ALLIANCE FOR HEALTH REFORM

Prescription Drug Costs: Trends and Tradeoffs in the Pipeline from Lab to Market
Ascension Health
Alliance for Health Reform
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ED HOWARD: Those of you still looking for seats there are some right up front, as well as some around the periphery, so shouldn't have any difficulty.

I'm Ed Howard. I'm with the Alliance for Health Reform – [Applause] – oh, thank you very much Mom. We always save a seat for her.

I want to welcome you on behalf of Senator Blunt, Senator Cardin, and our Board of Directors to today's program on prescription drugs, on how they improve health in the U.S., on how we pay for them, and how much we pay for them. Now, nearly half of everybody in the country takes some prescription drug each month, so it's an issue with very broad awareness, I guess is the best way to put it. Innovative drugs have been bringing significant progress in treating costly and complicated and sometimes debilitating conditions in this country. Not surprisingly, they come with a price and for some recently introduced drugs that price seems high to many who are footing the bill. Today we're going to look at how drug prices are determined and by whom, we're going to look at the factors affecting where the price is set, and we'll look at what the future might hold in pharmaceutical costs. This is something that we really can't afford to ignore, if only because of the immutable fact of this graying tsunami of which I am a part that's hitting America, more people are going to reach the age where more health problems are inevitable and we need to be clear headed in examining how much societal good flows from the development of new and innovative drugs, at what cost, and what policy options are out there to move us toward getting the best value for every dollar spent on healthcare, not just on pharmaceuticals but all of healthcare.

We're pleased to acknowledge support for today's briefing from Ascension Health, which is the largest non-profit health system in the United States, and before I introduce the panel, I'd like to do a little bit of housekeeping if I can. Forgive me if I seem repetitious if you are a veteran of these briefings, but there are new folks coming every day. If you're in a Twitter mode there's #@drugcosts, that you can see there. If you need Wi-Fi to tweet, the credentials are not on the screen but they are on the piece of paper in front of you on your desk. Feel free to use that. There's going to be a video recording of this briefing available in a couple days, maybe as early as Monday, and there'll be a transcript a few days after that, all at our website allhealth.org. You'll also find there all of the materials that are in your packets and a bunch that are only on the materials list that's in your packet.

Two pieces of paper I want to call your attention to. One's green, one's blue. There's a green question card that you can use once we get to the Q&A portion of the program, and we can't make these forums work unless you're an active participant, and there is a blue evaluation form, which is invaluable to us in trying to make these programs more responsive to what you need to do your jobs better.

We've got an incredibly knowledgeable panel today with a range of views on the issues being discussed and I'm going to take the time to introduce them all up front so that we won't disrupt the flow of the conversation. We're going to start with Richard Evans,

who's a leader of the healthcare practice at Sector and Sovereign Research, SSR. He's a former executive in the PhRMA industry and now, perhaps, the leading analyst in the U.S. of the pharmaceutical industry. So we've asked him to give us a sense of recent drug price trends and insights into what forces shape those trends. Then we'll turn to Michael Gray, Vice President and Chief Strategy Officer at the Resource Group which is part of Anthem. He'll lay out some of the concerns that providers have about recent increases in drug prices, including their impact on patients' ability to pay. Then we'll hear from Lori Reilly who's the Vice President for Policy and Research at the Pharmaceutical Research and Manufacturers of America, PhRMA. She'll explain the factors that manufacturers consider when setting prices, including R&D costs and long term value. And then, finally, we'll hear from Len Nichols who is the Director of the George Mason University Center for Health Policy Research and Ethics, and Len is going to focus on the consumer's role in the conversation and what effect increasing costs is having on their ability to get the care they need. And if we're lucky, he'll also talk a little bit about some future policy and action items that lawmakers and stakeholders may consider.

I've interrupted this conversation long enough. Let's turn to Richard Evans.

RICHARD EVANS: Thanks, Ed. Good afternoon, everyone. I'd like to thank the Alliance for inviting me. What I'd like to do is start with two fundamental assertions before we get into the details. The first involves the behavior of prices generally, and the second is just an assertion about industry in the capital markets. So let's start with prices.

Prices are very easy to understand. They're like helium balloons. You either tie them down or you put them in an enclosed space or they do exactly what you'd expect them to do, is they float for the sky. So typically we use market forces to link prices to either quality or quantity. Really good quality gets a good price, really poor quality gets a bad price; or, where market forces don't work or where we decide not to use them, we typically use administrative power to build constraints, to basically put the balloon in a room. But I think people to view pricing as a black art in some sense, and at its most fundamental level it is exceedingly simple. Price is a helium balloon. If you don't tie it down or put it in a confined space it does what it wants to do, which is it runs free.

The second premise is that individuals in industry and individuals in the capital market have the same moral compass that anybody else does; however, the capital markets tend to function in a more or less morally agnostic manner and here's why. If I'm a senior executive in a pharmaceutical company and I'm falling behind pace of pricing gains and earnings growth for other people in my sector I'm going to lose my job, and even if I keep my job and my company is below the pace in pricing gains in the sector, I'm going to lose my company. Someone else will buy my company and accelerate drug prices at whatever rate is possible. If I'm a portfolio manager and I'm buying and selling healthcare stocks and I'm managing people's assets—your retirement savings—and I'm generating returns that are below my competitors I'm either going to lose my job or you're going to take your assets and put them somewhere else.

So, industry and the capital markets are not – the capital markets function to efficiently allocate capital to the best possible economic returns, not necessarily the best possible socioeconomic returns. So if we move this discussion into healthcare, pricing quality and pricing quantity links in healthcare are exceedingly weak where they are even present. Price caps generally do not exist in healthcare. And then, one of the common sources of discipline on prices, which is substitutes, has a weak effect in healthcare because we all want the best available technology for completely valid reasons. We all want a Ferrari instead of the Corvette when our life is at stake. So because of this, prices for new innovations grow very rapidly for a very simple reason: because they want to and because nothing is stopping them.

One of the essential part of the backdrop to understand about drug pricing is sort of where the pressure has gotten to and where it is built. The typical American takes either zero prescriptions a year or 48 so a lot of people don't face prescription drug cost, but the people that do face a lot of them. So this table is basically showing you that a fifth of U.S. drug spending goes to households whose out of pocket cost are as high as their mortgage plus utilities or their rent plus utilities. That's 50% of total drug spending. Seventy percent goes to households whose out of pocket costs are on par with their grocery bill. So people can't afford to pay more out of pocket. If you ask people to pay more out of pocket for pharmaceuticals they just won't take them.

So I've been asked to address some of the dynamics in both the brand and the generic side and I'm going to start with the brand side. We're going to break this into two parts. One is new product pricing and then the other is inflation of products that are already on the market. So what we're looking at here, in the upper right-hand corner, this column graph is, I think, 2- or 3-year increments moving from earliest on the left to latest on the right, and the categories are just different categories of drug price. The green category is prices above $300,000. So these are specialty products launched in any particular year and what you see is the products that are launched most frequently tend to have higher odds of having prices that are in excess of $300,000. This is a balloon that's floating to the sky. If I bring out Abraxane for pancreatic cancer it's a fantastic discovery. What's my pricing reference point? I get to make it up. I literally get to make it up. There's no one—Medicare/Medicaid's not going to tell me that they won't cover it. United Healthcare is not going to tell me that they won't cover it. So I'm literally in a position to name my price and so what we're seeing is, without classic price quality or price quantity constraints, or administrative power-setting limits, those prices are steadily marching on.

What you see in the table at the bottom is even this absolute progression of launch prices is largely unfettered, within the specialty market you do see some rational behavior and what you're seeing here is that life-threatening conditions, on the left of the table, are a lot more expensive than diseases of management. You're just managing symptoms on the right side of the table. And then, at the top row, you see that therapies where there's only one choice tend to be more expensive than therapies where there's competition. So there's rational behavior on a relative basis within specialty pharma, but the height of the average balloon is growing without constraint.

So this is brand price inflation on a same-basket basis. What I'm showing you here is the rate at which prices increase for drugs that are already on the market. The black line is the list price and it's a 10-year period. This is in real terms, so what I'm showing you is inflation in excess of inflation on everything else you buy. So the list prices for pharmaceuticals have grown in real terms, CPI adjusted, two times as fast over the past 10 years than the prices for everything else you buy and that's obviously incredible, incredible growth. However, it's important to scale this appropriately. Discounts, rebates—things like that—are getting larger and they're getting larger fast. The green line is the net gain over that same 10-year period. In real terms it's about 18%. That's not trivial, right? So we're asking you to pay 18% more today for the exact same thing we sold you last year for 18% less. That's not economic efficiency. That's still serious real pricing power.

What's happening now is, as of the first quarter of 2014, formulary managers, especially on the commercial side, have finally been willing to throw brands off of formulary so it used to be that, the worst case scenario for a brand manager is maybe your brand's at the back of the line and the patient has to pay a higher co-pay for it, but you just give them a coupon and you get their out-of-pocket cost to the same as all the other drugs in the category. What's now happening is formulary managers, with the blessing of GE, GM, Ford, Caterpillar, the plan sponsors, are just saying no. I'll throw that brand off of formulary, and that's created serious price competition in the market. These four categories at the top of this graph—Hep C, [Unintelligible] lung categories, and COPD—are categories where formulary managers have just said no, in many cases, to the leading brand. This is a major shift because, in some cases like COPD, you've got patients who, if they don't die from something else they will die from COPD. It's a progressive disease. The only thing you can do is manage the symptoms and you're sending somebody a letter in the mail saying, okay, look, I know you're well regulated on Advair but, you know what, I'm going to need you to switch to Symbicort tomorrow. This is a patient who has a life-threatening disease so we've kind of crossed a rubicon of willingness to intervene to get price discounts in areas where there's clearly a medical impact.

Generic inflation—switching off of brands for a minute. The graph on the left is the rate of increase in generic prices in the United States and I believe it's over a 3-year period. That line is supposed to go down. This is a commodity market. Generic prices do not go up. It's like Newton's third law. But, over the past three years, they clearly have. The graph on the right is showing you what's happening. Over the past two years, three years, wholesalers have gotten control of about 75% of generic drug purchasing in the United States. Wholesalers benefit when generic prices go up. They make a bigger margin on those products, so they're the dominant buyer of the product but they actually want the price to go higher, not lower. They especially want the price to go higher on things that are already very cheap. So think about it. If you're operating a warehouse and you're paying people to drive skids to the far corner of the warehouse to pick up a box and put it on the truck and ship it to somebody else you want the pills in that box to be more expensive, not less expensive. A hundred percent of the generic price inflation is

explained by products that had very, very low unit cost, on average about 23 cents per pill, where the median in the market is more in the 70 cent range. A hundred percent of the inflation is those products that were 23 cent pills inflating up to the 70 cent range because as a wholesaler that's what you want. You don't want very cheap stuff that's low margin for you to distribute sitting around the warehouse. This continues until those product prices are basically up to the median and that's going to take another couple of years.

And then, finally, the only thing this is showing you is that wholesaler spreads on generic products are the difference between AMP, basically what they pay the generic manufacturer, and NADAC, which is basically what the retailer pays the wholesaler. And what you see in that middle row in the first set of rows is on the products that inflated, that spread went from 19 cents to 41 cents. This is all about wholesalers doing what you'd expect. It's rational behavior in terms of optimizing their own economic gains.

ED HOWARD: Alright. Thank you very much, Richard. Now I remember why I married an economist so that I could sort of read along with your explanations. We'll turn next to Michael Gray.

MICHAEL GRAY: Thank you so much and thank you for the time this afternoon. I'm going to spend a few minutes talking about the – provide a brief overview of Ascension, of the Resource Group, and provide some perspective and some detail regarding the hyperinflation of drugs that we're experiencing, and then close with a little bit of the things that we're doing to try to stem the tide, if you will, for the hyperinflation of drugs.

Ascension is a faith-based organization that is dedicated to innovate across the continuum of care. As the largest not-for-profit health system in the country and the world's largest Catholic health system, we're focused on person-centered care across the country.

In fiscal year 2015, Ascension provided 2 billion dollars in care to those that are poor and vulnerable and for community benefit. We had about 600,000 surgical visits last year, about 25 million outpatient visits in 1,900 facilities with 131 hospitals and 30 senior care facilities, all within 24 states and here in the District of Columbia.

The Resource Group is a subsidiary of Ascension and probably best described as a change management organization, a business transformation organization that focuses on our caregivers, providing operations and logistics services within the organization, implementation services, and a contract portfolio that allows us to reduce our costs. We focus on our physicians, our caregivers, our end users so that we can provide the products that they are requesting and that are providing the attributes for the patients that we serve so that we can not only reduce unnecessary variation across the organization, but improve quality and reduce costs.

Challenges that impact care. First, there's no question that prescription drugs have made positive people's lives. There's no question about that. The challenge that we have is

being able to afford the drug so that when a physician provides a prescription to a patient that they can remain complaint that can absolutely improve their life, improve their health. In August there was a poll released from Kaiser health that said 72% of Americans thought that drug prices were unreasonable. Thirty-three percent of the low income population and 43% of the people who were in the worst health said that they were struggling just to afford those drugs. So what's actually happening in the market, knowing that information?

I'm going to spend most of my time detailing products that I would call mature products, or age-old products, not the new technologies, not the block buster drugs, certainly the prices that are coming to market, those pricing parameters that were described earlier, are topics of conversation and debates that need to take place, but I wanted to spend the time today to focus on just those drugs that are mature and have been on the market for a great deal of time; drugs that their impact on patients' health haven't changed.

So the dot point that says increasing prices for age-old brand name and generic drugs, often two or three times a year, with no forewarning or expectation of the increases from the marketplace. You say so what. And you heard the economic dynamics here. The so what is, as health systems, as health providers are building integrated, person-centered care across our organizations across the country, 28% of our supply expense becomes unpredictable month to month. That makes it very challenging to build into our communities and provide that integrated system of care, that person-centered care, that we're all looking for.

The next dot point is designating products for higher cost specialty distribution channel with no reasonable basis for such designation. Now I know I have heard pharmacy leaders say the FDA designates that and the FDA does, at times, designate what needs to be consistent follow-up for the patients, but the designation of a specialty drug is certainly within the purview or the total control of the pharmacy company. When those products go through a specialty distribution channel it makes it much more costly for the providers and there's really, when there is not a therapeutic equivalent, there's really nothing more to do but then to pay that higher price and to sustain the added burden of that work.

So this slide, for those who are in the room and those who can't see the slide, it was in the packet a bit, but I think the slide is important and let me orient you to it just a little bit and then describe just a couple of the high notes here.

On the left side is 10 or so brand-name products and on the right side are 10 or so generic products that these produces have increased significantly over the last year. Now it's important that you understand that these are those mature products, those age-old products, if you will. I've constrained this model for that so that these are drugs that have not changed in any way, nor have they changed in their impact to the patient. So let's talk just about a couple of these, not very many. But we look at Miacalcin. Miacalcin has been providing the same value for patients for the last 29 years. This year we took a

3,033% price increase on that drug. Asaprol has been providing the exact same value for patients for 40 years. This year the price increased 725%. Nitropress, over 37 years, 317%. Oncaspar, 10 years, 125%. And I missed Mephyton. That particular pharmaceutical has been around providing the same level of care to patients for the last 60 years and the price went up 150%.

Now, if you look at the right side, those are the generic drugs. Those generic drugs have increased in price this last year, the ones that are on this slide, anywhere from 56% to 1700%. Now, the point in sharing that is because there's often conversation that all we need to do is wait until a drug goes generic and everything will be okay. I'm not certain that the trends show that to be true.

Let me orient you to this slide just a bit of the recent hyperinflation of the mature drugs in Ascension. Again, this is the real impact of the organization from August of 2014 to July of 2015. I've constrained this, as I mentioned earlier, to the drugs that were purchased in 2015 through the same methods as we purchased them in 2014, the exact same drugs, the exact same manufacturers, the exact same dosage that provide the same exact experience for the patient. In other words, I took out the new drugs. I took out even the mature drugs that had changed formulation. What you see here is that we had a little bit of a dip in the beginning, the first few months, and there were two pharmaceuticals that there were significant price changes in those two months and, certainly, I could have changed the time parameters but I wanted this chart to show exactly what our experience was this past year.

The inflation of these age-old products, constrained in the way I mentioned, increased our costs, our expense—real green dollars—84.5 million dollars and, projected at the same rate for next fiscal year, is over 100 million dollars. So what are we doing about it? We've developed really three different paths here just recently, actually in the last couple years here, we created a joint physician-pharmacist-nursing administrative leader group to determine evidence-based safe and cost-effective alternatives. We've developed and we are developing a national formulary to reduce the unnecessary variation across the organization, which focuses on patient and clinician needs, not drug supplier marketing efforts. And we've lost a national initiative that will further increase time for clinical, safe therapeutic exchange of drugs, all focused on the safe and effective care of our patients.

I hope that this has provided a bit of a background and a bit of detail that shows what this hyperinflation is about. Certainly it's impactful to an organization the size and scale of Ascension, but if you think about what we have available to us you know it's impactful to healthcare providers across the country and to their patients. Thank you.

ED HOWARD: Before we go on, can I just ask a clarifying question and it's probably a really ill-informed one. Flowing from the list of brand drugs and generics that you've referred to, in the case of the brand name drugs that have been around for 50 or 60 years, presumably there are generic substitutes for them?

MICHAEL GRAY: No, not necessarily.

ED HOWARD: No? Okay. That does clarify why some of those numbers might go up and I hope we can come back to that question. We'll turn now to Lori Reilly from PhRMA.

LORI REILLY: Thank you, Ed, and thank you to the Alliance for having me here today. I want to spend some time in a minute to talk about cost but before we get into a discussion about cost I think it's important to start this conversation also with a discussion about what new medicines have brought to patients. Just over the last 15 years there's been more than 500 new medicines that have made it to market and these medicines have had dramatic impact on patients all across this country and, quite honestly, all across the world. We know, in the last 100 years, medicines have been a key reason why life expectancy went from about 47 years of age to today 78 years of age. The 5-year cancer survival rate is up 39% across all types of cancers and in many cancers those numbers are much higher. We've seen, just since the mid-1990's, death rates in the United States from HIV-AIDS declined 86% as a result of new medicines, and cancer, which peaked in 1991, death rates have declined over 20%. And, just last year, we have new therapies now on the market that are curing a disease that kills 5 times as many people as HIV-AIDS in this country, the leading cause of liver transplants, the reason why liver cancer is on the rise, we now have new medicines that in 90-plus percent of the cases can cure patients in 10 to 12 weeks.

Looking forward, over the next decade and beyond, we have about 5,000 new medicines in development. About 70% of those have the potential to be first in class medicines, meaning there aren't necessarily treatments on the market similar to those today. We're learning more about the science and many really believe, in cancer and many other conditions, we are on the cusp of a revolution in treating many of these conditions like cancer. But the reality is, while there may be 5,000 new medicines in the pipeline the story of drug development, which often people don't recognize, is it's a story of failure. We unfortunately fail far more than we succeed. About 90% of medicines that enter clinical trials at the FDA never get approved. We've looked at many conditions just over the past 15 years. How many times have companies attempted to get a new medicine to market to treat Alzheimer's? Over 123 attempts. Four times have they been successful. In melanoma, 96 attempts, 7 have been successful. And in lung cancer, 167, 10 success stories. And those numbers are not the anomalies. That's the reality of drug development. For some conditions those numbers look a lot worse than that.

I apologize, this slide may be difficult to read, but essentially when you look at we, as a country, are spending on drugs, the national health expenditure data that CMS collects illustrates that about 10% of the healthcare dollar is spent on retail medicines. Now when you think about the fact that not all medicines are delivered in a retail setting, some are delivered in-hospital, inpatient, Altarum Institute looked at if you add in the percent of medicines that are used, not just at the retail level but inpatient as well, what's that percentage? It's about 13% to 14% and that number has been consistent, if you go back

to 2008, quite honestly, if you go back to 1960 it's the same percentage. And also, projecting forward, into 2024, the latest data, it still illustrates the same percentage across the board that we're going to be spending on medicines and that's with all of the new medicines that we hear and talk so much about.

Now, there's no doubt, last year we had an increase in drug cost spending and there's lots of reasons for that. One, we had the lowest number of patent expirees that we've had in a very long time. We also had a record number of new drug approvals—42 new medicines were approved last year. There were 16 million patients that, as a result of either the Affordable Care Act, Exchange Expansion, or Medicaid, that now have access to insurance so there's lots of reasons why those numbers increased last year. But, if you listen to what CMS, IMS, and others have said, that is not the new normal. Those numbers are projected to go down going forward. And there's a couple of reasons for that. One of them has to do with patent expiration. We've heard a lot in the past where people say, oh, the years of patents – drugs going off patent – those years are long gone. But the reality is, if you look at the last 5 years over 100 billion dollars of medicines went off patent. If you look forward over the next five years, it's also over 100 million dollars worth of medicines are expected to go off patent – billion. Excuse me. Thank you, Ed. Going off patent. And that doesn't include the entry of biosimilars. And we know that now that we have a biosimilar pathway—we have one biosimilar that's been approved by the FDA, many more that we can anticipate being approved going forward—those numbers are likely to increase even more.

One of the things, and obviously Michael talked about medicines that, over time, have gone up, but I would say the difference between the pharmaceutical industry and virtually every other industry is that prices generally do go down over time. This is an example of just five medicines, five very common well known medicines that many of you have probably heard about, illustrating what their price was back in 2010 when they were still on patent and a brand medicine and what happened once those medicines went off patent. And, as you can see, there's a dramatic decline. And this is very illustrative of the pharmaceutical life cycle. Medicines tend to be on the market on average 12 years before they get generic competition. They're on the market less than 2 years on average before they have competition from another brand and, in many instances, it's not 2 years, it's often significantly less than that. And when that happens we see a lot of what Richard talked about where payers have significant leverage to exclude medicines from formulary and hold cost down.

Part of the reason why the numbers that CMS and IMS have shown going forward and why costs are projected to stay relatively the same, is the role that the pharmacy benefit managers play in our healthcare system today. Today about the top 5 pharmacy benefit managers are negotiating on behalf of over 80% of all prescriptions in the United States. There's actually a merger that's pending, and when that merger goes through it'll likely be the top 4 PBMs that buy for over 80% of all prescriptions in the U.S. One of those, Express Scripts, buys on behalf of 90 million Americans. They exert significant leverage in the market because when they negotiate with a pharmaceutical company and they have

the power of 90 million lives behind them, they are able to tell a company, unless you're giving me the price I want I will exclude you from the formulary. Years ago, it used to be the case that PBMs covered every medicine. Express Scripts has been very vocal that they're not doing that anymore. Today they don't cover over 80 medicines that are approved in the market and that's significant leverage that they have.

I wanted to just have a case study up here because we obviously heard a lot about Hepatitis C over the last year and a half. Arguably, I'm not sure there's a medicine that many people have talked more about than the introduction of Sovaldi. And it's illustrative to look at what many folks said—Express Scripts, AHIP, and others—about the introduction of these new medicines and the effect they were going to have on the healthcare system. It was described as a tsunami. These were going to break the banks. In many states, like California, we heard we're going to have to choose between educating children and paying for these new medicines. What's actually happened has been something different and the slides on the other side of the column illustrate what folks are saying now. The price is sufficiently low that we can treat every patient with Hepatitis C.

Hardnosed bargaining and competitive market forces have been tremendously effective in addressing this issue. We're receiving market leading rates. So that's what happened, and just to take a pause also to talk about what's happened in Medicaid because obviously this was a big issue for Medicaid. A lot of patients who have Hepatitis C happen to be Medicaid patients. In the state of California, as I mentioned before, the Medicaid department in California spent .08% of their budget on Hepatitis C medicines last year. Point zero 8 percent. So, not that that is trivial, it's a big budget in the state of California, but it certainly wasn't the tsunami that many professed that it would be, in part, as a result of the hardnosed bargaining and market negotiations that happened.

Picking up a little bit on a point that Richard made, and this is data from IMS Health, not from SSR Health, but it illustrates a very similar point. A lot of the headlines and the information that we see today has to do with a list price. I think, in the case of many of the Hepatitis C medicines, there were lots of headlines with an $84,000 medicine, but the reality is, in the case of those medicines, the discounts are anywhere from 40% to 65% off of that list price. So it's not really fair to say that price costs $84,000 because people aren't paying that for that medicine. They're paying a significantly discounted rate. And what this chart illustrates is that projected price spending growth last year seemed to be about 13%. That's what we were spending, the cost growth, in drugs last year. But when you factor in the discounts and rebates that were given, the growth rate was about 5.5%. So again, not that 5.5% is not something that bears discussion—absolutely it does, but it wasn't the 13.5% that we heard so much about.

Just quickly to close, there is obviously rapid change going on in the healthcare system today. There are tools that are being used very aggressively by payers to help control costs and to drive value. We've got clinical pathways where payers today are incentivizing physicians $350 a month to keep patients that have different types of cancer on pathway. So they develop an evidence-based pathway and if a physician keeps a

patient on pathway they get $350 per patient per month. I mentioned the aggressive negotiation that's going on. We've got providers now that are at risk for drug costs and other costs. They have every incentive to use the least expensive drug they can because they're financially at risk. We have bundled payment. We've got Express Scripts who, today says, I think, about 80% of their medicines they have inflation caps on. So if a company wants to raise the price of their medicine after introduction they pay a penalty back to Express Scripts for that. We've got Accountable Care Organizations where, again, we've got providers that are at risk with a goal of holding down costs. And all of these factors are at play and all of these factors are, in part, part of the reason that IMS and CMS and others have noted that drug cost growth going forward is going to be in line with other forms of healthcare.

But medicines, again, we can be part of that solution. More can be done together. We're happy that the Alliance had this forum today because I think there is a lot that can be done when people talk together. We're supportive of paying for value. We're in a new era in terms of healthcare spending where there's heavy emphasis placed on paying for value but if we're going to pay for value then we should have a discussion not just about the cost of the medicines but the value they're bringing to patients, including reducing disease burden, keeping people out of the hospital and, in some instances, curing disease.

So, thank you very much, and look forward to the questions.

ED HOWARD: Great. Thank you, Lori, and turn to Dr. Nichols.

LEN NICHOLS: Well, thank you, Ed. You know, the advantage of going last is basically you get to agree with everything that's been said and I can just go home now. It's pretty impressive what I just heard. I mean, I think fundamentally, what this illustrates is how complex this issue is. I've managed to live 61 years and, for most of them, I avoided drug pricing and the Chinese language. I'm a pretty happy guy. It was a pretty nice life. And I would say, Sovaldi made me think I had to pay attention. Something's wrong. When something costs that much that long I take Lori's point. Now prices are coming down but in the first year of launch they did not, and the Medicaid programs were charged retail and a lot of them couldn't pay it and it was a very tough reality. And the main thing is it showed us that there's something broken and fundamentally, all I want to say is that I think we do have to take a step back and admit we're a little bit out of balance here. And I liken it, this is what you can do in simple PowerPoint here.

On the left-hand side there is stuff that's producing innovation. We want innovation. We need innovation. I take a pill now that costs $4.00 a year or something. It's really cheap and it keeps me pain free otherwise my head would hurt all the time and it's a wonderful thing, thank you very much. It was invented a long time ago. I'm in favor of it. We need innovation. But we also need competition. In our particular balance we have tried to strike in this country is to balance those two and to have things that encourage both. And what I'm simply trying to say is, if you add up the patent protection, the exclusivity

protection which makes it make the data private so that it's harder for a competitor to come online, and the pricing freedom that Richard talked about—I love that balloon analogy. I'm going to borrow that the rest of my life—what you end up with is a hell of a lot of incentive to innovate. And Lori just told you they're doing good stuff. On the other side is the stuff that produces competition and, I would submit, let's look hard at Hatch-Waxman. First of all, it's a very important bill. It's bi-partisan—hey, what a concept, y'all can do this again, I wish you good luck. It can happen.

Hatch-Waxman did what? It added exclusivity to small molecule manufacturers, gave them 5 extra years in exchange for having a very clear and effective pathway for generics to get to market so they could use the data that the brand company had revealed and, thereby, shorten the pathway. And so, today, roughly 85% of generics – I mean, 85% of small molecules are generic. That's what I call working. Ed's question—I would've asked the same question, Ed; glad you had to before I did—not everything is generic, but still that's pretty darn good. So that's working. On the biologic side, however, we have not been, in my opinion, quite so wise. Now it is unambiguously true. Takes longer to grow biologic. Literally, you have to grow them. It takes a longer time. There's less success so it's harder to do—all that stuff. So we gave them 12 years exclusivity in the ACA, and I would submit to you, that may be a tad long. Lot of debate about that. So I'm just looking at the reality, and the reality, you know, we've been through it and you could look at Richard's numbers or you could look at Michael's numbers, or even some of Lori's numbers. Let's be blunt here. Drugs cost too much. Everything costs too much. It's America. But let's look at this.

In the top end thing, specialty drugs are going way faster than everything else and that's sort of the point. That would be in the near 30's there, by the way, on average about 13. These are the data from Altarum. I love this organization, by the way. They do monthly health spending bisector, and they do price as well as overall spending, and what you see there is, yes, Lori's right. Prescription drug spend has fallen from the high in '14, but it's still the highest item on the category of services there so it's still above 9, and that's something we are going to have to grapple with. I hope Altarum's right about the projections. I'm not convinced yet. And, finally, I will look at these two facts. Look at the number of patients who spend more than $50,000 on drugs—increase 63% in the last year; 193% of increase in patients spending more than $100,000 on drugs. Those are not good, happy numbers.

So, what do we know about what really happens to patients? Well, Michael did a lot of that so I'm not going to belabor the point, I'll just remind you that for Part B drugs, our beneficiaries pay co-insurance and there is no out-of-pocket cap for them. And the average income for them is $23,000 and if you've got cancer that's quite a big hefty bill you've got to pay because some of those cancer drugs cost 100,000 bucks. Part D is increasingly using co-insurance. There is a cap, but $7,000 is a still a lot of money. In the marketplace plans, which a lot of us have supported for some time, and Lord knows they're doing a lot of good stuff, but they're using co-insurance for tiers 3 and 4. The average for Silver and Bronze is 40%. Some as high as 60%. And even with the out-of-

pock cap, under ACA plans you're still going to be paying between $6,000 and $13,000, depending on how many people are in your family. So it can be tougher. For ERISA Plans, there's no out-of-pocket cap and statutory restriction. Twenty to 30% is pretty common. And one survey published in the Journal of Managed Care Pharmacy found that most patients have 25% co-insurance or more for oral cancer drugs, and those are the most expensive ticket items on the planet, so that is a fundamental problem.

So, what are our policy options? Well, we could just, you know, listen to Lori long enough and get happy and go home. It's possible. We could accept the status quo. And I will say we could just say it's too complex to deal with for mere mortals. We could impose price controls. To me, that's a polar extreme. I'm an economist. I oppose price controls. I will stand with Lori firmly against price controls as long as possible, but that doesn't mean I think we have to do nothing. We could let Medicare bargain with manufacturers for Part B drugs. Now, Part B, in my view, is the most fertile area to think about bargaining because that's the area where there are no PBMs, that's the area where Medicare fee for services is alone, and so what you want is to think about, perhaps, allowing that to happen. What Sanders and Cummings recent legislation would do, interestingly, in addition to, of course, the usual allow importation from Canada, I don't have enough time to explain how dumb that is, but I'll be glad to answer questions after to deal with that.

But, anyway, they also require Medicare to negotiate under Part D. That would put Medicare in the middle of where the PBMs are now, and I think all of us would agree that—a lot of us would agree—PBM's done a pretty good job, so I'm not really sure about that. What's more interesting to me about their proposal is to require disclosure transaction prices. It might actually help Lori make some of the good points she's making when we've learned what transaction prices are, and then profits are in other countries. Of course, they want to know how you set prices, what's R&D, and so forth, and to outlaw the shenanigans that occur that delay generics from actually coming to market. So, that legislation, I would say, it puts down a marker. It's a little more political than it is policy, but we'll let it go. Okay.

So, a number of serious people, way smarter than me, have proposed replacing private capital with public capital. By that they mean identify which products look most promising in stage 1, use public capital to pay for stage 2 and 3 and, thereby, lower the amount of investment the company has to make so that the same rate of return can be earned with a lower launch price. It's clever. Only really smart people can think about things that hard and, you know, I wish them good luck. So, you could have fast access and indeed diagnostics for better matches. A lot of the criticism of the $100,000 cancer drugs comes from the fact that, on average, they seem to be adding a small number of months to life—2 to 3-4—and a lot of people think that's a lot of money to pay for not much more in life. Well, part of that is because those drugs are not as carefully targeted as they could be, and figuring out exactly which patient would benefit turns out to increase the effects of the drugs and, therefore, that's actually a pretty good thing to pursue. You could just say no to low value drugs as Michael indicated and Peter Bach

and others have advocated. You could use indication-specific pricing; that is, pay more for some uses than others. You could have binding arbitration for truly unique drugs.

This is a proposal by Joe Newhouse and Richard Frank, two of the smartest people on the planet, and I will say what's interesting about binding arbitration, it means that each side, in this case it would be Medicare and the drug company, has to propose a number and then an arbitrator, presumably an informed one, doesn't pick something in the middle. They pick one or the other. That forces both bids to be realistic because if you bid unrealistic then you'll pick the other one and you will lose. So, that's actually not a terrible idea going forward, but, of course, my favorite idea is the one I came up with when I felt compelled to write this paper, the link to which is in your packet, there; what I want to do is take the fact that most of the money is flowing into biologics now, as we probably want and needed to do. Biological manufacturers really need exclusivity because patent life is so short effectively because it takes so long to bring it to market, so exclusivity is the game for them, to maintain their monopoly. What I want to do is tie that exclusivity grant of 12 years to the price level they choose. You know, a modest proposal. This is – it didn't show up. That's too bad. The top of that says: This is America. You can price where you want. But if you set the price too high, and I'll define too high in about 30 seconds, you will not get the exclusivities that you thought you would, and we will fast track competitors to market.

How high is too high? A price that would allow earnings more than some multiple of the cost of capital. I would put the lower at 20% for a large firm. If you earn more than 20% of the cost of capital you are covering the true investment risk of your industry and you're making sure money can flow to finance R&D for the future. If you're a new firm I would go as high as 50, because they have to pay venture capitalists off. But, fundamentally, there's no reason on earth people need to earn as much as Gilead earned. They earned 12 billion dollars on 24 billion sales in 2014 and that, my friends, is more than necessary to encourage innovation. Thank you very much.

ED HOWARD: Alright. Thank you, Len. We encourage you now to join the conversation, although I want to try to set the stage here with a little bit of preliminary questioning. There are microphones that you can use to ask your question vocally. There are green cards that I mentioned. If you fill one out and hold it up it will be snatched from your hand and brought forward.

And let me just go back to something that confuses me, as a non economist. Michael and Lori both talked about PBMs. Lori pointed out that there's a concentration of negotiating power in 5, soon to be 4, entities and that that was a way that competition was working. Michael said that you've got an extra middle man in there and the fact that PBMs are endemic is one of the reasons why costs aren't coming down. So what's up? Or am I misreading what you're saying?

RICHARD EVANS: So, PBM, you could think of largely as a buying club and so if we're going to for-buying clubs, these buying clubs basically aggregate purchasing

power, so instead of you buying it individually you get in the club, the club aggregates your buying power and gets better prices for you. So, a buying club wants two things with regard to price. They want the price to be as high as possible for what they sell to you because they get a bigger margin, as long as the price that they have for you is lower than the best price you can get from another buying club. You follow? 0

ED HOWARD: Is that what you call shadow pricing?

RICHARD EVANS: No, it's not so much shadow pricing, it's just a PBM typically makes in the neighborhood of let's say 15% margin on whatever transactions they manage. If the absolute price of that transaction gets higher, i.e., if drug prices get higher than 15% times that drug price is a bigger absolute margin, so higher drug prices are actually good economically for PBMs. Now there are plenty of people that work in PBMs that want prices to go down and good and honest about that, but in terms of the equity value, if prices are going up those companies are making more money, they key being, as long as the price that they're delivering to the members of their buying club is lower than the others can provide.

ED HOWARD: Michael?

LEN NICHOLS: Michael was talking about wholesalers, though.

MICHAEL GRAY: I didn't talk about PBMs, really at all.

ED HOWARD: I realize they're different in nature. Are they different in function? Aren't they basically trying to do the same thing?

LEN NICHOLS: No.

ED HOWARD: No. Good.

LEN NICHOLS: I mean, Michael, you should speak to it, but it sounded to me like what you were saying it would be as if, Ed, the Washington Red Skins sell their tickets but somebody buys 70% of them before the season—a very optimistic fan, I might point out—but somebody buys before the season and then that person can sell at whatever price they want. If they win 2 games price goes through the roof, and that's what I read in Michael's face.

ED HOWARD: Assuming the Redskins don't retain the other 30% and raise—

LEN NICHOLS: Under price or something.

ED HOWARD: Right. Okay. Lori, do you want to weigh in on that one? Okay. One of the folks with a card question would like the panel to address a little more something that Len mentioned, and that is the projected impact of biosilimars on pricing. And now we

have biosimilars with FDA approval. Is that going to change the trajectory of what we're looking for in the biologicals? Lori?

LORI REILLY: Well, I think there's no question that the introduction of biosimilars will put downward pressure on pricing. Obviously we only have one that's been introduced thus far in the U.S., but there are other countries that have biosimilars on the market, Europe being one of them where in many instances the discounts are in the 30% to 40% range, depending on the product. So, unclear exactly what will happen in the U.S., but I think if you listen to what analysts are saying, or what a lot of the PBM's are saying, they look at these as an opportunity to, again, hold down costs in other areas and drive hard negotiating with the brand manufacturer. So I think absolutely they will put additional pressure and, as you noted, Ed, a lot of the newer products and even many products that are on the market today happen to be biologics, so there is a new opportunity, if you will, there that didn't exist 5 years ago.

LEN NICHOLS: Yes, I think biosimilars are the best hope we've got under current law. I just wish we could get them to market quicker. I will point out the one that's now on the market is competing with a brand that was launched in 1991, okay, so it takes a while. And the 12 years exclusivity is part of the issue here. If you had a shorter period of exclusivity then you could get them to market quicker. But I agree with Lori completely. It is a force that will be positive in the future and I just want more of it faster.

ED HOWARD: Anybody else?

MICHAEL GRAY: The only thing I would share on that is I agree with that entirely. I'm not sure about the percentages based on the articles and the discussions that we've had, it's more in that 10% to 15% range than the 30% and 40% range that gets discussed, but it certainly will have an impact.

ED HOWARD: Yes, sir. And if you are at the microphone, would you identify yourself and keep your question as brief as you can.

ARNE OWENS: I'm Arne Owens with the office of Senator David Vitter. Dr. Nichols mentioned that importing drugs from Canada is a dumb idea. I get that, but the reality is that American manufacturers of drugs sell them at a high price in the United States but there's the same drug sold by the American manufacturers in Europe, for instance, at far less cost, yet Americans can't buy those drugs. Can somebody explain the reasons for that and why re-importation is such a bad idea? Or not such a bad idea.

LORI REILLY: Well, I think importation is a bad idea for lots of different reasons, one being from a safety perspective. You know, the notion of importing drugs from Canada sounds, to some people, like a good idea except when you listen to what the Canadian government has said in the past, which is we're not going to be responsible for insuring that any drugs that come through our country and go to your country are safe. That's one

problem. Two, there's many in Canada that say, no, we don't want all of our drug supply going to the U.S. But safety, obviously, being the paramount concern there.

With regards to why prices differ between countries I think, again, oftentimes when we look at the comparisons that get trotted out they look at a list price in the U.S. and they say this list price compared to this price in a foreign country, and that foreign country has chosen to control the price of their medicines through mechanisms like price controls, when we've looked at, for example—and I'll just use Part D as an example—when we've looked at the top 10 drugs used by American seniors, what they pay in terms of a monthly premium, what they pay in terms of a co-pay for that drug and compare that to a Canadian price, for example, American beneficiaries, through programs like Part D, win, in part because people make this assumption that, again, that no negotiation is happening in this country. It's far from it. There are very powerful negotiators that are negotiating on behalf of hundreds of millions of people and they're using that negotiating power to drive down costs.

The Medicare Part D program is a program that's been widely successful with premiums that have stayed constant over its entire existence. High beneficiary satisfaction, and many seniors today have access to medicines for the first time. So, again, a lot of it has to do with what you're choosing as your comparative where you're going to choose a list price that doesn't reflect the negotiation and the discounts and the rebates and you're going to compare that to a price controlled price, yeah, there's going to be differences. I'm not going to argue that. But, in many instances, when negotiation happens, while there may still be some differences the differences aren't as big as you would imagine. And I would argue, also, when you look at some of the new medicines like Hepatitis C, some of the discounts that the public programs like Medicaid are getting, are 65% discounts, which are often cheaper than where they are in the European countries. So, again, I don't think you can just assume, on list price to non-negotiated price is the right arbiter when you're making those kind of comparisons.

LEN NICHOLS: I think Lori makes a good point about list prices, but I think we all know there are lots of prices where your point would be clear. An American would say, why can't I buy it for that? And so here's my economic issue. How many of you have ever flown stand-by? How many of you have ever gotten tickets at Broadway when you were a student through student rush? Yeah. So you know what I'm talking about. What are those things? Those are prices that are offered cheaper than the basically monopoly price because they want to fill the stadium or they want to fill the theater, or they want to fill the plane. Okay, that's price discrimination. Price discrimination sounds bad, evil, oh, my god. But price discrimination actually is what we call welfare enhancing. Why? Because it means more people get the thing and it means that the companies end up making more money and that's actually not a bad thing. What's going on is, America's paying for innovation but so are they, and all those profits are coming here and here's the fundamental problem, sir. And I don't mean to be nasty about it, I just think this is pure economics. If you shut down the opportunity to let airlines fly stand-by, if you shut down the opportunity to have student rush, if you shut down the opportunity to sell cheaper

overseas they're not going to stop selling in the United States, they're going to stop selling there. They're going to have one price nationwide, it'll be our price. So we don't get any difference at all and nobody in the world gets this drug.

I would also submit what happens when the other companies do their work to get the other countries—do their work to get prices down however they do it, we get a better sense of what the cost structure actually is, which helps the PBMs back home drive bargain. So, I submit to you that is a form of transparency that's analytically useful.

RICHARD EVANS: Ed, effectively, the senators spent a lot of time on this question but I would say that the net prices outside the United States versus inside of the United States, the net prices outside are lower. I agree that we shouldn't be making less price comparison, but let's strip away, let's go to the net price, the net price outside of the United States is lower. The reason is, if I sit down to negotiate with a European government, that government has a legitimate threat of exclusion. If you don't give me a good price I won't cover the drug. Look at the decision that the National Institute in the UK made on Abraxane—life saving drug for pancreatic cancer, only option. They chose not to cover it. When I negotiate access here in the United States, or when I used to negotiate access here in the United States, I knew my drug would be covered. Every time Medicare has gone to Capitol Hill to try to get more pricing authority they've left having less pricing authority than they had when they showed up with.

So I'm not suggesting that the UK model is something that we want to import, but the reason those prices are lower is if I don't meet those demands I don't get access to those patient populations and, outside the United States, the single buyer for each one of those patient populations is the government.

ED HOWARD: Yes, go right ahead.

ANDREA WEDDLE: Hi. Thank you for this session. My name is Andrea Weddle and I'm with the HIV Medicine Association and we're used to high drug prices for the antiretroviral drugs but right now HIV providers and their patients are dealing with the trend that Mr. Gray spoke of, where generics that have been in use for a long time are being significantly hiked in price. And just one really dramatic example is a drug that was approved by the FDA in 1953 and it's used to treat toxoplasmosis, which affects a relatively small number of people. The CDC estimates somewhere around 1400 to 2000 people with HIV every year are affected. The price increased overnight in hospital pharmacies from $13.50 per tablet to $750.00 per tablet, which is a 5000% increase. And, in talking with the company, you know, they justified that. It was a new company that bought the drug this summer, to support R&D, similar to your arguments.

So, but that's not sustainable. It's certainly not sustainable for providers or for their patients to have access to the drugs they need, so what are some policy recommendations to really deal with markets where there isn't competition in the market and these drugs

have already been paid for, essentially, and they are of high value to the patient but that doesn't mean that they can afford to pay the value that the PhRMA puts on it.

LORI REILLY: I don't know all of the specifics of that particular product. I don't represent the generic manufacturer so I don't want to speak on their behalf necessarily, but oftentimes what has happened with medicines that were approved before key FDA law that passed in the early 1960's is that FDA has told a lot of companies that produce those medicines, often the generic company, you need to go back and do clinical trials on these because the standards that got put into place in the early 1960's are not the standards that your medicine got used to approve. And then, what has happened is companies often that are original generic manufacturers, says well, we can't do that. That isn't what we do. We don't do clinical trials, we do bio-equivalency studies. And so, they've abandoned the product and companies will come in and buy that product. They go, they go through a process of doing clinical studies and they get three years of exclusivity for doing the clinical studies that FDA has asked to do. So, they've got a 3-year period to recoup an investment that they made to do clinical trials.

Now, I'm not – I understand from a patient perspective how that can be concerning. Again, I've heard of this happening with a handful of medicines that were approved mostly in the kind of '40s and '50s era before some of the new laws that went into effect in the early '60s, and that is, in part, as a result of the FDA telling companies you can't stay on the market unless you come and do clinical trials to establish safety and efficacy.

ANDREA WEDDLE: I don't think that's the case with this. I mean, that's good to know, but I'm pretty certain that's not the case with this particular drug and manufacturer.

LEN NICHOLS: Well, all I would say, when you say what can we do about this, what do we do when there's no competition? I mean, that's kind of the situation we've created in lots of cases by design because we thought we needed to enable monopoly to get innovation, okay, so you want to be really careful about choking off the innovation. It sounds like, in this case, and if it's not the retro clinical trial demand, then it's sheer market power and the only counter to market power, in the absence of competition, is some kind of regulation. Again, I'm extremely reluctant to go all the way to price controls, mostly because price controls inevitably get driven down below the real cost and so you end up having, you know, rent controlled New York City and all that stuff.

So, all I can tell you is, some kind of regulation to come in. What could happen, perhaps, is you have a public buyer buy it and sell it at a loss and basically use taxpayer dollars to do it. Somebody's got to pay for it and that's the only way I can think of.

ED HOWARD: Are you folks lined up and waiting? Well, go ahead.

SUSAN LORD: Thank you for this panel. I'm Susie Lord and I'm with the Department of Health and Human Services and I'm wondering what your thoughts are on regulating

formularies and defining what drugs should be in what tier, such as the situation where you have all HIV drugs, even generics, into specialty tiers. Some states are enacting laws and regulations now identifying – putting caps on out of pocket spending for certain tiers or certain drugs, so I'm just wondering what your thoughts are on that and that is, perhaps, a mechanism that can help put drugs in a reasonable cost for people with certain conditions.

LORI REILLY: Sure, thank you for the question, and you're absolutely right. I guess a growing phenomenon that we've seen, in part, some of the exchange plans is that in some disease conditions—HIV/AIDS, rheumatoid arthritis, multiple sclerosis—where we've seen patterns of plans putting every single medicine on the highest tier of the formulary, and even the generic, and it's a concern, obviously, from a discrimination perspective. I think the concern being that if you're a patient that has one of these conditions and you're looking to buy a medicine on the Exchange and every single plan, in this instance in some states it really is almost every single plan, putting all the medicines, the signal that it is sending is HIV/AIDS patients need not apply to get coverage here. And that's concerning.

You know, the purpose of insurance and, in some ways, you know, HIV/AIDS, MS, and RA are three conditions where today patients primarily rely on medicines for their treatment. They're not necessarily needing a lot of hospitalization stays—they may, but it's really concentrated medical spending. And, you know, the worry there is, are we punishing people based on their biology, based on the condition that they have? So, such that if I'm sick and I need to go to the hospital, the amount of money I'm going to have to pay out of pocket is actually pretty low, but if, God forbid, I need a medicine, if I have MS or RA, then I'm going to be subject to 40%, sometimes 50% cost sharing or co-insurance. You know, thankfully, the Exchange plans have an out-of-pocket cap so there is some limit, but for a lot of these patients, also a difference between medicine and a lot of other healthcare, is patients show up at the pharmacy counter, they don't have that money out of pocket. They don't have it and that is a problem.

If you go into the hospital you have to get treated. They're going to treat you and maybe, on the back end, they will, you know, write some of it off as bad debt, they have charity care payments, a lot of the hospitals that Michael has, have access to the 340B program where they get, you know, 20% to 50% discounts on medicines. There's a lot of opportunities on the hospital side to at least be able to work with the patient. For many people that need drugs there isn't that opportunity. If you can't pay and you're sitting at the pharmacy counter you're not getting that medicine. And so, you know, that is an area where, I think, we have growing concern and people will say well it's the price of medicine. Well, the reality is, that's the purpose of insurance.

You know, we've heard a lot today on the panel about specialty medicines. About 3% of the population rely on a specialty medicine. I read some of the headlines and the presumption is every single person in America takes a specialty medicine. It's 3% of patients. And these patients tend to be very sick. They tend to need sometimes expensive

forms of healthcare, but that's why we have insurance. It is to be able to take care of patients that truly need care. And I worry that what we're seeing in some of these plans is discriminatory and we've talked in our comment letters, I know, to HHS that we believe there is discrimination. We think tools need states need greater tools to be able to look at a formulary and assess whether or not it is potentially discriminatory. I think this is a new world that a lot of states that are running their own exchanges are in where they're trying to assess, you know, is this formulary good or not? It's hard know. I will say, a lot of the groups, particularly the HIV/AIDS groups have been very engaged in this debate and have been working in many of the states to try and raise attention and awareness and some of those policies have changed.

Addressing your point on caps, my association is not in favor of co-pay caps, in part because we do believe payers need to have some mechanism to control costs, but we do need to look at affordability issues for patients, and it isn't just the price of the medicine. It is a price that patients are charged in terms of co-pays and we want them to be reasonable for patients and not discriminatory. We also need to make sure, though, that there is a breadth of a formulary that patients have access to, that there's actually reasonable choices there.

MICHAEL GRAY: A formulary, from our perspective, is very different in that we're talking about within our health system, and the care of the patient through the continuum of care. So, when we think about a formulary it's much more the consistency of how a patient is cared for throughout our facilities so that there's protocols in every location so we get safe and effective outcomes throughout.

Certainly the 340B program mentioned is incredibly important for us. Our rural facilities, our safety net hospitals, it's incredibly important for that. It means about 114 million dollars to the organization that can provide free and discounted drugs to people who need those drugs. So it's an incredibly important program but, to be clear, I excluded all of those from the numbers I used today.

LEN NICHOLS: I would just add, if I could, Ed, that I think it's really important when you think about that problem to remember the tradeoff involved. If you move to capping out of pocket or whatever, you're going to push it into the premium and I'm not opposed to that. In fact, I think, in fact it may be the most fair way to go because then, in a sense, you're spreading the cost of the complex specialty situations over a larger population but you kind of got to have buy-in for that from the rest of the population. And we obviously, I think Lori said it very well, early in the marketplace life, it's been up 2 years now, plans are under incredible pressure to get premium low to compete for market share and that was one tactic they used. I think as more people get more aware of the implications of those choices there may be some limits. But I would just say, every time you put a cap on you're going—it's a balloon, I got the balloon metaphor again—it's going to push out somewhere else. It's going to come through premium, so be careful.

RICHARD EVANS: As a former drug executive and Wall Street analyst, I'm in the bizarre position of coming to the defense of health plans here. Plainly, if health plans put all the specialty drugs on the top tier we should legitimately be concerned about adverse selection, that they're telling HIV patients to go away or ACV patients to go away. But let's not forget, there are reinsurance mechanisms in the health insurance exchanges so if I do that and I accrue a lower risk than the folks in my area, I wind up writing a check for that. So I agree. We should never tolerate any formulary design that is meant to exclude patients. We should never tolerate that. But, let's also recognize that these formularies are doing this, in large part in many cases, because they need negotiating leverage. That's why we have things on higher tiers.

One of the things that catalyzed that and enabled it are co-pay cards—coupons—from brand managers that in a case where, you know, your drug is on the specialty tier, it's a very high out of pocket, the manufacturer gives you a co-pay card or a coupon so that your actual out of pocket is down near, you know, kind of that tier 2 affordable level. One of the things the health plans are doing is saying, fine, if you're going to have those coupon programs, knock yourself out. I'll put your drugs on a higher tier. So, I'm not saying that's good or bad, but let's be objective and fair that the health plans putting these drugs on higher tiers, it's not always about trying to get the HIV patients under the other guy's roles. It really is often about just sheer negotiating power.

ED HOWARD: We have less than 15 minutes left. Let me just remind you that before you leave we'd be in your debt forever if you would fill out the blue evaluation form to try to give us some feedback. We have time for these two folks to ask their questions and our panel to give insightful and terse responses, and then I want to try to get to a couple of the multiple card question topics that have come in from you folks in the audience. Yes, ma'am.

SOPHIE KASIMOW: Hi. I'm Sophie Kasimow, I work for Senator Bernie Sanders and I would encourage all of my colleagues to look up the bill you mentioned, Len, as 2023 and take a look at the very serious and, in some cases, many bipartisan priorities that are in that bill. And if you have any questions you can give me a call about it.

I appreciated the turn to conversation about affordability. I think that we haven't seen in this conversation yet, drawing out the point that the Commonwealth study just came out and reported that one in five adult Americans, 35 million Americans, don't fill a prescription due to cost and, at the same time, how are we supposed to reconcile that with the fact that the pharmaceutical industry is the most profitable industry in the world—more than oil and gas—you know, more profits than oil and gas companies, more profitable than banks, more profitable than major media conglomerates. How do we – and there's a little bit of hand waving that goes on here in the presentation. Lori, maybe you can respond to this, about well, yes, we know drug development is extremely expensive and here's a couple cherry picked examples of cases where there were lots of trials that failed, but I'd like to see some—and that's one of the things the bill does, is show us all of the data. You know, give us not just a few examples or a dozen examples,

but give us, show us there are lots of federal taxpayer – hundreds of millions if not billions of tax credits that the pharmaceutical industry gets, grants that are being made. Our taxpayers are heavily invested in pharmaceutical development then we pay the most of anyone in the world on the other end.

So, maybe you can respond to sort of the affordability, how we reconcile transparency with cost in America? That'd be great. Thanks.

LORI REILLY: Sure. Thanks for the question. Obviously, the bill that Senator Sanders introduced, and there are a number of bills across the states that would argue for "transparency" in terms of research and development costs and sales and marketing costs and the like, and I would say a couple of things.

One, a lot of that information is actually contained in our SEC reports. They're pretty big and Sarbanes-Oxley required a lot more things in them as you can imagine. I think part of what a lot of folks, and I hear this a lot, have said is that we want to know how much you spent to get that medicine to market. And I understand that. I understand that issue. I would say, if you take a condition like Alzheimer's, one of our member companies has been working on Alzheimer's research for 29 years. They've never brought a product to market. Maybe one day they'll be successful. So what's the R&D cost associated with that one product? Is it the full 29 years that they've spent researching and developing to try and get an Alzheimer's medicine to market? Or is it just the clinical trials when they were actually successful?

I think part of the hard part with the business model of the pharmaceutical companies is that we do fail a lot more than we succeed, and that failure is not always bad. We learn from that failure and we hopefully improve what we're doing and we go forward. But if the notion is that we can only recover costs for those times we succeed I worry that the message that sends is don't go after the real hard stuff because you're probably not necessarily going to be successful and you're not going to be able to recoup that investment. Go, instead, after things that are easier to innovate from.

But, when you think about where the healthcare needs are, Alzheimer's is a great example. By 2050 we're going to be spending 1.2 trillion dollars in this country to treat patients with Alzheimer's—1.2 trillion dollars if we do nothing. I think the only hope we have for treating patients with Alzheimer's is innovation. And my guess is, you know, if a new medicine comes and delays progression into a nursing home, delays progression to disease, that medicine's probably going to be expensive and we'll probably have a debate similar to this about it, but it is going to offset cost down the road. But if the message to companies is, if you happen to be that company that is successful, well, we're going to penalize you by either setting the price of the product, only letting you charge 20% above what the research and development costs were to bring that product to market. I don't know that you're going to see companies saying I'm willing to invest 30 years, 30 years of capital expenditures, to try and get to market a product where there is very little hope

of being successful. As I said before, 120 some attempts to get an Alzheimer's drug to medicine, 4 successful. And we need companies doing that. We need them.

I have a personal story. I lost my mother last year to ALS. This is a condition that she was on Medicaid the last four years of her life and when she passed I got a letter from Nebraska Medicaid saying we're making a claim for $852,000 on your mother's estate because that is what Medicaid spent to keep your mother in institutional care for the last 4 years of her life. $852,000. No one questioned it, no one had a panel here talking about the costs associated with Medicaid and institutional care. The only hope we have for patients, and our healthcare system, to deal with those kinds of costs is the hope that one day someone has a cure for ALS, or a treatment that delays the progression. And, will it be expensive? It probably will. There's less than 200,000 patients that have ALS but I will tell you, it's a devastating condition, not just from a human perspective, but from an economic perspective in this country. And we spend, obviously, a lot of time it's a fair debate to talk about drug prices and, yes, there are companies that are profitable. But the companies that you see that are profitable, for every 20 of them there are thousands that you've never heard of. There are thousands that never open the doors and actually brought a product to market and that's an important part of the perspective, too. If it was so easy and so profitable we probably wouldn't have 20 big companies doing it. We'd have a lot of people doing it because, you know, it was so easy.

I'm not saying that profitability is not a part of the discussion but I also think the reason why people invest in companies is the expectation of a return. And with us there's not always an expectation of return but we need people willing to take a risk in this country. We need people willing to put resources in saying I'm hoping that maybe you'll be successful and if I know you're not, you're not going to be profitable and your doors will be shut. And I understand the passion around this debate and the costs associated with it and it's a fair debate to have. I just worry that some of the policy discussions that are getting put forward send a very strong signal that if you're innovative we're going to penalize you. We're going to hold your costs down. That doesn't encourage an investor to invest in them if they know that if you happen to be successful that you're not going to get a return. That doesn't encourage investment. It just doesn't, unfortunately.

ED HOWARD: Quick comments?

RICHARD EVANS: I'd like to make a fundamental economic point. Drug pricing and affordability is a very tough thing to solve. Let me use a transportation analogy. So, most people can time and scale their consumption purchases based on what they can afford so I'll ride my bike, I'll take the bus, I'll walk if I don't have money or I'll save and buy a Yugo or I'll go out and use cash to buy a Ferrari, depending on my needs. I can time and scale my transportation consumptions.

If I have pancreatic cancer I need Abraxane, period. And I need it now. I cannot time, nor can I scale that consumption decision. Now, the manufacturer of Abraxane will never, and should never be expected, to price it so that it is affordable by the poorest person, and

I do believe the poorest person has as much a moral claim on Abraxane as the wealthiest person. In order for there to be enough price on Abraxane we have to do one or a combination of two things. We have to subsidize, preferably through the tax code, the consumption of folks that couldn't afford the price otherwise. And, I think, to an extent we do with Medicaid, with HIE insurance subsidies and we also, and/or, we also have to moderate the price that's charged to folks in those income strata who can't afford the price that was set, 340B, Medicaid mandatory rebates. So I think those mechanisms for getting affordability for everyone who has a legitimate moral claim on Abraxane, by God, should get it without having to wait, is a matter of titrating subsidization of coverage in pricing to the appropriate point. But it'll never be an easy solution because people simply cannot time or scale their consumption of many of these products.

MICHAEL GRAY: Just a quick thing. And Lori, your comments are well thought out and thoughtful. The challenge, I think, for the question is when you look at the financials from pharmaceutical organizations and you see 60% to 80% gross profit, but you see that their sales and general administrative costs are 200% to 700% more than they are in decosts, it's hard to think through that structure of all the losses through the research and development.

ED HOWARD: And I don't want to interrupt in the middle of the back and forth, but I do want to make sure that there's time for this gentleman, who's been very patient, to ask his question, which probably is the last question.

JOHN WILKERSON: John Wilkerson, Inside Health Policy. This might be kind of a tertiary policy consideration, but should Medicare cover less of the financial risk with Part D plans than it does now? Premiums are not going up on drug plans, which Lori pointed out, which doesn't seem to jibe with rising drug prices and that's, in large part, because Part D plans have three different types of risk sharing with Medicare. Should the risk corridors be taken away, or the risk adjustment be taken away, or the reinsurance be taken away? Should one of those three be taken away?

RICHARD EVANS: I would say no to taking reinsurance away because you create the scenario that came up with the representative from the HIV patient community where people can drive adverse selection.

To risk corridors, my bias says you should probably pull them back. If you go back to the emergence of Part D you're basically asking prescription drug plans to come in and write premiums for a market that had never existed before, so they're guessing at what the actual claims experience would be. So, in that setting, you need risk corridors because you know the gas is going to be really different than the reality, and so those risk corridors help attract capital into the PDP or the Prescription Drug Plan space. That's done. That job is finished.

So my personal bias is that risk should be borne by the underwriters, not by the taxpayer but you still, I feel very strongly you have to have reinsurance because you can't get into the scenario where formulary design drives adverse selection.

LEN NICHOLS: Where I grew up they had a saying: If it ain't broke don't fix it. Leave it alone.

ED HOWARD: How about that for a definitive period.

We have two minutes and I'm going to try to get the panel to take a quick stab at a question that showed up on several of the cards, and actually also in several of your remarks, and that is the question of value.

Lori talked about the support for a value concept from her constituent companies. Does that mean that we should be seriously considering something the Congress shied away from in the course of the Affordable Care Act deliberations—cost effectiveness evaluation? And if the answer is we should be doing it, how do we start down that road?

LORI REILLY: I'm happy to start. I think with regards to value, I do think that is the discussion that our companies are actually anxious to have and there's lots of different ways that our companies would like to work with payers, private payers, to negotiate contracts that are based on value, that are based on things like outcomes.

I think there is a lot of interest, but I will say today what does need to get looked at is the regulatory and legal frameworks that exist that actually make it harder to do that than they probably should be, and just two examples.

Take an integrated healthcare system that's responsible for sharing risks, maybe an ACO. That ACO is responsible, financially, to control costs and if a company is talking to that ACO and they want to negotiate to use a medicine the limitations, in terms of what that company can talk about with regards to their medicine, are limited to what's on the label. But they may have engaged in a study, comparative effectiveness study or the like, where they looked at the use of that medicine in terms of reducing hospitalization and found, for example, that use of their medicine reduced hospitalization. They can't, then, go to the ACO and say we want to enter into this contract. We know reducing hospitalization is important to you and here's the way our companies could do that. That's against the law today. So there are prohibitions on the kinds of communication that I think would help those types of arrangements.

There's also prohibitions in, for example, the Anti Kickback Statute. So, if a company says, we think it's really important that medicines, this medicine's available and we want to make sure patients are adherent to it, and the ACO has a similar interest. They want to make sure that if we're paying for the drug that the patient is adherent. Well, a lot of those ACOs come to our companies and say, well, we'd like you to pay for an adherence

program. Okay. Our companies say we'd love to pay for an adherence program, but under the Anti Kickback Statute today, those programs are viewed as a kickback.

And so, I think, as we go further down this discussion of moving towards a value-based healthcare system, a lot of the rules that are in place are rules that were in place for a system that existed 20-30 years ago that probably today need to be examined where people can say if we want to encourage these kinds of relationships, if we want to put companies more at financial risk, that's great, but let's make sure that the laws and the guidelines that we have in place today provide an opportunity for companies to engage in those kind of relationships. And I think there is a lot of eagerness for our companies to move in that direction but we need a healthcare system that we can work with to get us there.

ED HOWARD: Quick comments from anybody else?

MICHAEL GRAY: From our perspective, certainly moving to a value equation from a fee for service equation is something that is very attractive for us and as we develop our integrated systems of care in the communities that we serve that's exactly where we're trying to go as well.

ED HOWARD: Len?

LEN NICHOLS: It's hard to argue with going toward value. I think it will require more information and will take a step toward transparency as Lori was talking about but I think fundamentally that kind of transparency I think everybody's for.

ED HOWARD: Okay.

RICHARD EVANS: I think there's a challenge we face. If you decide that the value of a medicine is X and the manufacturer comes forward with 2X what do you do? Right? We don't currently have, at the government level, pricing authority to say no, I'm sorry. It's actually going to be X, or to say no. And I'm not saying that we necessarily want to cross that bridge, but it's important to realize that if we're going to have a value discussion we really should. What do we say when we decide the value is X and the company says I'm going to price it 2X? What's the next step?

ED HOWARD: Alright. Well, thank you very much for those comments. Let me just say that I apologize for not getting to some very good questions that many of you submitted on cards. What that says to me is that we're going to find a way to continue this conversation and not leave with as many loose ends as we are required to do today.

Thank you for being part of it. Thanks to our friends at Ascension for supporting it. Thank you for filling out your evaluation and let me just put in a commercial. We actually—I've slave-driven the staff at the Alliance into putting together another program on Monday. If you haven't taken a look at it, please do. It has to do with tools that help

consumers navigate the kind of chasms that you've heard described here today with our health system and we'd love to see you on Monday.

And, finally, please join me in thanking the panel for shedding an awful lot of light.

[Applause]