



## **Medicare and Prescription Drug Prices**

**The Commonwealth Fund  
Alliance for Health Reform**

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SARAH DASH: On behalf of the Alliance for Health Reform, thank you for being here for this briefing on prescription drug prices in the Medicare program. We would like to thank our partners in this program: The Commonwealth Fund and I will be introducing the panel in a moment. Obviously a very important issue for healthcare policy going forward and we have some really terrific panelists.

Just a couple housekeeping items, please as you are listening to the presentations, you want to write questions down on your green question cards, you can also tweet them to [#MedicareRx](#) you can also tweet along to MedicareRx during the conversation. We hope everyone is going to stay right till the end at 11:00, but if you do have to head out a little bit early, please do fill out your blue evaluation form, it's really important for us in shaping our programming.

So, I am going to introduce Shawn Bishop. She is my co-moderator here today; she is Vice President for Controlling Healthcare Costs and Advancing Medicare with the Commonwealth Fund and she is going to make a couple of – show a couple of slides to frame the conversation. And before I turn it over to Shawn, let me go ahead and introduce our panelists today. To my right, Laura Keohane, who is an assistant professor at Vanderbilt University in the Department of Health Policy. Dr. Mark McClellan, who is Director of the Robert J. Margolis Center for Health Policy at Duke University. And to his left, Gerard Anderson, a professor at the Johns Hopkins Bloomberg School of Public Health. They have very extensive and impressive bios, are in your packets today, along with a number of interesting reading materials. So, without further ado, let me go ahead and turn it over to Shawn. If you do need wi-fi, the password is here and also on your tables. Thanks.

SHAWN BISHOP: Thanks, Sarah, thank you to the Alliance for organizing this briefing and thank you all for attending, taking time out of your busy schedules to attend this briefing. Prescription drugs are getting a lot of attention and there is good reason. On one hand, prescription drugs now make up 17% of personal healthcare spending in the U.S., with just one percent or drugs on the market comprising 50% of total drug spending. Launch prices for drugs and increases in list prices for most drugs sold in the U.S., including generics, have shocked consumers, payers and policy makers and created concern about the affordability of some drug treatments. On the other hand, the curative effect of some newer drugs and the potential of precision medicine, to provide better treatment, is giving new hope to patients. So, what we have seen lately is truly a tale of two cities. The best of times and the worst of times when it comes to prescription drugs. Today, we focus our attention on Medicare and prescription drugs. Before we turn to our experts, I would like to take a moment to remind us of a few key facts and present a finding on the value of cancer drugs from a study funded by the Commonwealth Fund. First, the percentage of Americans with insurance coverage for outpatient prescription drugs has increased dramatically over the last 20 years. In 1998, 25% or one in four Americans did not have coverage for prescription drugs. By 2014, that number fell to 12% or one in eight Americans. Medicare is a major source of the expanded coverage. In 1998, Medicare had no outpatient drug benefit and we can see Medicare beneficiaries

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made up a small fraction of the population with drug coverage. But by 2014, Medicare beneficiaries with Part D coverage made up 12% of the U.S. population.

Second, while Medicare provides outpatient drug coverage to 12% of the population today, Medicare pays for 29% of all retail pharmacy drug spending in the U.S. Medicare covers even more of the U.S. Drug Bill if you include drugs administered by physicians in hospitals.

Third, although we have made great strides in improving coverage for prescription drugs, affordability can still impede access to medicine in the U.S., according to a bi-annual survey conducted by the Commonwealth Fund. As you can see from this slide, the blue bars on this chart show that 19% of adults under 65 years of age reported not filling the prescription due to cost in 2014. While this is a decline from 23% in 2003, it still represents one in five Americans. Also, as you can see in this chart, by the red bars, 10% of adults over 65 years of age report not filling a prescription in 2014. That is also a decline from the rate in 2003, but still represents one in ten elderly Americans who have not filled a prescription due to cost.

Fourth, as this chart shows, annual per capita growth in Medicare Part D spending spiked in 2014 and 2015 and is expected to remain above growth and spending for Medicare Part A service and Part B service over the next decade, according to the Congressional Budget Office. It is important to know that these figures are on a per capita basis, which means they represent growth per person and they remove the effect of Medicare's population growth on spending. When CBO includes population growth, they expect Medicare Part D spending to grow by more than 8% per year over the next decade. I will say quickly, the dip in the Part D of spending in 2012 that you see on this chart was due to a patent cliff for several blockbuster drugs that allowed the entry of several lower cost generic products in that year.

Finally, I would like to talk very briefly about a new international comparison that finds that U.S. outspends its peer countries on cancer drugs by about five to one. This study was conducted by Elias Mossialos of the London School of Economics. It is a very new study funded by the Commonwealth Fund, it's very interesting. We included a copy of it outside for you to read the entire thing. I am taking one piece of this study to show that he added the drug cancer expenditures in the U.S. and you can see by the red bar on the far right, that United States spend almost 120 billion dollars on cancer drugs in 2014 compared to 53 billion in 2004, ten years earlier. But that relative to the peer – our peer countries, we spent about five times the amount of the next highest country, which is Japan, which spent about 25 billion dollars on cancer drugs. So, that is the first thing I wanted to show you.

What is interesting about what he did in this study is that of course you would expect the United States to spend more on cancer drugs if we have a higher incidence of cancer in our country. So, we might have more people who have, unfortunately, cancer burden. So, we would spend more on drugs. What he does is he adjusts for the incidence of cancer

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across all countries and he shows that once you adjust for the incidence of cancer, the burden of disease in each country – the United States still outspends the next highest country, the peer country, by almost two to one. So, we spent on an incidence adjusted basis, 74 billion dollars in 2014 on cancer drugs and the next highest country, which is Italy this time, not Japan, on an incidence adjusted basis spent 45 billion dollars.

So, what he continues to do in this study that we provided is that he looks at expenditures, he also looks at the health gains from the cancer expenditures in all of the countries and he calculates the value of cancer drugs, so, expenditures made and health gains made. And he finds that, as you can imagine, the United States is not getting the best value for the expenditures and the life gains that we are making. Other countries are getting more value out of the expenditures and the life gains. It's a very interesting study, I highly recommend it. I didn't want to present all of the findings, because we have a lot to share with you today and with that, I will pass this baton on to Laura.

LAURA KEOHANE: Good morning. I would like to thank the Alliance for Health Reform for inviting me to speak today and I would also like to thank the Commonwealth Foundation for funding Vanderbilt's work on Medicare spending growth.

Today, I'm going to talk about how drug spending in the Medicare program looks relative to other sectors in the Medicare program. I'm going to give a very broad overview of factors effecting Medicare spending growth in Part D and I'm going to focus on how we insure beneficiaries who have particularly high drug costs in the Part D program.

So, in recent years, Medicare has had a period of historically low spending growth. And this graph presents the average annual rate of spend growth for several key sectors in Medicare. The bars present the average annual growth for 2008 to 2010 and the blue bars present the average spending growth for 2011 to 2014. And you can see that for several key sectors, inpatient services, position services and post-acute care, in recent years we have actually had spending declines. Outpatient hospital spending has continued to increase, but you can see that it is increasing at a slower rate in 2011 to 2014 than it was in earlier years. The exception to these patterns is Part D drugs and Part B drugs. Part D spending is now increasing at about an average annual rate of growth of 7% per year, while Part B drugs went from relatively flat spending in 2008 to 2010 to increasing at about a rate of 3% in most recent years. And so, when we have this kind of pattern where drug spending is the only thing that is having accelerating growth, relative to other sectors, it raises questions about what is unique to drug spending that underlies these trends.

One thing that is unique to drugs is that they can be a substitute for other expensive medical services. So, in 2012, the Congressional budget office determined that there was enough evidence based on the launch of Part D and other studies to determine that as Medicare beneficiaries fill more drugs, they tend to reduce their spending in other sectors. So, for example, closing the Part D donut hole, which is happening under the

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Affordable Care Act and is being phased in over the next few years, is expected to increase the number of drugs filled by beneficiaries by about 5%. In turn, total medical care spending in Part A and Part B are on things like hospital services and position services, is expected to decline by 1%, thanks to this increase in drug use among Medicare beneficiaries. So, to the extent that we are seeing high drug spending, because beneficiaries are taking more drugs, that might be resulting in some lower spending in other areas of Medicare. And I think this is an important point to bring up as we are considering the incentives for whether insurers have incentives to control high drug costs. If beneficiaries are opting to get their drug benefits through the Medicare Advantage program, where beneficiaries have their hospital insurance, physician services all covered by the Medicare Advantage plan, as well as their prescription drug costs, those Medicare Advantage plans are reaping the benefits of these type of offsets if they are having high drug spending growth, because it might be lowering spending in these other areas. Whereas if beneficiaries are getting their drug benefits from standalone Part D plans, then they are not – those standalone Part D plans are not reaping the benefits of those offsets. So, I think that is an important context to think about as we think about some of the proposals that Gerry and Mark are going to be talking about later.

Of course, we are still concerned that Part D spending is increasing and when we think about why Part D spending is increasing; there is two main parts that we can break this into. First is just, are we spending more per person who is involved in Part D? And that could be considered a factor of many effects, whether it's beneficiaries' health status and how that has changed since the Part D program has started, whether new treatment choices in drugs have come up over the last few years and also, even if beneficiaries are taking the same types of drugs, are there increases in drug prices? But the other big factor is that when we look at average Part D spending for Medicare beneficiary, especially among those aged 65 and over, we have just had increasing Part D enrollment. Participation in the Part D program is up from 51% to 65% in 2014. We have seen that Medicare beneficiaries are shifting from other drug sources and enrolling in the Part D program, which would expect to increase Part D expenditures.

We are still concerned that Part D spending per Part D enrollee is increasing and in one very quick slide I'm going to give a high-level overview of some of those factors. We do have new specialty and biologic drugs coming on the market in recent years that have few competitors. Part D launched during a period of a really slow period in the drug pipeline and as Shawn mentioned, we also had several major drugs that came off patent during the early years of Part D which led to some spending reductions. Of course, as a researcher, it is difficult to pin down exactly how much these new brand name drugs are contributing to spending growth, because we know how much beneficiaries are paying for these drugs at the pharmacy, we know how much plans are planning for these drugs at the pharmacy level, but we don't know how much the Part D plans are getting from rebates exactly for each of these drugs. So, we know, according to the Medicare trustees report that it's about 14% of total Part D costs in 2014. That is expected to growth. We also know, thanks to some work done from the GIO, that there has been an overall decline in prices for generic drugs since Part D launched. Of course, there are some

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notable exceptions where the price more than doubled and I'm guessing most people in this room could name a couple of those exceptions. And then we finally have some incentives for plans and consumers to contain costs. As the Part D program, has evolved, we have seen more plans use things like tiered co-pays for both generic and brand name drugs. We have seen more and more Part D plans set up pharmacy networks where beneficiaries have lower cost sharing if they go to pharmacies that are in networks. But there are also some quirks in the system. So, for example, brand name drugs are currently less costly than generics in the donut hole as under the way that the donut hole is being closed. I'm going to explain some of the details about that. So, the basic premise of the Part D coverage and how the benefit is determined is that there is a period of initial coverage where the beneficiary has cost sharing and then the plan picks up the majority of the cost. And then once the beneficiary spends a certain amount of money on drugs, then they enter into the donut hole. Historically, beneficiaries paid all of their drug costs while they were in the donut hole. The donut hole is being phased out by having beneficiaries gradually ratchet down how much they are paying out-of-pocket. So, for example, for a brand name drug in 2016, a beneficiary would pay 45% of the actual cost of that brand name drug. One of the parts of the Affordable Care Act was that drug manufacturers were required to provide a 50% discount on drugs in the donut hole. What happens is that 50% discount is counted towards how much beneficiaries are spending out-of-pocket. So instead of being credited 45% in out-of-pocket spending, they are being credited 95% of the out-of-pocket spending. So, you can think of this as a shortcut out of the donut hole. Beneficiaries who just took brand name drugs, would have lower out-of-pocket spending before they reached the catastrophic coverage phase, then beneficiaries who just took generic drugs. From the perspective of the Medicare program, we care about that because once Medicare beneficiaries reach that catastrophic coverage portion of the Part D benefit, then Medicare is picking up 80% of the cost for beneficiaries in catastrophic coverage. This was originally set up as an incentive for plans to enter the market so that plans who might be nervous about taking on a new insurance product and in a new market. This would be a reassurance to plans that they wouldn't be stuck paying for the cost of particularly high cost beneficiaries, but this has also turned into one of the greatest areas of spending growth in the Part D program with an average annual rate of growth 20% on reinsurance payments.

I will conclude with that and pass it off to Mark.

SARAH DASH: Thank you, Laura, and while we are getting set up with Mark's presentation, just a reminder, if you want to tweet along, you can use #MedicareRx, thanks.

MARK McCLELLAN: Thank you, it's great to be here with all of you today. I feel very elevated up here on this high perch. But let me assure you that addressing some of these challenges as Shawn emphasized at the beginning with real opportunities for curing diseases and improving people's lives through new pharmaceuticals on the one hand, but affordability and sustainability and support for using drugs effectively on the other. This is a challenge that is going to require us all to work together.

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There are not many easy solutions that come down from on high. But I do want to talk about a few approaches to this problem that I think haven't been getting quite as much attention, but should, given some overall trends and where healthcare financing is going, that so far prescription drugs haven't been a part of, particularly this notion of value-based purchasing. There are a few background points before that. I think many of you know this, but remember that there are different kinds of policy issues and different ways of influencing prices and use for different types of drugs. We have talked a lot about Medicare Part D, that is for oral drugs that people pick up at their pharmacies and administer themselves; typically those are the main cost control mechanisms for influencing use there. Involve PBMs and formularies where the drug plans negotiate lower prices for preferred drugs that they think have higher value or can help them get cost down and that is a big influence on how they are used. It is a big contributor to lower costs for Medicare spending growth over – for drugs over the last decade. The oral drugs covered under Medicare Part B, which under subject of a different set of CMS proposals, are – these IV drugs are administered by physicians in their offices. They do not involved formularies; they involve so-called ASP pricing. So, there is not those same kinds of mechanisms to try to influence prices with Part D. Generic drugs are supposed to have lots of competitors around and the issues there for the price spikes have different causes than in these cases that I have talked about before. And for large molecule biologics, there will be new competition coming soon from biosimilars and how that plays out involves a different set of issue as well.

So, there are a lot of things we could talk about today. What I want to talk about in the next few minutes, is mechanisms that are designed to both promote innovation and keep overall costs down better than our system does today. It's not about directly trying to lower prices based on the traditional approach, you get a bigger discount if you can switch more drug use into a particular medication. It's about shifting to negotiations and models that are about value and not volume based discounts, would be a good way to summarize this. I also want to talk about how this can fit into the big trend with a lot of bipartisan support to moving payments away from being volume-based for other medical services – hospitalizations, doctor visits and so forth. And into so-called alternative payment models that are more at the episode level or the person level where the healthcare providers involved get more flexibility in how they treat individual patients and there of an increasingly personalized medicine, but also some more accountability for keeping total cost down. Drugs and drug manufacturers are not part of that effort as a general rule right now. And that could change in a way that I think could lead to significantly higher value.

I have some extra slides in the deck about better evidence on the value of pharmaceuticals if you are going to pay based on value, you really need evidence. I'm probably not going to have time to talk about that. In terms of the direct value based models for drug payments, I think it's helpful to view two categories here. One is payments based on evidence that exists going in on how well the drug is going to work on a particular patient. Peter Bach has written a lot about this, highlighting the wide

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variations and average benefits to patients of cancer drugs when they are used for different indications. The basic idea here, which is being used by some PBMs now for oral cancer drugs, is to adjust the price based on the characteristics, the indication that a patient has. This is harder to do in Medicare Part B, CMS had a proposal about it that really hasn't been fleshed out, because there is no – that is not the pricing mechanism. Negotiation with a PBM for preferred drugs doesn't really take place for physician administered drugs today. So, you need something like that to make this work there. In addition, you need good measures of value in particular kinds of patients and you need to be able to track not only whether or not a drug is being used, which is typically the basis for all of our payment mechanisms now, but what the patient's indication is for using it.

The other way of doing these kinds of value based payments directly for drugs is looking at the results of how the patients who are getting drugs in a particular population, are doing. Instead of having the drug rebate linked to volume of sales, as is typical today, it could be linked to the quality of care or outcome measures for patients. And this is probably particularly useful when patients who could get a drug, might vary in how well it works, depending on things their adherence or their specific disease characteristics – things that really need to be dealt with at the patient level. More personalized care. There are a growing number of examples of this in the U.S. today. I listed some on here. Just as one example, for some of the new so-called PCS K-9 drugs to lower cholesterol and a very powerful and clinical trials, the payments with some of the PBMs for those drugs and some of the insurance plans for those drugs are tied to whether the patients who are taking them, actually achieve in real world practice, those substantial reductions in cholesterol levels. There are a lot of challenges to implementing these models on a larger scale. Some people highlighted the fact that, well, if a drug doesn't work in a particular instance and therefore there is a very big rebate or maybe even no payment for the drug at all. That could complicate the use of the so-called Medicaid or 340 B or other federal best price approaches, you know, where the federal government in these programs automatically gets the lowest price that is negotiated anywhere for the drug. There are concerns about anti-kickback regulations and the OIG's interpretation. If there is sharing of information or data or support for how you help a patient adhere to a drug between the manufacturer and providers who are involved in using these drugs. Or a health plan – is that an improper payment? Integrating with Part D, I think Gerry is going to talk about that a bit more. Off-label communications, typically the data and the evidence that are used for these have not risen to the level of something and be captured – FDA standards for putting on the label for a product. So, a number of obstacles, but I think there will be a lot more attention to implementing these models in the next few years.

The other thing I want to emphasize here is that it's not just about changing the payment for the drug and on the provider side, but on the patient side as well. So, there are I guess what you might call value-based tiers now and that generic drugs are typically free or close to free in Part D plans. Whereas drugs that have higher price relative to impact, typically have much larger co-pays, they are on higher tiers. Those tiers to date have been driven in good part by the price of the drug rather than the overall value of the drug. So,

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some alignment there as these models get implemented, is also going to be very important and again, it's very difficult to do that in the absence of negotiated formularies.

I do want to close out my remarks by shifting gears to putting drug payment reform in a broader context of payment reforms taking place today. One of the things that I do is co-chair the Healthcare Payment Learning Action Network, which involves CMS, private payers – really a broad group of provider, consumer, patient group, stakeholder around trying to support this movement away from paying for volume for other healthcare service and towards what we called Category 3 and Category 4 payments or the Alternative Payment Models that also had bipartisan support and in MACRA, that move away from paying for specific services. Just to give you one example of that, CMS is implementing an oncology care model, it's turned out to be pretty popular with both small and larger oncology practices around the country. And this model, instead of just getting fee-for-service payments for administering drugs or treating a patient in the hospital, the oncology practices get a per member, per month payment and they also have some new accountability for demonstrating that those patients are getting better experience of care, better quality of care, and lower overall costs. So, it's a shift away from fee-for-service and it is going to influence, I think, the way that they use prescription drugs. I want to contrast that with the main known part of the CMS Part B proposal, which reduced further the payments for administering particular drugs and I think the thing to take away from this chart, which also reflects some work that Peter Bach has done and I have been involved with to some extent, is that that proposal resulted in a net reduction – would result in a net reduction in payments to oncology practices. Money that they could use potentially for other stuff. So, contrast that approach with like, the oncology care model, which has turned out to be much more popular, relatively uncontroversial, being implemented now, that gives oncologists more ability to decide which drugs are right for which patient, without it being tied to the price of drugs. So, the price of drugs administered so much and giving them more of an opportunity to use drugs and actually all other aspects of care effectively. So, that is what I mean by alternative payment models and I expect that CMS does revise its Part B proposal, they do something to better align it with those models.

And just very briefly, since I'm out of time, I think there are some real opportunities to align drug payments with these alternative payment models. Gerry is going to talk about this, but I think Gerry's version is a bit a different, where the healthcare provider is going to be held accountable for the cost of drugs in an episode more directly. What I'm talking about here is, having the drug manufacturer contract as part of sharing the risk in those episode payments or ACO payments for better outcomes and lower cost. There is precedence for doing this and CMS's current proposals for alternate payment models in Medicare, where a hospital may be accountable for an episode of care or a primary care group may be accountable for the overall cost of care for a group of patients and then they can subcontract or form new kinds of relationships to share those risks with post-acute care providers, specialists, or others. Doing something exactly analogous for drugs, would do a lot more to align the goals of effective medication use – better outcomes and lower cost for a patient, with things that are happening in other payment models right

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now, effecting the other healthcare providers. Drugs really should be a part of that in order to get the most value and the lowest cost per patient. So, let me pause there, thank you.

SARAH DASH: Thanks, Mark. Gerry.

GERARD ANDERSON: So, thanks for the Alliance for allowing me to talk about including bundled payments – drugs in bundled payments and catastrophic spending under Part D. I have the opportunities from funding from the Commonwealth Fund and from the Arnold Foundation to direct a whole group of faculty [loss of audio].

One of the most important parts – I'm used to talking to large groups, so – is bundled payments. And essentially, I had the opportunity a long time ago to work on designing the first bundled payment system, which was the DRG system, when I worked in the Secretary's office back in the 1980's. And what we have seen is a growth of the bundled payment program over time to include physicians, to include hospitals, to encode now post-acute care, readmissions, a whole variety of things. And pharmaceuticals are a very important part of all of these treatment plans and yet, in most every case, they are outside of the bundled payment. And they continued to pay fee-for-service, so they are not value-based payments. And so, the question is, how do we get them, if we want to, into the whole issue of bundled payments? So, an example that we have right now is the whole issue of knee and hip replacements. And you have it as – you include all of these services, which are on your slide, and someone gets a bundled payment that includes all of those payments. There is strong, clinical evidence, even within hips and knees, that including pharmaceuticals, could make a significant difference in outcome in terms of pain management and a whole variety of other types of approaches. But drugs are not a very large portion of the spending for hips and knees, so that is part of the reason, probably, they weren't included. Well, what I think is important in all of these policies, is the idea of incremental uh, steps or baby steps in taking certain kinds of changes. So yes, pharmaceuticals are not a large portion of the hips and knees. They are a large portion of the oncology expenditures that Mark talked about earlier and yet, they are not typically included in the oncology demonstration. So, you know, you are giving somebody chemotherapy, but you are not typically including the drugs in that bundled payment for it and it would strike me as an important thing to be able to do. So essentially what we have to figure out is, how starting small with things like hips and knees, can we then grow when the drug expenditures are quite large for things like diabetes and other chronic diseases? We learn in the small ways to do something much larger. So why should we include drugs in Part D? There is a whole series of reasons. If you go onto the appendix of the materials I have, I will give you a whole series of reasons. But essentially what I really want to say is, it really places the physician, the clinician, in charge of the process. And so, they are the ones who know the patient best. They know the patient better than the PBM. They know better than the PDP what that patient needs, what is their ability to comply with practice? A whole variety of things. What is their specific clinical condition? What other drugs are they taking? Their family situation? They know all this information. So, they can do it much more effectively than anyone else can do it, and so

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that is the major reason to include drugs into Part D drugs into the bundle. Now, as I said, it's not very common that drugs are included in the bundled payment, but Congress in 2011 mandated that for the end stage renal disease program, they in fact would be included into the bundled payment. And so, what has happened over a period of time is Congress and then CMS had developed a program to include drugs into bundled payment. And there were a whole series of challenges, but the rationale is what essentially the Office of the Inspector General said when they did that first analysis of the ESRD program. And it said, by implementing the bundled payment rates, CMS thought to eliminate incentives to overuse separately billable drugs and to promote equitable payment and access to services in ESRD facilities that treat more costly patients. So, we have an example of doing this. They ran into a whole series of challenges about which drugs to include, how much to pay, the technology change, drugs that were in the bundle went off patent and changed the whole status thing. So, they had to overcome a whole series of challenges in designing the system. But essentially what they were able to do was overcome all of those challenges. So, if you take and you build on the experience that we have had first with DRGs and then with all the bundled payments, we had to go through a whole series of challenges in those and then we learned from what happens when we do end-stage renal disease and include drugs. I think it's something that we can do. It's a way to include drugs into bundled payments. Again, a lot of challenges, but a doable kind of thing.

Let me just briefly then turn to catastrophic spending in Part D. Laura did a very nice job and Shawn did, of explaining the issue. And what we know is that expenditures are rising much more rapidly in the catastrophic part of Part D than other ones. When Mark and others originally created the program, the concern in Part D catastrophic were people with multiple chronic conditions who had a lot of – took a lot of pharmaceuticals and they would essentially – if there wasn't a catastrophic point, the Part D plans would be less likely to enroll them. But what's happened over time is, it's not that people have gotten sicker, the problem is that all of a sudden we have these Part D drugs that essentially – are very expensive, that essentially are the ones that automatically, because of their high price, put you into the catastrophic phase. So right now, what happens is the Medicare beneficiary pays what they have to pay to get to the catastrophic amount and then they have to pay 5% once they enter the catastrophic amount. And for a drug that costs \$100,000, that is \$5,000. That is a significant amount just in the catastrophic part. And then the Part D plans pays 15% of it and the Medicare program is the reinsurer and pays 80% of the cost. But the Medicare program has no ability paying 80% of the cost, to say anything about the price that is in fact being paid. In the past, it probably wasn't gonna be a major concern because it was a lot of people taking small, not very expensive drugs, but now it's people taking one drug. So, the situation since 2003 has changed dramatically but the Medicare program still doesn't have an ability to negotiate price.

So, what has Medpac taken a look at this and said? Well, what we should do is shift it from 20% - from 80% Medicare to 20% Medicare, from 15% private insurance to 80% private insurance, to increase the subsidies to the Part D plans because they are taking on this additional risk, to eliminate all the cost-sharing to Medicare beneficiaries. And I look

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at this and I say, this is a definite improvement, but my concern is, now there is this probability since the Part D plans are paying 80% of the cost, that they would essentially be not willing to take somebody who has multiple chronic conditions, not willing to take somebody who has a disease like Hepatitis C and other things, because they know they are going to lose money on that if they have to pay 80% of the cost of those things. So, I'm very concerned about that.

So, what do we essentially do? Another alternative to Medpac is basically to allow Medicare to negotiate prices when the drug costs more than \$7500, because this immediately puts Medicare in the catastrophic amount and Medicare paying 80% of the cost. You could means test the program instead of eliminating it, so only the most expensive and the most affluent people have to pay for the drugs in the catastrophic amount. We think there are some incentives for the drug companies to participate and following up on what Mark suggested, although I'm not sure he would agree with this, is essentially Medicare could determine the value of the drug to the Medicare beneficiary or Medicare beneficiaries in order to set the price, because we know CVO is reluctant without a formulary to say that Medicare can negotiate.

MARK McCLELLAN: I probably wouldn't fully agree with that, but thanks for the preface.

SARAH DASH: Do you want to respond to that since we are on it? Shall we move on?

MARK McCLELLAN: Okay, maybe quickly on his last point about price negotiation by Medicare. So, remember that there is price negotiation in Part D, even for drugs in the catastrophic range, it's just done by the drug plan and the concern is that because the drug plan isn't bearing much of the cost, it's 95% reinsurance, that they don't have as much incentive as they might, otherwise negotiate a lower price. But add to that that some of the changes in the ACA that Laura did a nice job of going through earlier, where basically the manufacturer is sort of giving something like a coupon in the donut hole, that too reduces the incentive for plans to really negotiate more strongly. So, it does seem like if there is a first step and maybe in the direction that Medpac described, to actually get some lower prices, you might want to start with making the plans a bit more sensitive. The challenge that I have with a lot of the government price negotiation proposals, there really aren't any out there that CBO thinks would actually save money, because none of them give CMS or some entity in CMS the authority that is really needed to negotiate lower prices, which is, at least under traditional models, telling patients that you are not going to get the drug, or being able to influence how the drugs are used. And having a CMS entity – starting out with solving the problem for these very sick patients with serious illnesses, starting out with trying to solve this problem by setting up an entirely new government entity that would have real authority to restrict access to drugs to Medicare beneficiaries seems challenging and I think there are other ways to get at the same concern.

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GERARD ANDERSON: So, that is why I think you move towards value-based pricing, which is essentially what Nice has been doing for 30 years or so, it's a different model and I certainly wouldn't advocate it for most pharmaceuticals, but for the very expensive drugs where Medicare is paying a lot. I'm not sure that the private insurers will have any better ability to negotiate if they are more on the hook and then I'm very much concerned about the access side. This is just a way that we can disagree.

SARAH DASH: So, we have reached the Q&A and discussion portion of today's briefing and so I want to invite you to write a question on a green card. You may stand at the microphones on either side of the room or you can tweet your question to #MedicareRx and someone will bring it up to me. But while we are getting settled, I also want to invite those who are standing to come forward if you would like, there are some seats up front, don't be embarrassed, it's okay. You can come and sit if that would be more comfortable for you. But I want to kind of just mention or continue on this question of negotiation and just to clarify a point and then I also want to take the moderator's prerogative and I want to ask a totally different question. So, I get the first two questions. So, just on the negotiation question. I mean, so, my understanding is that part of why or maybe the reason why CBO says that Medicare negotiating will not save money, is because in the absence of a formulary where the government can essentially restrict access to a particular drug, they do not have that negotiating leverage. And so, while public opinion is very strongly in favor of negotiating, I wonder if you can speak to that question of the formulary and the ability to exclude a drug from the formulary and then just to really throw a zinger in there, if you can look ahead to the future and you talked a little bit about precision medicine, Mark and how is that going to affect things down the road? When it comes to this question?

MARK McCLELLAN: Well, I think we sort of covered the formulary issues. I don't care, if you want to take that one. I'd actually like to hear how your CMS entity that would determine value and then exclude drugs based on value determination, I mean, that's not a legislative proposal yet.

GERARD ANDERSON: Well, it's certainly not a legislation proposal, but that's why we're here today. So essentially, the idea here is that there's a number of groups that are developing what's the appropriate price to pay. ICER and a whole variety of other entities out there in terms of trying to identify value. They are used in the private sector to do the negotiations. I'm not sure that they are the only factor, and probably are not the only factor but they are a very important factor so we are moving ahead and trying to identify value in this and it would be, in this case, value to the Medicare program through the Medicare beneficiaries. So, there are methodologies for specific drugs to essentially identify the value of that drug and that would be essentially the approach, so it's no longer a negotiation because I agree with CBO that probably Medicare can't negotiate very effectively for these drugs, but if there was an ability to determine the price based upon value, that's a different approach to consider.

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MARK McCLELLAN: So that does essentially sound like shifting the system we have now, something more like nice and explicit ability to say, you know, beneficiaries can and can't get the drugs based on this value score that comes out.

GERARD ANDERSON: Correct. Only for a very narrow set of drugs.

MARK McCLELLAN: So, the other approach for doing that is to continue to build out the more privately competitively based drug negotiation approaches that exist now. Those ICER calculations, frankly the nice calculations, a lot of the growing value valuations that are out there are actually used by Part D plans now when they set their formulary. So, it's not they're – and I was trying to emphasize this point earlier – it's not like there's no attention to value at all in formulary design. I think we're just saying that it could be greater. So, the alternative to what Gerry was saying is to take some steps to encourage and create incentives for the drug plans. We're doing this negotiation now using a system that already exists to have stronger incentives to get prices down, which would not require setting up a new government entity which, again, I don't see a lot of political support for that, even among people who are generally advocating for more government role; that would be an alternative. So, I would suggest that there are ways to modify the current rules that build on that system that's actually worked fairly well for Part D and has done it in a competitive way. So, again, these value determinations are done by PBM's, by the different drug plans, but there's not just one government entity doing it and they are negotiating on behalf of millions of Medicare beneficiaries.

Sarah, I just want to get to your other question about more personalized care, and this is the reason that many drug manufacturers and payers are exploring some of the value based models that we discussed where the main value of the drug doesn't come only from the fact that it really works in some way, but also depends on things like which patient gets it based on all kinds of patient characteristics, how adherence works, which depends on characteristics of the setting in which it's used, and putting the manufacturers accountable for that is behind some of the models that I mentioned earlier.

I would draw a distinction, I think, between Gerry, and you can correct me if I'm wrong, the way that you're describing how these episode models which, as you said, you know, basically just try to make the doctor, the hospital accountable for these drug costs and essentially take them out from Part D or wherever they are, and the model that I was talking about, which is about aligning the financial incentives for drug manufacturers within an alternative payment model contract, you know, aside from deciding what's in and what's out, one of the problems with that is for, you mentioned, ESRD, but that was done for sort of Part B drives and I think you did it for Part D and it's actually started influencing the way that drugs were used that would have a significant interaction with the discounts that Part D plans are able to get. I'm not quite sure how that plays out. But I think, more importantly, if you think about alternative payment models now, the real goal is to get everybody aligned—the doctor, the hospital, the specialist, the post-acute care providers—and while I do think that doctors know a lot about how to use a medication, manufacturers do too, in terms of which exact patients would benefit and a lot of

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characteristics of the safety and efficacy profiles, the drug for certain kinds of patients, and a lot about what adherence systems work, and just as, you know, it's kind of a contrast between saying an alternative payment model should just be for primary care doctors and they can save money if they use less expensive specialists, there are, I think, more successful models now that bring in the specialists, too, and change the way, say, the oncologists are paid or the specialty doctors are paid. Similarly, doing the same thing with drug payments, I think, would make a bigger difference and could also be implemented more incrementally.

GERARD ANDERSON: The only thing I would say is that you really want to have them as aligned as possible and, for me, putting them all in the same bundled payment is the most efficient way to do the alignment. I think the pharmaceutical industry has a lot to contribute. The PBM's have a lot to contribute and a whole variety of people already do it, but I still want my doctor making the decision of which drug I get and I want them to have the same financial incentives to do that, or to have an extra day in the post-acute care or something else. So, I just want the alignment.

MARK McClellan: In the model that I was describing, the manufacturer would actually help share in some of the risks that the doctors face now. If the patient costs are too high or if outcomes are bad. I mean, that should be on the drug manufacturer too to get them fully aligned. But rather just still as a separate, independent contract.

GERARD ANDERSON: And they could do that as part of the bundled payment. They could still participate with the doctor in that way.

MARK McCLELLAN: Alright. Well, maybe we disagree less than I thought. We'll see.

SARAH DASH: So a lot of great discussion. You are talking about alignment and we actually have a couple of questions on cards, and Dr. Poplin, I see you at the mic so we will get to your question, but since we're talking about alignment and since Laura and her side has also mentioned this possibility for perhaps greater alignment between the drug plans and the medical side in a sort of an MA Part D combined plan versus a standalone, I want to explore that a little bit more, because that does get to this question of integrating the data and the use of prescription medicines in a broader context of medical care.

So, one question here was how could bundled payments that include Part D drugs address the lack of alignment between Part A and B and Part D, which I think is kind of where we're going with this, and there was a similar question on a card and Shawn may have something to add before we get into this discussion.

SHAWN BISHOP: I have a follow up to Mark, but I'll wait for other folks, too. I'll follow up with you in a minute, but this is something on the bundled payment for Gerry. This is an interesting question, and they want to know: does the fact that beneficiaries are in standalone Part D plans—and it would be great, Mark, if you could comment, too—is the fact that they're in separate plans, separate formularies and all that, is that the

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challenge for integrating D into the bundle? What is the challenge? You mentioned challenges and I know that you were brief in your comments. What are the challenges about doing it either what you're talking about, Mark, with the standalone plans, standalone Part D plans, or Gerry, putting them into your bundle? Are there challenges in the fact that they're standalone plans? Does that create its own challenge?

GERARD ANDERSON: Well, there's a number of challenges as a result of standalone plans. One is that only about 70% of Medicare beneficiaries are in Part D plans, so 30% of the people are not and, therefore, if you did a bundled payment you would give those 30% of the people a significant benefit that they would not be paying for, so somehow you've got to recoup that amount of money. Also, somehow, when the Part D plans provide a bid, you've got to figure out a way to take the money out of that bid that goes into the bundled payment. Again, I think there's a number of technical solutions that you could do to do that, and I could go into those in much greater detail. There is the idea that when Medicare sets the rate, it's based upon historical data and drug pricing, drug utilization, what goes on and off patent changes dramatically. All those things have been worked out in the ESRD payment and a whole variety of other ones. In my appendix of the slides I go through each one of those. I could go through them in much greater detail but I think most of you would be quite bored.

MARK McCLELLAN: So, I think what I'm talking about is a bit different and, again, ESRD is an interesting example. We could talk about that more. There are some other things that happened at the same time like new evidence suggesting that some of the most costly drugs raise red blood cell levels were actually harmful, but those were occurring in the Part B context, so these are drugs that are administered in, in that case, dialysis centers or, you know, think of it as physician offices as opposed to drugs that people get on their own in a pharmacy and they're just handled in a different set of contracts and that leads to a lot of those special problems that Gerry was describing and integrating into Part D. There's no question that this is a lot easier, these models are a lot easier to do if you've got one plan that kind of covering everything. So maybe one reason why we're seeing more of these models in programs like Medicare Advantage plans or commercial plans for like the PCSP 9 drugs that I mentioned earlier that really do have all of those costs in together. What I was emphasizing in the version of integrating with alternative payment models in Medicare was something a bit different. It's rather than the government trying to decide what all exactly is in the bundle or not and redoing incrementally and I think in a pretty complex way, all of the Part D contracts and maybe having trouble keeping up with changes in relevant medications, instead have an opportunity for the drug manufacturer to enter into a direct risk sharing contract with the providers that are going at risk. So, that would be very much like what CMS has allowed so far in some of the more advanced alternative payment models, like the next generation ACO or in some of the fully at risk bundled episode payments for cardiac and joint care where a hospital can subcontract, in the latter case, the hospital that's in control can subcontract with a post-acute care provider or with physicians where they share in the risk and also share in some of the upside benefits. It requires things like modifying anti-kickback rules which are designed for fee-for-service payments, not where everybody's

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aligned and trying to get overall costs down and improvements up. It requires modifying things like off label communications, since this really is about alignment, and you need communication and sharing of data for alignment. But I think it's a different way, without having to disrupt the whole Part D structure, to get at the same goal.

GERARD ANDERSON: Drugs have been part of Medicare Part A expenditures for hospitals since the beginning, since 1983, so you know, there's been lots of changes in practice over time in the hospital setting and hospitals have been able to adapt. So, it's possible to adapt to changes in pharmaceutical pricing and new drugs coming onto the market and off the market. And in end stage renal disease, some Part D drugs are, in fact, included in the bundle. They've done a very clever way of including certain Part D drugs in the SRD bundle. So, there are precedents for including this and they've been worked out.

SARAH DASH: Thanks. Anyone else want to comment on that? We have had someone at the mic very patiently waiting. Go ahead.

AUDIENCE MEMBER: I'm Dr. Caroline Poplin. I'm a primary care physician. My question is for Shawn. In the international comparisons, did the countries achieve their lower per capita expenses by eliminating expensive drugs or by reducing the prices? Before you answer, let me just say, one of my day jobs is working at a law firm that represents whistle blowers who contend that there's off-label marketing and that's considered a false claim against the government and it's illegal. We sued Amgen for erythropoietin, that's the ESRD drug, and one of the concerning things—and we won—one of the concerning things that we saw was that the PBM's who negotiated rebates and discounts did not pass those along to the consumers. So, the consumers ended up—the nursing home patients in our case—ended up paying the high price.

SHAWN BISHOP: Thanks for that question and comment. So, in the study, it's a great question. So, there's different moving pieces in the value equation. So, according to the study, quoting this researcher, for the countries that achieved a higher value, okay, so they had a higher value relative to the United States, there was multiple drivers, but generally speaking, these countries had utilized techniques to negotiate the entry of drugs to the market that added more health gains than the United States. So, we don't have a way of, how do I put this, negotiating which drugs come to the market based on their health gain, right? It is, they are approved by the FDA for safety and efficacy, and they're on the market. The health gains are not a part of the equation when a drug comes to the market in the U.S. That's the current system. In these other countries, they have organizations, some of them are government organizations, some of them are quasi-governmental, and they negotiate with the drug companies based on whether or not they think that they're adding enough health gains. They also negotiate price, so they can, but it's the health gains have that. So, they have less drugs on the market, in other words, that have low health gains. We have more drugs on the market in the U.S. for cancer but some of them have very low health gains and that's leading to his calculation that part of the reason for his conclusion is that the United States has less value overall for cancer drugs.

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So, that's your answer. But it's a little bit more complicated than that, but that's the general trend that he saw.

MARK McCLELLAN: I could just add, I mean, that's behind the proposal Gerry was discussing earlier, right, is having one government where you say, you know, if this drug isn't low priced enough relative to its value you're not going to be able to have access to it. And I'm just saying that there hasn't been a U.S. proposal to do that. Another way to address the same goal, as you pointed out, these volume-based contracts that really encourage more marketing and maybe low value uses, would be to bring in drugs to these other payment reforms where now the doctors, the hospitals, they're paying a lot more attention to value and drugs are not part of that. And it just seems like it's not sustainable. There's no question that I think our country is moving in this direction of paying more on a value basis overall and right now drugs are kind of behind all of that even though these are the kinds of treatments that really should be more personalized and the cost of another pill is really low, you know, it's not the kind of thing that you want to pay for on a fee-for-service basis in the future, I think. So, I think another way to go, besides Gerry's, is to bring in the drugs more into the payment reforms that are actually being implemented in the country now and putting manufacturers more directly at sharing in the risk for results.

GERARD ANDERSON: Well, that would be bundled payment. But the other issue is essentially that I don't want to take away access to people. What I want to do is say the value of this drug is X. This is how much you're willing to pay for it, and if the pharmaceutical company doesn't want to sell it for that X, that's their choice, but essentially saying this is the value of the drug to the Medicare beneficiary. So, I'm not saying there is a formulary and if you don't make it like NICE does, this is the price that we're willing to pay.

MARK McCLELLAN: The related challenge to that as we move into more personalized medicine is that the availability definitive evidence on the value of a particular drug for a given population of patients is, number 1, uncertain; number 2, likely to – does vary a lot and we're likely, over the coming years, hopefully as we get into more personalized medicine, learn more and more about what works. So I think what I'd like to see is more incentives for the drug manufacturers, the providers that now are trying really hard under difficult circumstances, to pull more data together, develop more real world evidence on what exactly they can do to treat patients better in particular circumstances, that that seems like the direction to go and I don't see – we just don't have the evidence base for that yet for, I think, decisions about value for broad groups of patients that most physicians and the American public would be comfortable with.

GERARD ANDERSON: Right. And if you paid on the basis of value, the data would become available.

MARK McCLELLAN: I guess the difference is, I think you're describing value that would be set by the government as opposed to value that could be determined by doctors, patients, working with specialists and manufacturers to get the greatest value in particular

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circumstances. And I don't think the approach that you're describing will get there. And this may be a disagreement.

GERARD ANDERSON: Right. But again, I'm only focused on the very expensive drugs.

SARAH DASH: I want to let Shawn get a follow up question and then I think she has a question for Laura, too.

SHAWN BISHOP: Well, it's more of a comment and then I want to go to Stu, standing at the mic. I just wanted to just comment on Mark's point that, and using the example of the study, where there's a difference in the value of what each country's getting for cancer drugs. Mark is right that the difference in the value basically this is the opportunity for the United States. There is a tremendous opportunity for the U.S. to get better value out of cancer drugs. We're hearing different approaches, but I think that there's really agreement on we need to get better value. Now, whether or not other countries they have more centralized ways of negotiating value, we have a more, you know, decentralized system here in the United States with different payers, but we're talking about moving towards getting higher value for our drugs in the United States, I think that's a positive. Mark, I had a quick question for you, and then we have lots of folks at the mic.

Right now, the payers in the United States, you mentioned in your studies – very true – you mentioned that they're mostly getting volume based discounts, and so that's the more drug that you sell the more discount, the more rebate that you will get from the manufacturer. How do we move from a volume-based system to a value-based, and how do we get those payers, our disparate payers, how do we get them to do this because they now have a system that's built on volume-based discounts? How do we get them to move? Are they going to do this on their own? Should we have some kind of a requirement that this happens? How do go from volume to value within our system?

MARK McCLELLAN: We are going from volume to value in most other parts of our system, right? Where now, you know, physicians—I'm going to give the example of oncologists who are entering into these new payment models where they don't get paid just based on the traditional services they provided. They get paid some on that basis but not just fee for service, fee for volume. They also get a payment to take care of patients that gives them more flexibility in what they can do and if they reduce overall costs, if they improve outcomes, they get more support for that. So, that's moving towards paying for value. There has only been limited progress in that dimension and including pharmaceuticals. And Gerry and I have talked about a couple of different approaches to doing it. I think with Gerry, and I like that the ESRD bundle would put the accountability essentially just on the provider, you know, not any role for manufacturers in taking on risk and taking on accountability for getting better outcomes. I think the approach that I've described is more incorporating drug manufacturers in those bundles. I'll give you another example. We've been doing a lot of work related to anti-microbial resistance

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where if you could ever imagine a system where fee-for-service payments for drugs should not be used that's it, right, because you want to make these new medications available to treat resistant organisms and then not use them, except in the cases where you actually need to. Well, right now, under our current payment system for drugs, there's very little incentive to develop those kinds of medications because, you know, it's costly to get it to market and then once it's on the market you should not really use it very much. Well, a payment system there that was not related to volume but, instead, had at least part of the payments related to something like a per member per month, you know? Make this drug available to a population if it's needed but don't tie the payments so much to when it's actually used. That's exactly the same kind of thing that's happening in every other part of the U.S. healthcare system now, where we're making—it's still got a long ways to go—but big steps and just announced yesterday 25% plus of healthcare payments, aside from drugs, in so-called alternative payment models system wide. Thirty percent plus in Medicare. Drugs is much, much lower than that, even though there are lots of ways in which this could work better.

SARAH DASH: Great. Thank you. So, we saw folks at the mic, we've gotten some really good questions on the cards and through Twitter. Just as a reminder, if you do want to tweet a question, #MedicareRx, or write it on a card. We have about 20 minutes left, don't go anywhere, but if you have to, fill out your blue evaluation or I will find you.

So, we've had a couple questions here about essential and, in some cases, perhaps, lifesaving drugs, and I want to ask these as they relate to the value question. One question is that there have been concerns about insulin being placed on higher specialty tiers and there are, of course, other examples. And there's a related question about the protected classes and the specific question is would loosening them move the needle on cost and what would the downsides be. So, I want to give Laura a chance to answer that and then give other a chance to comment.

LAURA KEOHANE: I think one program that hasn't come up today is the low-income subsidy for Part D. If your income is below 150% of the federal poverty line you can qualify for assistance with your cost sharing amounts under the Part D program as well as your Part D premiums, so I think, to the extent that that program protects access for low income beneficiaries and, in particular, I think it also is important to note what Gerry mentioned during his presentation, that there's no overall cap on for drug spending, even if you enter the catastrophic coverage phase you're still going to be spending 5% of whatever your drug costs are. So, one thing that MedPAC has recommended that Gerry didn't mention is an overall cap on drug spending which I think would provide better access to beneficiaries in these types of situations where whether it's insulin or other medications that are particularly high cost, having some sort of overall cap would help provide access. In the case of insulin, in particular, one issue that's been raised about the FDA drug approval process is whether we should be prioritizing applications for generic drug applications to be able to get more competition in the market. We've seen that as generic drugs either have more manufacturers move into the market or fewer manufacturers move into the market, that type of competition among the generic drugs

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has moved prices. So, to the extent that we can get more generics on the market, that might help improve the insulin situation.

GERARD ANDERSON: I'm concerned about high prices, but I'm really concerned about access. And as I look at the high prices for drugs like the hepatitis C drug, hepatitis C is the major infectious disease killer in the United States right now, and yet only about 10% of the people who have hepatitis C are getting the drug and that's because the states, the prisons, and many of the Medicaid programs can't afford that drug. And so, we actually have an infectious disease that we could cure in the United States if everybody got the drug and yet the high price is the major influence why we are not having universal coverage for this drug. So, for me, it's not the high price of the drug, although I am actually concerned about it, it's really the concern over access.

MARK McCLELLAN: Just back to the point on insulin and generics, as I mentioned at the outside, you know, think about that there are different kinds of problems for different types of drugs and sort of in these non-branded markets, or not fully branded markets like insulin, finding ways to improve competition would be really helpful. A lot of people, you know, that suggestion about reducing the FDA backlog is out there. I have to say, knowing something about the FDA staff and how hard they try to work on these issues, if there were some applications for some of these high priced non-branded drugs in the pipeline I think they would get acted on pretty quickly. I think it raises the deeper question of why isn't there more market entry in these areas? And that goes to issues like are there ways to clarify the regulatory pathway for manufacturing generic drugs to bring down the cost of entry and make it easier for manufacturers to compete and are there other incentives that could help, too. So, important set of issues but different from some of the other ones we've been talking about.

SARAH DASH: But is this more of a competition problem or is it more of a benefit design problem, and maybe one is shorter term and one is longer term?

GERARD ANDERSON: So in the generic space I think it's a competition problem more than it is a benefit problem. We guess, and we don't know exactly, but we guess that about 17% of the generic drugs have no competitors and these are the Turing pharmaceuticals and those kinds of things that we've heard about and it's partially because the market is very small. There's only like 6,000 people that were taking the Turing drug, and so why would a second manufacturer enter that? There are the burdens of going through and there are a whole series of reasons why they're not doing it. What we proposed, in the JAMA article, is essentially three things. One is expedited review when there was no competition. The second is until there was competition allowing compounding, and the third thing, again, when there's no competition, if there was an original manufacturer, in this case it was GSK, that was still manufacturing the drug, that they could import it from other countries and not have to go through the process because they've already gone through that process a long, long time ago. So, I think there are some fixes where there is no competition, but that's very different than the drugs in the generic space where there is competition.

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MARK McCLELLAN: I'll also add to that, regulatory steps to make it easier for manufacturers to enter, and not necessarily exit, a small molecule market. So many of these drugs—insulin is not exactly in this category—but many of these drugs are small, they're sort of high school chemistry. Now high school chemistry is not the same thing as reliable safe manufacturing, but there are a large number of really good generic drug manufacturers out there who currently have to go through a regulatory process kind of drug by drug to get into the market. Well, if they're good for doing a range of pharmaceuticals, maybe there's a pre-approval process that could work for them. But I don't think it's the backlog at the FDA or FDA not acting quickly enough. It's sort of the cost benefit calculation from a manufacturer's standpoint of entering, you know, how quickly can they get into the market and how much is it going to cost if they get in, and the current high price manufacturer then, you know, significantly drops their price.

SARAH DASH: We have people patiently standing at the mic. I want to go to Stu and then Mike and then back and forth – or was Mike there, first?

AUDIENCE MEMBER: Well, thanks. This has been a great session and Mark and Gerry have come up with some interesting, although maybe conflicting, suggestions. And Laura has made some great points. One of the points Laura made was that unlike Medicare Advantage Part D and traditional Medicare has drug decisions being made totally separately from medical decisions, and it occurs to me that one easy thing to do, I think, right away would be to have a demonstration that would have shared savings for Part D plans, and that would also bring the Part D plans into the decision-making process which really hasn't been mentioned that much. But it would also allow them to benefit from good decisions about how to use drugs to control medical conditions. What do you think of that?

GERARD ANDERSON: Well, again, I think what we're trying to do is to incorporate pharmaceuticals into the decision-making process and so, you know, mine sort of on one end of, you know, a full bundled payment, which your – and what Mark has, you're sort of halfway there in a number of ways in keeping them separate. And I just have trouble, since I believe that drugs are so important to decision making and we've been able to do it for post-acute care and other things, why we wouldn't put them into the bundle.

AUDIENCE MEMBER: I'm just talking about a demonstration that you could do really quickly with the current system.

GERARD ANDERSON: I understand. But we've done it with end stage renal disease, so, you know, we have a demonstration but it's a real program already. But you could do it. I mean, I think any steps along the way are great.

MARK McCLELLAN: So, more along these lines, if CMS were to clarify that you, as a Part D plan, can enter into a contract with healthcare organizations to be part of their shared savings approach, I think that would work actually quite well potentially with, you

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know, more advanced ACO's or some of the organizations that are implementing episode payment models, maybe some of these oncology care model practices. The challenge is that, you know, nobody's done this before either, so it is complicated from that standpoint. You don't have to fundamentally disrupt Part D, but just like sort of the early ACO contracts, you know, people thought this was a good concept but since they hadn't worked through the details and there are lots of different providers and lots of different drug plans, you know, how do you get to critical mass, and if there were a push behind that, which CMS could give it, I think that could be an interesting avenue to pursue.

LAURA KEOHANE: I just wanted to add more context for that question as well, particularly in relation for the standalone Part D plans versus the Medicare Advantage plans. As I was mentioning, the Part D low income subsidy program does exist, and if you are a beneficiary in the Part D low income subsidy program you are much more likely to be in a standalone Part D, partly because the Part D low income subsidy plan also includes dual eligible beneficiaries. If those beneficiaries don't choose a Part D plan, they are automatically assigned to a standalone Part D plan. They cannot be assigned automatically to a Medicare Advantage plan unless they choose it. So, in the standalone market, we have a lot more beneficiaries who are on the low-income subsidy program and who are dual eligible. And that raises the question of not only how we're thinking about sharing drug spending across Part A and B, but also how we think about sharing spending across the Medicaid program, for example, to the extent that high cost drug users are more likely to be nursing home residents, how do we think about spending on long term care and how Medicaid is funding long term care services for those beneficiaries.

MARK McCLELLAN: If there is one population that would benefit from more coordinated care and more coordinated financing to support it, it's that population. And there are some dual pilots involving managed care organizations in some states, involving just direct contracts with providers, including social services organizations, and I think it would be really helpful to get the drug payments better aligned with those.

SARAH DASH: Great. Thank you. So, we're getting close on time. I'm going to turn to Mike who's been waiting, and then Emily, and then the gentleman, and why don't I ask you guys, I'm just going to do something different. Can you guys each ask your questions and then we're going to have the panelists try to answer them so that we can get to a final round in the last 5 minutes. Thanks.

AUDIENCE MEMBER: Thank, Sarah. Mike Miller. I'm a physician at Foley Hoag and Gerry talked about the SRD that includes Part B and Part D drugs and Mark talked about the oncology care model, which isn't exactly bundled but it's an alternative payment model, and that includes all Part B drugs and some Part D drugs. So, I guess Gerry doesn't consider that bundling, but it puts the physician at the center of making the decisions about what care to provide, what drugs to use in the total spectrum aside from non-oncology Part D drugs. So, I wonder if you could talk about how alternative payment models that aren't bundled might fit into this construct of providing better value and

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better decision making, shared decision making from the physician, clinician, and patient context. Thanks.

SARAH DASH: Let me ask Emily to ask her question in case there's some synergies here. Thanks.

AUDIENCE MEMBER: I'm Emily Katz with Express Scripts. There's not much synergy with that question but luckily, since I've been standing here you guys have been answering more about FDA and things. I know when the topic is Medicare it really seems like we're going to talk just about CMS solutions, but the FDA and what's going on with competition really will affect Medicare drug pricing. And so, I know there was also some conversation about Part D negotiation with high priced drugs, and I just want to point out that we're finding now that net prices, negotiated prices in the U.S. by PBM's for hepatitis C drugs are now rivaling, and in some cases beating, their prices in Europe and Japan. So, I just want to point out, in that circumstance, there is competition. It's not generic competition but there are therapeutic equivalents and so I think there's more to address here. You guys have done an excellent job touching on generics and speeding things through FDA, but there's a discussion on patents, evergreening, all of these things that do relate to Medicare ultimately. So, that's just mostly my statement, and if you guys want to comment more on these other issues that are sort of outside of CMS that would be great.

SARAH DASH: Thank you. And the gentleman over here. Thank you.

AUDIENCE MEMBER: I'm Carl Polzer. I'm a long-term care and health policy consultant. So, what I'm going to do is introduce the concept of a productivity adjustment for the pharmaceutical sector and that'll look at hospitals, how Medicare pays hospitals and nursing homes. The relative value is set by whatever Medicare thinks based on history and minus one percent. Under the Affordable Care Act, we expect, Medicare expects those sectors to improve their productivity 1% per year to break even, and in the case of nursing homes, it's labor intensive. Seventy percent labor cost is very difficult to do. It would be easier for the pharmaceutical industry to do because they're highly technological, arguably. Anyhow, why don't we expect better productivity from this sector?

SARAH DASH: Thank you. So, three very different questions and comments. Again, the first question about putting physicians more at the center of decision making and particularly with respect to the mention of the Medicare oncology care model, but are there ways to improve the value equation without bundling was the first question. The second question had to do with negotiation and in some ways, relates to the first question because we have, you know, if you're moving more to the value-based models, in some ways you are putting the providers more at the center. And, then the third question to productivity. So, if you guys want to try to tackle those.

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GERARD ANDERSON: So let me start at the end. So, essentially, the whole issue of oncology, you know, when I look at the demonstration I do want to put the doctors at the center at the activity and I want them to make the choice of which oncology drug I am, in fact, going to be taking, and I want them to have some financial incentives to choose the drug as opposed to some other approach that they may want to do.

In terms of the hepatitis C drugs, what we know is that the prices are, in fact, going down, but because of a lack of price transparency we don't know how much they are, in fact, going down. But I don't even care so much about that, although I do, in that I really care about the fact is that only about 10%, 15% of people with hepatitis C are, in fact, getting the drug because of the price, because it's a drug that really works, that really is effective, has very few side effects and so people would take it if it was less expensive, however it's done.

In terms of greater productivity of the industry, I mean, one way to look at it is could they produce a drug less expensively in terms of R&D? Probably. But I think they're probably doing their best to be as effective as they can in R&D. Most of these drugs, with the exception of biologics, are pretty inexpensive to actually manufacture, so I think they're doing very well on that activity. Where the real issue, and that's why I come back to the bundled payment, is are they being used appropriately and in the most cost effective way and, in some ways, they are and in other ways they are not.

MARK McCLELLAN: So just to pick up on a few of these points quickly. On the first one about oncology care model and payment reform for oncologists, so Medicare's not the first payer to try this out. Anthem, United, others have versions of the same kind of program and they've had some fairly positive results. Anthem has payments that are tied to using clinical pathways that are defined by the oncologist is effective for particular types of patients that has led to some drug and overall savings. Interestingly, in United's pilot of this, they went in thinking that delinking the oncology practices' payment from the expense of the drugs they use, you know, moving away from volume-based payment, would have a primary effect on reducing drug cost, but what it turned out was that giving the oncology practices more ability to have revenues that were not tied to drugs led them to spend more time with patients, extended office hours, more use of nurses, and they got the biggest savings in reduced emergency room and hospital complications. It seems like a win-win. And really emphasizes the point that putting all of these costs together and having some accountability for the drug manufacturers, too, would be helpful.

You know, on the point about PBM negotiation, it does bring down prices. It is hard to get exact net prices, but they're about 50% of what they were in many programs compared to a couple of years ago and, boy, if we could, again, get this more into an overall patient context you can envision ways in which manufacturers could get total revenues similar to what they're getting now but treating a lot more patients if they weren't being paid on a fee-for-volume basis.

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And I just want to end with a comment about FDA. Yes, a very important agency for access to drugs and how all these things play out. One of the other areas I mentioned, I'm actually getting to watch soon is biosimilars. So, they are starting to get approved by FDA. There are still some important questions around naming, around how strong the evidence is for interchangeability as opposed to similarity. You know, is the drug going to work the same way in particular patients, where, once again, getting more real world evidence would really help. But FDA has really expressed some interest under Rob Califf's leadership, for getting more involved in supporting real world evidence networks that could address these questions. They're just very hard to answer in pre-market clinical trials.

SARAH DASH: Thank you, Laura, any last words and then we will close.

LAURA KEOHANE: Sure. I just wanted to pick up the point about value-based payments and thinking about alternatives to bundling. One, you know, kind of baby step that Mark mentioned was the whole idea of pay for performance. To some extent, we are trying to do that in aspects of the Medicare program, for example, Part D plans do have quality ratings that are based on a whole series of metrics and they get star ratings. If we want to think more about paying value for services, if we think carefully about what we put in those quality metrics and how we're evaluating both Part D plans and other providers in terms of how they're using drugs for their patients, that might be another alternative way to go.

SARAH DASH: Great. Thank you so much. We are out of time. Please do fill out your blue evaluations, but first join me in thanking our panelists and thanks again to the Fund.

[Applause]