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Health Reform for New Health Reform Reporters
Kaiser Family Foundation
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LARRY [ph 00:00:00]: Thank you. Welcome to this web conversation about prescription drug spending. Prescription drugs are the fastest-growing part of the US healthcare system. Retail drug spending spiked 11-percent in 2014. At the same time, the growth in overall health spending remained relatively modest. All indications are that drug spending has decelerated more recently, but it is still increasing faster than care provided by doctors in hospital throughout the health system.

The dynamics of drug spending are complex. New drugs carrying higher prices drive spending up while patents expiring pave the way for cheaper generics that push spending down. The prices that we pay for drugs are based on a complicated and largely opaque set of transactions involving manufacturers, wholesalers, pharmacy benefit managers, insurers, pharmacies, and ultimately patients. For the more than 90-percent of us who have health insurance, what we pay for drugs is largely a function of our insurance policy, which drugs are on our formulary, which tier they are on and how much the co-pay or co-insurance is.

Recent developments have put drug pricing in the news. Turing Pharmaceuticals bought the rights to a decades-old drug used to treat parasitic infections and increased the price more than 50 fold. Valeant Pharmaceuticals also sparked controversy by raising the prices on certain generic drugs significantly.

Increases in drug costs have resonated as a public concern. Ensuring that high-cost drugs are affordable for those who need them has emerged as the public's top healthcare priority in polling done by the Kaiser Family Foundation.

A substantial majority believe that drug prices are unreasonable and support a variety of proposals aimed at keeping drug costs down including greater price transparency, federal negotiation of drug prices in Medicare and importation of lower-priced drugs from Canada.

To discuss these issues, we are joined by a terrific panel of experts. Steve Miller is the Medical Director and Pharmacy Benefit Manager at Express Scripts, Kirsten Axelsen is Vice President for Global Policy at Pfizer, and Celynda Tadlock is Vice President of Pharmacy Business Development at Aetna. The full discussion is being recorded and will be available at kff.org/healthcosts. During the live discussion, please submit written questions in the chat window and we'll get to as many of them as we can.

To get things started, Steve, fair pricing is one of the most complicated topics in healthcare at least for those of us who aren't in the panel. Can you start us off with just a very quick rundown of who pays what for retail drugs? From what the manufacturer charges to ultimately what the patients pay, and how the behind-the-scenes rebates work?

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STEVE MILLER, M.D.: Yes, Larry. Thanks for the question and thanks for asking me to be on the panel. As you said, drug pricing is very complicated. The pharmaceutical manufacturer will set the drug price, so that would be its list price. As you know, just like with hospitals or with doctors' services, very few people pay the list price. Those drugs are then sold to a distributor who then sells it to a pharmacy. The pharmacy benefit managers or the payers try to aggregate large numbers of patients, and they will prefer one drug over another and try to negotiate discounts, and these are usually in the form of rebates. Those are netted out from the drug price and you get what will be the actual cost of the drug.

The patient pays on average about 18 to 19-percent of it in the form of their co-pay if it's a drug through the pharmacy and their plan sponsor will pay the remainder, 82-percent. It's a very complicated system that makes up for drug prices. As the patients know, because they're bearing more and more of that expense each year, they're feeling a greater burden, so people are really upset these days, because not only are drug prices going up, but the percent of the product being paid for patients continues to go up, and that's actually causing a lot of stress in the system.

LARRY: Give us a sense, I mean these rebates obviously vary from drug to drug, but how big are they? Give us a sense of what the range is for these rebates.

STEVE MILLER, M.D.: Yes. If a pharmaceutical manufacturer has a drug that is totally unique, no one makes a drug like it, they may give no discount at all. No rebates whatsoever. Rebates will vary from zero, the list price will be what people actually have to pay, to dramatic rebates that are often greater than 50-percent. If you are in a class where there's a lot of competition and you want to keep market share, you often have to discount it pretty dramatically. Then, if you think about generics, generics are actually the best buy, because generics are typically 60 to 90-percent off the list price of the branded product.

LARRY: Kiersten, as Steve said, it all starts with the manufacturer list price. Give us some insight into what the thinking is that a pharmaceutical company in terms of how you set that list price?

KIRSTEN AXELSEN: Wonderful. Thank you. Again, thank you for asking me to join and also for the other panelists. This is an incredibly important issue and one that we have to work on together, and of course with medicines being among the most powerful tools in treating and fighting illness, it is our priority that all patients have affordable access to them.

To answer your question about what manufacturers think about when we are going to set a list price for medicine, and as Steve already pointed out, that list price is often just a starting point for a negotiation with a health plan. We

consider the value of the medicine, what other types of treatments are available to treat the same condition, and then we also think about affordability, and that comes in a number of ways. You think about the size of the population, the impact covering that medicine is going to have on a health insurance plan, because, as you already mentioned, most patients get their medicine through their insurance. You put all that into the consideration both for the list price and then at a discount you're willing to offer. Of course, there are patients who either don't have health insurance or find that their medicine is unaffordable with their health insurance, because their co-pay is high or they have a deductible. Then, Pfizer and other companies make their medicines available for free or for a reduced price through their patient assistance program. In fact, Pfizer increased the eligibility limit on their patient assistance program to 400-percent of the federal poverty level, which is around $100,000 for a family of four in recognition of the trend that Steve had noted for patients that are being asked to pay out-of-pocket for certain medicines is increasing.

Then, there are of course classes where there is very high generic penetration. Now, in those classes, the price of the brand becomes less relevant, because the vast majority of patients switch onto the generic medicine. In fact, if you look at what we are paying now for patients per person for two

of the most prevalent conditions, hyperlipidemia and hypertension, we are actually paying the same now for patients that we paid in 1996 for their prescription medicines while the cost of their other services, including office visits and hospitalizations, have increased.

LARRY: Kirsten, you mentioned affordability being a factor, can you give an example of where Pfizer took that into account in setting the price for a drug?

KIRSTEN AXELSEN: I think in all of our drugs, but most recently we launched a new medicine for cancer in 2015. It was the first innovation for this particular type of breast cancer in a decade. We consulted with over 80 payers, 120 oncologists and cancer specialists, spoke with patient groups, and thought again about the epidemiology of the disease, and set a price that we felt was going to maximize access to the drug. It will be affordable and then, of course, we set up a patient assistance program for those people who could not get it through their insurance.

LARRY: Great. Steve, let me come back to you. As we said, the spending for drugs has been going up and price is only one factor in that, although it certainly is a big factor. You have data that spans manufacturers, it spans payers, what does your data show about what is driving the recent growth in drug spending overall?

STEVE MILLER, M.D.: I think there are three major factors people have to consider, one is we are in this great period of innovation, and we have had an enormous number of new drug launches. In 2015, there were more new drugs launched than any time in almost the last 20 years. The price of the new drugs coming into the marketplace has gone up over four fold in the last seven years. It costs almost $10,000 per month for a new drug to come to the market in 2015. Not only are we having lots of new drugs, but they are coming in at prices we have ever experienced in the past. The second is, which is probably the biggest driver and that is brand inflation, if a drug has no competition, it is still branded, the inflation with the pharmaceutical manufacturers have taken over the last seven years is 164-percent. Now, remember this has been a low inflationary period, so the consumer price index during that same period of time has gone up only about 14-percent. The biggest driver of drug cost has actually been brand inflation.

Then, the third thing we have to consider is the decreasing impact of the generic wave. While we still have tens of billions of dollars of drugs that go generic each year, as a percent of total drugs spend, that becomes smaller and smaller. If you go back just five years ago, every time I had to put a patient on an expensive new specialty medication, I had 10 patients that I could put on generic drugs and I could

keep total drugs spend relatively flat. In the last several years, as we have approached generic utilization rates of 85 to 90-percent, we do not have additional patients to move to those generics. Every time you put someone on one of these great new products that falls directly to the bottom line, so drug spend has gone through 350 to 400 to 450 billion dollars a year, and it is going to continue to climb because we are in a great era of innovation. If we continue to have drug brand inflation like this, we will also continue to see prices go up at a pace that probably exceeds affordability.

LARRY: One thing you mentioned was new drugs coming on the market at higher prices than was previously seen, one of the categories are so-called specialty drugs. The most notable example recently being medications to treat and in fact cure hepatitis C. I think there is a lot of confusion about these specialty drugs and what they are. Kirsten, let me come back to you. How would you define a specialty drug? Do you have a standard definition?

KIRSTEN AXELSEN: Yes. Specialty drugs are defined by the Medicare program as drugs that exceed a certain cost threshold per month, which is about $600 per month. For a patient and for their provider, specialty drugs are often medicines that require special handling, such as a need to be stored in a particular way or infused in the office or injected. They tend to be for people with the highest burden

condition. A specialty drug really encompasses two things, the cost of the medicine and then the way it is handled and the type of disease.

Then, many of these drugs are administered through a specialty pharmacy where additional services are provided to the patient, particularly these who do have these very difficult-to-treat diseases such as counselling or information about how to use their medicine appropriately.

LARRY: Why are these drugs so much more expensive?

KIRSTEN AXELSEN: The kinds of drugs that were developed in 2014 really were radically different than those we had seen 10 years ago. They are drugs that tend to be approved for conditions that have a high unmet need, relatively few other treatments, and they mark significant improvements over the standard of care. Those drugs, like any treatment, that are a significant improvement over the standard of care tend to be more expensive.

LARRY: Is that partly because that is what the market will bear for a drug like that?

KIRSTEN AXELSEN: What the market will bear is—I think it is kind of an interesting terminology, because the market is health insurance plans, providers, and patients, so of course we think about what the drug means to all of those constituents, and affordability is a consideration, and you cannot just put the price of the drug at anything. It has to

be something that you think will be afforded by the health plan and then consequently by the patients. We have a system in drugs that does a relatively good job of containing costs over time. As Steve mentioned, there was a big wave of patent expirations that then slowed down. While we had a big spike in drug spending in 2014, it has already come down in 2015, and it is expected to be lower in the years to come.

What we do not have is a system that handles these spikes very well, right? The same drugs that came out to treat hepatitis C are going to be available in generic form at a much cheaper cost in just over a decade from now. We saw the exact same thing happen, double-digit spending growth in the last part of the 1990s and the early 2000s. These medicines contributed to much lower healthcare spending. What all of us on the phone are working on is ways to innovate in our reimbursement the same way that we have innovated in the drug, so that we can try to smooth out these trends a little bit so that the patients are not hit with these high out-of-pocket costs at precisely the moment they need these medicines. These are really truly transformative medicines and the goal is to have them available and accessible to everyone who needs them.

LARRY: Celynda has had some technical difficulties, but I believe she is on, and it is the perfect transition to her talking about patient out-of-pocket costs, which of course is driven as much by the cost sharing and their insurance plans

as the actual price of the drugs. Celynda, you have tiers of cost sharing for different drugs. It used to be two tiers, just generic and brand. Then, moved to three tiers, four tiers, and even five tiers of drugs. How do you go about deciding what tier a drug should be on, and also whether a patient pays a flat dollar co-payment $10, $20, $30 for a drug or a percentage of the price, a co-insurance?

CELYNDA G. TADLOCK, PHARM.D, MBA: Thanks Larry. Thanks for including me in the conference today. Relative to patient cost sharing, your comments are absolutely accurate. I really think that we have come full circle over the last 20 years or so. You can really look back into those old [inaudible 00:16:36] days and so see those 70/30-percent co-insurance-type plans with high deductibles. That really then moved into more the HMO/PPO era where we did have flat co-pays and no deductibles. Those really became not affordable and then we saw exclusion lists added. Those actually then moved on to multi-tiered co-pays and certainly now we are seeing more employers adopt high-deductible plans.

Our strategy is really to develop different price points of formularies and structures. The clinical basis is at the heart of all of our benefit design and our formularies. That starts with our P&T committee evaluations. From there, we work to really design products that meet our customers where they are. We do have formularies that are more tightly managed

that have higher deductibles and higher cost shares. Then, we also offer products that have many more brand medications to choose from and a lot less utilization management strategies. We have a portfolio of products and our employers are able to choose what meets their employer population to the best degree.

LARRY: A similar question for you as I asked Kirsten, can you give an example of how affordability might enter the decision about setting cost-sharing, if it does? For example, are there discussions within Aetna that a 22-percent co-insurance for a drug that might carry a price tag of $60,000, $70,000, $80,000 for a course of treatment is just too much?

CELYNDA G. TADLOCK, PHARM.D, MBA: Absolutely. We have a lot of discussions about affordability. In fact, as we kind of look at the consumers that are calling us about prescription coverage, we are having more and more of them express questions about affordability, questions about alternative medications, questions about how we might help them finance their high deductibles. This is a really important discussion. After we have our P&T committee discussion, we move on to our value assessment committee where we do look at the placement of these high-cost drugs and various tiers.

It's important, I think, to note that we do put limitations on products. We have some capitations, maximum patient out-of-pocket, that are hit. During the period of time when the consumer is subjected to a deductible, we do offer

some financing options for them to help them finance that deductible until they hit that integrated deductible and then pay a flat co-pay for their medications.

LARRY: We have had several questions about this increase in prices for brand name drugs that Steve mentioned. One question was whether the 164-percent figure that Steve gave was a net rebate or a gross price increase. Steve, can you answer that?

STEVE MILLER, M.D.: Yes. The 164-percent is the list price increase over the last seven years.

LARRY: Great. What is your explanation of why this is happening? Why are we seeing these increases in existing brand-name drugs?

STEVE MILLER, M.D.: A lot of it is the management of the pipeline and the management of products over time. What happens is for pharmaceutical companies—there is a spectrum of pharmaceutical companies out there. There are companies that bring in a lot of new products to the marketplace and so their revenues continue up without having to take big price increases. In fact, one of the pharmaceutical companies has not raised prices at all over the last seven years. That is a company whose revenues have continued to go up, because they continue to bring new products to the market. They are highly innovative.

There are other companies that have struggled to bring new products to the marketplace and the only way that they can continue to sustain and improve their bottom line is to actually charge more for existing products. It varies across the companies why they have to raise prices and the price increases we are seeing. Just in the last couple of weeks, we have seen announcements from both Gilead and Pfizer of big price increases on June 1st. This has become fairly typical that a company will take a price increase twice a year; once in January and once in June. The list price, as mentioned, is only part of the story. The discounts are less or make the price less.

Last year, from our drug trend report, prices went up net of rebates, so this is the actual price people were paying, was 5.2-percent. That is still substantially greater than inflation.

LARRY: Kirsten, first, whether you agree with those numbers or not that brand-name prices are increasing faster than inflation and what would you say are behind them?

KIRSTEN AXELSEN: According to the most recent data from IMS in 2015, net of rebates, brand prices went up 2.8-percent. What you see, if you look since about 2012, the list prices have been going up steadily, again, at these double digit rates, but the rebates have been taking those back down. Again, between 2014 and 2015, we saw an even bigger impact of

rebates. That is owing to the fact that the health plans and PBMs have a lot of [inaudible 00:22:57] and a lot of leverage. They do the same kinds of value assessments that you hear about from other external organizations, and they negotiate and they negotiate hard, and as we have seen this wave of new innovation, there are competitors and there are other alternatives. They are able to negotiate down the price.

These discounts are passed on to the patient in one of two ways, either by reducing their premium or by reducing their co-pays and deductibles. They do not necessarily reduce the co-pay and the deductible for that particular drug, so you could negotiate a big discount on a branded drug and use it to make a generic free for example or use it to make the premium lower. It is true that the—like I said, the kinds of drugs that are being developed do tend to be more the specialty drugs, so you are seeing higher prices on those drugs. You are also seeing the effect of discounting, bringing down that brand inflation.

LARRY: We have also gotten several questions about prices in the US compared to other countries; notably Canada or Western Europe, Japan and Australia. This has become an issue on the campaign trail with both presumptive presidential candidates calling for allowing people to import cheaper drugs from Canada. Kirsten, is it true that you do get higher prices in the US than other countries for the same drug?

KIRSTEN AXELSEN: Yes. You do see higher prices in the US for drugs, for hospitalizations, for doctors, for everything in healthcare. The way you get lower prices for anything in healthcare is by getting a lot of leverage and then setting a price and excluding other providers. That is, again, for the commercial market, and Medicaid and the VA, these programs that are really designed for special populations, you do see prices in the US that are closer to the prices that are obtained outside of the US.

It is a trade-off of access and value. If we decided to make that decision in the US that we wanted to make that trade-off, we would be making the trade-off at the expense of access. Much of the world's innovation is funded by the US market, just under half of the world's biopharmaceutical business does come from the US. What we see is faster uptake of new medicines and faster access to new medicines in this country.

LARRY: If, for example, importation was eased from Canada, what would you see happening?

KIRSTEN AXELSEN: First of all, the FDA would need to make the importation safe and effective. That would be something that they would need to certify. If you were to just somehow import those prices, it would be less money going to biopharmaceutical innovation. Investors have a choice about whether they want to invest in a high-risk high-reward

business. If that business becomes less rewarding, then the money from investors would flow to other types of industries or you would see different kinds of pharmaceuticals being developed.

A pharmaceutical company starts thinking about reimbursement in around the Phase 2 of development. You also think about other things that I already mentioned, unmet needs, affordability, but if the reimbursement is not there then some of those drug candidates would not be pursued. I did see different kinds of drugs being developed that were paid for out of pocket.

LARRY: Celynda, could you see importation working from a health plan perspective?

CELYNDA G. TADLOCK, PHARM.D, MBA: Yes, from a health plan perspective, I think, I definitely share the same comments that we heard from Kirsten. First of all, we want to make sure that the medications are safe and effective for the population. That would be job one for us to evaluate and then there would certainly be a lot of other things that we would need to tackle as far as how we achieve those drug prices. I think there is probably a lot of unknowns. Certainly, the administration has a lot of different ideas that they can look at, and some may be more fruitful than others as we look to save dollars across the entire industry.

LARRY: You have also gotten several questions about patient financial assistance and drug companies have long provided that kind of financial assistance to patients, as Kirsten mentioned, who cannot for the drugs they need. Recently, there seems to be a trend towards providing coupons or vouchers to assist patients with their co-pays. Steve, Express Scripts has raised issues with that. What is the problem of a drug company giving someone a coupon like a supermarket does?

STEVE MILLER, M.D.: Yes, Larry. There are two different topics. One is coupons and one is co-pay assistance. Coupons are when I am trying to preserve market share, so there are not financially based. We do not need to show need.

This is just you know that there's clinical products out there that compete against each other and I want to keep the patient on my particular product. We are very against coupons because they undermine the co-pay structure. If a drug is not preferred and you give someone a coupon, and say you do not have to pay your co-pay, then what happens is the plan sponsor is stuck with a very expensive drug that they have to pay for. Remember, the patient is only paying for 18-percent of the drug. Their plan is paying for 82-percent of the drug. If you excuse the member's co-pay with a coupon what happens is you then get stuck with a more expensive drug.

Patient assistance programs, however, we do like, because patient assistance programs are financially based. These are people who actually have a need for the drug. They do not have the financial resources to afford it and the pharmaceutical manufacturer is willing to provide them a discount and even sometimes the payer a discount for the patient to have that drug. In those cases, we actually do work very closely with the pharmaceutical manufacturers to make that available.

Remember, going back to the coupons, that the federal government recognizes that this raises the total cost of healthcare and that is why they do not allow coupons in their programs. They recognize that it will raise total healthcare costs for society.

LARRY: That includes Medicare?

STEVE MILLER, M.D.: That includes Medicare.

LARRY: Kirsten, can you give a sense of the scale of the use of coupons from Pfizer as well as patient assistance?

KIRSTEN AXELSEN: It really varies by the therapeutic area and obviously the price and whether or not a drug is typically on a specialty tier where there is a high co-pay versus a low co-pay. I have seen figures of around 20-percent from IMS. Pfizer does offer a co-pay card or coupons. Our feeling behind that is we do want our patients to get affordable access to the medicines that they and their

physicians decide are appropriate for their care. Sometimes they can do that by choosing a health plan that has that medicine on the formulary and available. Other times, they are on a health plan where the P&T committee has made a decision not to put that drug on a co-pay tier that they can afford. Ideally, again, I know that Steve, Celynda, and I, and all of our companies, are working on ways of innovating in our business models, so that we could have the formulary more tied to the value that it brings for that individual patient as opposed to a one-formulary structure for everybody. We do hear Steve's concerns and others' concerns about coupons and co-pay cards. In the meantime, they are offered as a measure to make sure patients get the medicines they need.

LARRY: We have also had questions about whether the pricing of drugs can be tied more closely to patient outcomes and this has certainly come up recently in the pilot for drugs provided under Part D in Medicare. Celynda, is that experimenting or moving at all to value-based insurance design or tiers that are related to or reference pricing that are related to the outcomes of particular therapies?

CELYNDA G. TADLOCK, PHARM.D, MBA: Absolutely. I think two components there. First of all, we are looking at categories of disease states that are proven to have some great offsets in overall care. We are ensuring that those categories have a very low flat co-pay. A good example of a pilot that we

have going on right now, in our individual marketplace, is relative to diabetes. We are showing some really good initial results there relative to the success and the adherence rates in that population that needs to be treated consistently over time for great outcome.

The second thing is more related to value-based contracting. We are getting to think about value-based contracting from a pharmacy provider as well as from a drug manufacturer perspective. We are being very selective with our partners and we are really looking for those value-based agreements where in the real world we can partner with the manufacturer to be able to see if that clinical trial data did come to fruition, and will we really see that type of an offset in something like a hospitalization or another type of comorbidity that we can factor into the offset.

Again, there are two really types of value-based structures I think that we can talk about that we are exploring both.

LARRY: How much of a challenge is it for you as a health plan in thinking about those offsets that people tend to switch insurance plans? They may switch employers and have to switch plans if they are in the individual market. There has been a lot of churn and switching of insurers, switching in Medicare Advantage as well. Those offsets are down the road.

How much of a challenge does that present for these kind of more value-based arrangements?

CELYNDA G. TADLOCK, PHARM.D, MBA: While it does present a challenge, cost is really a problem for everyone no matter who is paying the bill. Whether it is Aetna, Express Scripts, or an individual employer. While that is a challenge, I would say it is not our biggest challenge. One of the greater challenge is probably with these value-based agreements is the design of what you are going to measure, having to agree on what that outcome looks like, what success looks like, and then from an administrative perspective how do we really gather that data in a way that is not creating a large administrative burden.

LARRY: We talked a lot about innovation and it certainly comes up in almost any debate about drug prices and striking this balance between prices, profits, and innovation, and we have gotten several questions along these lines. Kirsten, let me come back to you. First, what share of your revenues would you say you put into drug research as opposed to marketing or other administrative expenses?

KIRSTEN AXELSEN: The pharmaceutical industry invests more in R&D than any other industry in the US. It is around 19-percent on average. Pfizer spent around 7 billion on R&D last year. You will often see people say you spent more on marketing than you do on R&D. That is not the case. When they

are doing that they are typically looking at our financial filings and looking at 100-percent of our administrative costs, and comparing them to what we spend on R&D. Also, the pharmaceutical industry spends about twice the NIH budget on R&D, so it is a huge part of our expenses.

Then, as far as how that connects to reimbursement and the type of drugs that get developed, I guess I just kind of reiterated an earlier point I made, which is you try to pursue the drugs that are going to be both financially successful and meet the patients' needs. Most of the drugs are not financially successful, because of the money that you invest in developing them. A few drugs are very successful and those fuel the future innovation and cover the costs of the drugs that were developed that either never made it to the market or made it to the market and ended up serving a smaller population than was initially expected or did not have the kind of uptake in the market.

LARRY: Steve, how do you see this balance between prices, profits, and innovation? Are we striking the right balance now? Has it shifted over time?

STEVE MILLER, M.D.: Larry. Express Scripts, we have been trying to push for what we consider sustainability. That is actually how do we let the pharmaceutical companies continue to do what they do best and innovate to bring these great new products to the market, but also have access and affordability.

Right now, we do not think the system is in balance. We actually think that we do not have adequate access and affordability. We have actually made recommendations to the pharmaceutical manufacturers what they could do, to government what they could do, what payers could do, what physicians could do.

I will give you just a couple of those ideas. For instance, with the pharmaceutical manufacturers, a lot of it truly has to be around a social contract. That is in the past they did not want to maximize the profitability of every product. In fact, if you go back to an unbelievable episode at Merck, when they invented ivermectin for river blindness, the leading cause of blindness in Africa, they were recommended not to bring the product to the marketplace, because there was no one to pay for it, yet they went ahead and did it anyway and they prevented blindness in millions of people in Africa. Roy Vagelos at that time, it was a high drug inflationary period, he took a CPI pledge. He said he would never raise the price of this product more than consumer price index. It is that type of leadership and it is that agreement to the social contract that we need from the pharmaceutical manufacturers.

From the government, we need things like better funding for the FDA to modernize it so we can get products through that less expensively and faster, because once you have competitive products in the marketplace that is when Express Scripts and

others in the payer community can actually pit those products against each other and drive down the prices.

Then, obviously, the payers not only have to continue to pay, but they have to design co-pays that make sense. We recommend never having a co-pay greater than $150 per drug per month, because we know non-adherence goes up at a higher price than that. We would like to see not only the payers stay in the game, but also design their plans so that the patients have affordability and access.

LARRY: Kirsten, I know you can only speak for Pfizer, but what is your view on this social contract [ph 00:40:18], and whether it has been broken?

KIRSTEN AXELSEN: I guess first we'll start with the giving both inside the United States and outside of the United States. Pfizer and a number of other leading companies have really extraordinary access programs. There is a Diflucan partnership. There are huge amounts of Zithromax or azithromycin donated to relieve blinding trachoma and, in fact, trachoma has been eradicated in a number of countries around the world due to successful use of donated medicine along with handwashing and surgery. Eradicating disease and making sure that people who need our medicines who cannot afford them is a part of our business model, has been for decades, and continues to be going out into the future. In fact, we are working with the Gates Foundation, GAVI, other organizations to make sure

that our vaccines and other medicines are getting to the people who need them. That is absolutely a part of our social contract that just has not changed one bit.

Biopharmaceutical companies also lead in corporate giving with around 19-percent of total giving, pre-taxes and profits. The sector continues to lead both in terms of donated medicines and cash donations. Also infrastructure support in countries where they do not even have basic healthcare services. Our medicines are available at a lower cost to people who need them the most in the United States, both through Medicaid discounts, VA discounts, and through free and donated drugs.

LARRY: We also had a question about when you mentioned the VA and the Medicaid discounts. We had a question about whether there could be savings if the federal government were able to negotiate a better price across all its programs and certainly price negotiation and Medicare has been an issue on the campaign trail. In California, there is an initiative on the ballot in November that would require state programs to pay no more than the VA. Do you think there is any room for savings from greater price negotiation, Kirsten?

KIRSTEN AXELSEN: In Medicare, there is negotiation. Health plans negotiate on behalf of the government and many of them have as many lives [ph 00:42:52] in them as you would see in any country in Europe or outside of the US. The difference

is patients also have choice. There is this balance where the plans are very effectively negotiating rebates and holding down premium growth in Medicare Part D, but also wanting to put medicines on their formulary that will attract patients to their benefits.

Is there room for negotiation? You can have a single pair [ph 00:43:24] negotiation like you have outside of the US and the cost would be access to medicine. Access to medicine now and that you would need to put in a restrictive formulary, which is what you see in preferred drug lists or in the VA. That is how you get the cheapest prices is you limit the number of drugs or hospitals or doctors and that is how you can get the price down the lowest. If you do not want to go that route, then you tend to have higher prices. If there were to be a mandatory price control put in across all the United States and all the drug companies were required to offer at that, you would see less innovation in the future. It really depends on whether we feel like we have all the drugs we need to treat our health conditions now and in the future.

LARRY: Celynda, as a private payer, do you think you can get as good a price as the federal government could negotiating prices in Medicare?

CELYNDA G. TADLOCK, PHARM.D, MBA: Absolutely. I think what really needs to occur in order for us to be able to leverage further discounts is to enhance that choice and

competition. Certain fundamental things could probably change to improve that ability for us to achieve even better pricing than what we have today. One of those things, for example, might be thinking about eliminating the protected class of drugs for Medicare. Another thing might be thinking about how we create a fast-track pathway for the FDA in some of these classes where we only have one or two competitors, so that we have more competition.

Then, if you look away from Medicare and look to the Accountable Care Act, we as well have some more [ph 00:45:22] limitations where there are requirements for drugs counts. If we were able to look at those requirements of drug counts going away, we could still provide a very clinically-based solid formulary, but have that ability to really negotiate deeper discounts to bring back to our clients into the marketplace.

LARRY: Steve, I want to come back to you. You talked about the FDA approval process and I assume at Express Scripts, you have a keen interest in what drugs are in the pipeline. We have seen this explosion of high-priced specialty drugs. What do you see happening over the next several years? Is this a trend that has plateaued or are we likely to see it accelerate?

STEVE MILLER, M.D.: There are currently 7000 products in clinical trials in the United States according Pharma [ph 00:46:18]. We are in this era of great riches when it comes to innovation. When you look at the biggest areas where

innovation is occurring, it is mostly in the area of oncology, which is historically one of the most difficult areas to manage. Because of some of the issues that Celynda and Kirsten have brought up, for instance, the federal government wanting to have relatively broad access to drugs and give people lots of choice. They do not take advantage of essentially commercial best practice. When you have commercial best practice, which Celynda was essentially alluding to, and that is you let us manage the formulary, we make sure that the patients get every product they need at the appropriate time, but we are able to narrow those formularies, so we can drive greater discounts.

We are going to have a huge numbers of products coming to the marketplace, many of them are going to be in cancer where it is more difficult to manage the formularies, but we are also going to have products for unmet medical needs, and we see that the price of these products are going to continue to be astronomic. We're going to have the first gene drugs in the marketplace in the near future. Glybera was approved in Germany for the equivalent of $1.4 million, so when that comes to the United States, while it treats a very small population, it is going to be at a price we've never experienced before. We're going to see lots of new products, we're going to see lots of high prices, and we're going to have to be more innovative in our payment models if we're going to be

successful at creating what we believe is sustainability; that is innovations plus affordability and access.

LARRY: It's certainly a good use bad news story. We also have had several questions about drug advertising and promotion. This too has become an issue on the campaign trail. Kirsten, has Pfizer been increasing or decreasing its direct promotion to consumers?

KIRSTEN AXELSEN: Pfizer does use direct-to-consumer promotion both on television and through social media and other forums. That promotion makes—I believe it is about the same as in prior years, but that is a figure I would need to confirm for you. That promotion often results in patients going in to their doctor, asking about a condition, asking about a medicine. It doesn't always result in those patients getting that medicine, but we believe it's an important tool to make patients aware of what options are out there for them.

LARRY: I assume in your view you believe it works?

KIRSTEN AXELSEN: I guess the question is what does it works mean? If it drives a patient to their doctor to ask about a condition, results in their diagnosis and treatment, and then their doctor deciding with them what is the appropriate medicine, then yes, it works.

LARRY: Kirsten, let me stick with you. Another issue that has emerged is transparency. A number of states have considered legislation to require greater transparency on the

part of drug manufacturers around pricing. Are there measures that you feel would be appropriate or reasonable to provide more information to the public?

KIRSTEN AXELSEN: Sure. That's a great question. The list prices of drugs are among the most transparent in healthcare. You can look online and there are various sources that will tell you what the list price of the drug is. There are also good ways to find out what the prices are at different pharmacies. Most publicly traded pharmaceutical companies, including Pfizer, disclose our total amount of rebates.

What we don't disclose is the rebate for an individual drug to an individual health plan. That's part of a confidential negotiation between us and Aetna or us and Express Scripts or any one of the other health plans. We would like to see more transparency and many of the plans, including Aetna, do a great job, and Express Scripts, at demonstrating what's on the formulary, but a patient should be able to very easily see what their co-pay is for their medicine, what their co-pay is for their hospital visit and their doctor. We're very supportive of any effort at transparency that help patients figure out the real cost of their care.

LARRY: Celynda, we are talking about transparency for drug manufacturers, but in terms of formularies, how easy is it for a patient or a prospective enrollee to find out which drugs are on the formulary and which tier they are on?

CELYNDA G. TADLOCK, PHARM.D, MBA: I think the technology and the digital capabilities that all of the companies have that provide health insurance and pharmacy benefit management coverage to the population has really evolved. Now, there are great mechanisms on the web and also on apps to be able to look specifically for that member for their plan at what tier after the integrated deductible to look at how much that they are going to pay. I think what has to continue to evolve is during that high deductible period that is a little less predictable for the members until they get to that flat co-pay phase. We really believe in promoting simplicity and promoting that transparency with a member relative to their co-pays.

LARRY: Steve, in the name of transparency, you as a pharmacy benefit manager have a lot more information than I do. Do you think there are transparency initiatives that would potentially be effective at bringing prices down?

STEVE MILLER, M.D.: Yes. I believe that transparency is really important for the patients like you have heard. A patient should be able to go online or go on their app and know exactly how much their co-pay is going to be for any given drug in any given pharmacy. We also believe there has to be tremendous transparency for our clients. Our clients should be able to come in, audit their contracts, know exactly what deal

they are getting, and are we living up to the letter of the contract.

Where you do not want transparency is between competitors. We would have never been able to drive down the price of the hepatitis drugs by more than 50-percent if others knew exactly what discount we were getting. This point has been made over and over again that you do not want transparency against—the FTC has looked at it. The FEC has looked at it. It has been shown that when you have a bidding situation like this, transparency with competitors actually sets a floor and actually does the exact opposite. It does not drive down prices. It just allows a floor price.

LARRY: Thanks. We are coming to the end of the hour. I want to ask a final question of each of you. Celynda, I will start with you. As we discussed, there have been a lot of public concern about drug costs. It has been rising. It has been talked about in the campaign trail. States have started to take action. There's this initiative on the ballot in California in the fall. Actually two questions, one is what do you think will be the biggest issue around drug pricing that Congress or the states will consider over the next year? If it's not the same thing, what do you think should be the issue that Congress or the states should be working on?

CELYNDA G. TADLOCK, PHARM.D, MBA: Thank you. Great question. Certainly, the new administration is going to be

looking for large drug savings, so that they can show some budgetary offsets. I think that there is great potential probably in four key areas. Medicare Part D, Medicare Part B, Medicaid and potentially also A [ph 00:54:58] prescribing.

As we look as to what might be the most important, I think the administration is going to look to things that will offer savings, but maybe not be controversial across all the stakeholders. I think patient safety could be something that would emerge. As we look at patient safety, I think enabling the use of some value-based preferred pharmacy networks in some of the populations where we haven't been able to have that in the past such as Medicaid would be a good area. The rising opioid abuse. No one is going to argue that that is a problem that the country needs to come together on to address. Perhaps, looking at the ability to have some of the lock-in programs on controlled substances that in the past have been very resistant for the government population might also be somewhere to look that would also tie into that patient safety domain.

LARRY: Steve, same questions for you. What do you think will be the biggest policy issue either in the states or federally and what should they be addressing?

STEVE MILLER, M.D.: Yes. Again, I want to thank you Larry for allowing us to participate. I think when we look going forward we have this story of riches. We are going to

have a lot of new pharmaceutical products come to the marketplace. I would look at it in several buckets. One is I think we need biosimilars to be successfully launched in the United States, just like generics have allowed us to have affordability for pharmaceuticals in the past decade, biosimilars could have that same salient effect going forward. We need to do everything we can from a policy perspective to get biosimilars successfully in the US marketplace. Unfortunately, the pharmaceutical manufacturers have been suing [ph 00:56:57] the product into submission. We're going to have to really make it clear how we're going to get these successfully into the marketplace. There have been in Europe for over eight years and we believe the savings in the US could be over $200 billion over the next decade if we get them [ph 00:57:13] into the market.

The second is we actually do have to modernize several of the federal programs, because we cannot do, for instance, value-based reimbursement if we're going to have some of the existing rules. Modernizing Medicare and Medicaid so that we can do more value type contracting is going to be crucial and I think some of the experiments that have been suggested by HHS are going down that pathway, but there's other things that can be done.

The third thing is we have to go after waste in every opportunity. Some have estimated that in the $3 trillion of

healthcare spend, there is approximately one third of that is waste. We really need to drive waste out wherever possible. Using best commercial practices, getting into formularies that work, getting into narrow networks that work, where you can demonstrate great health outcomes, but at a lower price is really going to be crucial.

LARRY: Great. Kirsten, you get the last word. What do you think we will be debating over the next year and what do you think we should be debating?

KIRSTEN AXELSEN: I think we will be looking for ways to innovate in reimbursement as much as we have seen innovation in the kinds of drug that are being developed. We need to find ways that the patients with the highest need conditions are not paying the highest co-pays. We also need to find ways to, as Steve mentioned, really drive up the competition, and really have a bake-off between different competing medicines. Part of doing that means you need to have interconnected electronic health records. We need to open up access of information so that anybody who can use it responsibly while preserving patient safety can use it. There are limitations on our ability to do value-based contracts on real-world evidence. We need to be able to use that real-world evidence to have a value-based formulary, so that if someone has tried and failed on a generic, they could be eligible for a lower co-pay on the medicine that works for them even if it is a higher cost

medicine that isn't available to every single person. I anticipate a lot more creativity and reimbursement; some of that will be regulatory, some of that could be legislative.

LARRY: Thank you. We will need to stop it there. Thanks to our great panelists, Kirsten, Steve, and Celynda, and thanks to everyone out there for listening. You'll be able to find a recording of the discussion if you do want to listen to it again and more information on drug spending and healthcare costs generally at kff.org/healthcosts. Thank you very much.

[END RECORDING]