatment options affect their lives, the lives of their families, etcetera.

In a way, we weave that into our report and then we actually, all of our reports are debated in public by independent panels of doctors and public representatives who actually take all of this information and

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will take a vote on whether the value is high, intermediate or low. And sometimes that vote is strongly influenced by these kinds of “other” potential benefits or disadvantages sometimes that aren’t even captured by the clinical studies and so not part of the cost effectiveness model, necessarily. So that’s why the range is important. So, remember, I talked about the range that we leave in our value-based prices? Because we want people to understand that there may be good reasons to think of a range and to weave in these other factors in thinking about what a price would be. But, obviously we can’t have a price for you and you and you and you and you that differs. That’s not the way the system is going to work. So we have to try to still make some kind of broader judgment and that’s always going to require some tradeoffs. But, I guess my point was, that we try really hard to be sensitive to the voice of patients as it should be expressed in understanding what is important and how that should be taken into consideration by all the stakeholders who are going to be making decisions about the drug.

Sarah Dash: Thanks. And let me just push on that point really quick and then we’ll get to your question. I mean, you mentioned some of the clinical studies don’t really take into account the patient voice as far as the outcomes. Can you say a little bit more about that? I mean, by the time it gets to your framework, I don’t want to say it’s almost too late, but would it be more valuable if the data were incorporated earlier?

Steven Pearson: Well, yes. I mean, part of this, and PCORI has been strong in talking about this. Part of this effort is to have information about what’s important to patients go back upstream into the thinking of the FDA and companies as they make drugs so that we can try to capture that. But especially, at the end of the day, when there’s evidence. I’ll give you one example from our own work. We were looking at treatments for prostate cancer and we had patients, we said what’s really important to you about their outcomes from prostate cancer. And several of them said, well, the doc kept talking to me about what was going to happen, you know, two weeks out, four weeks out. I don’t care. I’ll put up with anything for 2, 4, 6 weeks. I’m really more concerned about two to four years. So, tell me what’s going on there. That’s what I really value the most. And, sure enough, we went to the published literature in all the journals, the best research done, 4, 6-week, you know, data. A few went out four to six years so we were able to basically say we’re going to, in a sense, over emphasize the longer term data even though there’s very little of it, because that’s really what patients care about. So it’s at least understanding, because you can get really blindsided and focus in on what the paper has in front of you and miss what’s really important to patients and families.

Leigh Purvis: Obviously, we think that kind of information is incredibly important, but as Steve keeps mentioning, it’s very difficult to take everybody into account. Personalized medicine for every single American would be complicated and, quite frankly, prohibitively expensive so we do have to find a way to kind of take all of those opinions and attitudes into account as we’re coming up with the definitions.

Sarah Dash: Thanks. Time for one more question from the mic. Thanks.

Carl Polser: Hi. Carl Polser. I’m just trying to follow up on a previous question about pricing and it just seems this existence of such large and complex discounts or rebates makes it very hard to even answer a very straightforward question. How can we make this more transparent and more like a market? For example, could you limit the range of rebates, the aggregate rebate? Have people talked about that? What would be the impact of that?

Sarah Dash: Thanks. And as you answer that question, we did have a few questions I just want to acknowledge that people wrote down about transparency of rebates and also of pricing.

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William Shrank: That's a good question. So we are entirely transparent with our clients. So whether it's government, clients, Medicare Part D, we are, by law, required to give them very discreet, entirely discreet information about discounts and rebates. And in all of our contracts with our clients that is – it's part of the contracting process to have access to full transparency on pricing. However, we believe findings from the Congressional Budget Office, the Federal Trade Commission, other government agencies that have all looked at what it would mean if we moved towards entirely transparent drug prices and it would really meaningfully limit our ability to negotiate and would lead to higher drug prices overall.

That competition that we have, and our ability to sort of not show our cards, allows us to negotiate more effectively and negotiate better prices, better deals for our clients and our members. So we believe that right now, while there are folks on the outside that don't necessarily have clarity about all of that process, the folks that we're dealing with every day, our clients do and we are doing our very best job to provide them with medications that are affordable and that meet their needs.

Leigh Purvis: Transparency is definitely a hot topic these days. We're seeing a lot of activity both at the state and the federal level. And a lot of it comes down to the fact that, speaking of someone who's been tracking prescription drug prices for over a decade, every time I release results I immediately get the well, what about the rebates and the discounts? Mind you, in that entire decade, I've not once been offered that type of information but that is usually how the push back, and I completely understand your point; that we're not going to be able to have an informed conversation without a little bit more information. Not trying to disrupt the market but at least have a little bit more information than what we do now. That said, these conversations about price and what's seen and what's not, at least from AARP's perspective, are important but they're not the most important. For us, what's most important is whether people are actually able to access and afford their drugs. So, to us, the price trends are interesting. They're certainly informative. They're certainly something we need to keep an eye on, but the reality is, a lot of what people are dealing with on a personal level is more of the co-insurance, the high co-pays, that type of information to us is also incredibly valuable.

Sarah Dash: Great. Thank you. Well, I had hoped to ask a really complicated kind of ending question to give everyone a send off but I think we're really towards the end of our time. So, with that, I'll ask our panelists if anyone wants to add any last words to the discussion. Go ahead.

Steven Pearson: Just, in all the fun that you'll have in thinking and hearing arguments about this, I was caught by Bobby's picture of the teeter-totter you know, the see-saw that showed innovation going up or down depending on kind of return on investment, I tend to think that there are different ways to think about innovation in this sense. I was actually talking to a Texas oil man the other day who was actually interested in drug policy for vague reasons. And when he understood how drugs are sold and priced in this country, he just said, wow, really? That's how it works? And we were talking about innovation and he said, I will tell you, the greatest innovation ever seen in the oil industry is when prices go down. 'Cause when prices go down people get serious about innovation. They have to innovate. He said there were unbelievable fat, happy people running around when oil was \$120 a barrel, and all seemed great and we thought we needed those profits to survive but, he said, the real innovation when we had to deal with lower prices.

So, it's not an either-or. There's a tension, but it's not fully either-or, and I think if we can get smarter about our pricing, line it up with value, link that to a different kind of innovation, a better, smarter innovation I really do think we can do right by patients as well as by the state governments and everybody else.

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Sarah Dash: Well, thank you. With that, let me ask you all to join me in thanking our panel for a great discussion.

(Applause)

Please fill out your evaluation and thanks for joining us today.

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