Reviewing Prescription Drug Coverage: Policies and Practices Across Several Health Systems
Alliance for Health Reform and Commonwealth Fund
June 23, 2006

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ED HOWARD: I'm Ed Howard with the Alliance for Health Reform. Thank you for coming this afternoon. On behalf of Jay Rockefeller, our chairman, Bill Frist our vice chairman, welcome to our program on coverage policies for prescription drug in a number of countries, including ours. Our partner in today's program is the Commonwealth Fund. I want to thank Karen Davis, Ann Gauthier. We'll hear in a moment from Robin Osborne of the fund — for their help in arranging this program and shaping the issue in a very useful way for our audience.

We're just a few months into the operation of the Medicare Part D prescription drug benefit, and no matter who's estimates you believe we're talking hundreds of billions of dollars here over a number of years for prescription drugs. And deciding what drugs are going to be covered, what drugs aren't going to be covered, affects not only the health of 40 million beneficiaries but also the fiscal health of the Medicare program and the government itself. So this involves factors that are very important to all of us interested in health policy. And today's program rests on the premise that we can actually learn from the experiences that others have had with prescription drug programs of various kinds operating in other countries.

It is in fact a two-way street. I know others are emulating some of our best practices, and we're smart enough to pick up a pointer or two from our friends abroad. I've actually heard Mark McClelland admit that. So we know that it's true.

Just yesterday I got an email from a benefits consulting firm about a drug that is about to be approved by the British agency that looks at prescription drugs for the national health system. This drug is for the early stage breast cancer treatment, and it costs – if I've got my exchange rates correct – something like $60,000 a year per patient. And what we hope to look at today is how those kinds of decisions are made in the UK and elsewhere and how well those other decision making processes are working and what lessons we can learn about those processes to help us in the Part D program.

So logistics, details, you know you have lots of good background information, including short papers from each of our international speakers about this topic. I commend them to you. They are available both in hard copy and online at our website – that is allhealth.org – and also at Kaisernetwork.org where you will be able on Monday to see a web cast of this briefing as well and there'll be a transcript on both those websites in just a few days. And

you'll find in those packets both a blue evaluation form that I would urge you to fill out at the appropriate time to help us make these programs better and a green question card, which you can use to bring any topic you would like to the entire audience. There are also, of course, at the appropriate time, places where you can vocalize that question with a floor mic.

As I noted, we have with us today Robin Osborne. She's the vice president and director of the Commonwealth Fund's international program on health policy and practice. She's got a distinguished background in health policy and practice, and as I told her, I'm going to be even less fulsome in my description of her considerable talents than I am with our other speakers. So Robin thank you for working a fine panel up, and we look forward to your discussion.

ROBIN OSBORN, MBA: Good afternoon. On behalf of the Commonwealth Fund let me say how delighted I am to welcome you here and to thank you for joining us for this briefing. I know that I'm speaking for Karen Davis, president of the fund, when I say how pleased we are to co-sponsor this international session here on the Hill and to be able to bring to the attention of this broad audience of Washington policy makers important developments in other industrialized countries. We're particularly grateful to the Alliance for

Health Reform, to Ed Howard, Ann Montgomery and [inaudible] for their collaboration in organizing this program.

As many of you already know, the Commonwealth Fund is a private foundation established in 1918 by Anna Harkness with the broad charge to enhance the common good. The mission of the fund is to promote a high-performing healthcare system that achieves better access, improved quality and greater efficiency. In doing so, our efforts are particularly committed to helping America's most vulnerable populations, the poor, the uninsured, minority Americans, young children and the elderly.

Since 1918, the fund has sponsored research and innovations in healthcare delivery to address many of the most urgent problems in the American healthcare system. And recognizing, however, that many of the issues of greatest concern to the fund – access to adequate primary and preventive care, quality of care, responsiveness to patients' concerns, barriers to healthcare for vulnerable populations, long-term care for the elderly – are matters of concern in other industrialized countries. The fund established an international program in health policy and practice, and it's premised on the belief that despite the differences in the ways healthcare systems are organized and financed, the different cultural and political context in which they

operate, there are valuable lessons to be learned by looking beyond our own borders at the experiences of other countries.

The core countries of the fund's international program – many of which are represented here – Australia, Canada, New Zealand, the UK, the US, and we've been pleased to expand the program in the last year or two to include Germany and the Netherlands. In addition to events like an annual international symposium, which is co-hosted by the US secretary of health, that brings together health ministers from all of those countries and leading experts to look at a high profile cross-cutting issue, the program also produces cross-national data and analyses that are valuable both for benchmarking and for comparing US healthcare system performance with other countries.

In the briefing packets that are distributed today, which I hope you all take a look at, you can find findings from the fund's most recent annual international survey, which is on the experience of sicker adults in the six countries that I mentioned. That was published in Health Affairs. Also a fund report entitled "Mirror, Mirror on the Wall," which ranks the US healthcare system on six different dimensions compared to these other countries. As these reports show, industrialized countries are all grappling with issues around soaring costs, public demand for expensive new

drugs and technologies, medical errors, underuse of some services, overuse of others, wide variations in translating evidence-based practice medicine into practice, poor coordination of care, failures in making the healthcare system responsible to patients' needs.

And on a policy level, industrialized countries are all similarly concerned with the parallel theme of getting value for money. And for the US, this theme has particular resonance. The US healthcare system is the most costly healthcare system in the world. US per capita spending on healthcare is more than twice the OECD average. And while we outspend all other countries, and you can see from the papers in the briefing book, our system fails to deliver superior value for the money spent. And in many cases, the US ranks at the bottom of the six countries that are compared.

With the passage of Medicare Part D, the historic expansion of Medicare to include a prescription drug benefit, there are increasingly compelling reasons to look across other countries and to look at the approaches they take to pharmaceutical policy, including evaluating the relative effectiveness of prescription drugs, ensuring quality, achieving best prices and encouraging innovation.

We have today a panel of international experts, which I'm delighted to welcome and thank very much for joining us.

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And in addition we have our US experts and commentators who will talk about the relevance of the country approaches to the US. This afternoon's presentations promise to be timely, highly relevant and I suspect they're going to be somewhat provocative. So without further ado I'm pleased to now turn the program back over to Ed. Thank you.

ED HOWARD: Thanks very much Robin. We're going to start right in here. We've got a great panel for you.

And first up is Steven Morgan. He's a health economist at the University of British Columbia. There he's the research leader on their program on pharmaceutical policy. He's also on the faculty at the Department of Health Care and Epidemiology there. His biography that's in the materials frames the central thesis of Professor Morgan's work as – let me read this – examining how to design public policies to balance equitable access to medically necessary technologies with the need to control costs. Now I couldn't ask for a theme that's closer to what we hope to focus on today, and we're very pleased to have you with us.

STEVEN MORGAN, PhD: Thank you very much. Thank you to the Commonwealth Fund for the invitation to speak and to the Alliance for Health Reform for putting together the panel today. I hope this microphone's working.

ED HOWARD: It doesn't seem to be working very well. Try getting closer.

STEVEN MORGAN, PhD: Is it working now? Here we go. I'll just stand really close.

So I'm just going to get right into this because I know that we've got a great panel together and I'm looking forward to hearing Libby and Panos.

This slide is just to put this in context – why are we all here? It's really because in the US you're spending close to $800 per capita on prescription drugs in 2005. Whereas in 1995, just 10 years ago, you were spending close to $200 per capita. Along that same slide I provided Canada as a country of comparison for the US, not because I think Canada does a particularly wonderful job. In fact I put my country up there to say we are the second worst country in the OECD in terms of maintaining control on prescription drug costs. We're second worst. You here in the United States are worst on that front. So bear in mind if you look at this chart you'll get a sense of why we're here. Costs are spiraling. We want to make sure we're getting value for money.

Why review medicines? Well simply speaking, we need secondary review of medicines in order to make this market efficient in terms of reimbursement policy and using the

right drugs for the right patient at the right time and right time. The two basic facts here are that licensing processes are not meant to develop and to disseminate information on comparative effectiveness and comparative cost effectiveness. That's not the purpose of the licensing process. They are a basic hurdle with regard to safety and efficacy, and so they should be.

The second issue here is that the science involved in comparing medicines is complex. It's extremely difficult to do, and we can no longer rely on the '50s model of individual trial and error under the doctor's supervision. We do need well-designed, randomized, controlled trials and careful and very diligent evaluation of the data that comes from those trials. And lastly, comparators abound – over 90-percent of prescription drugs licensed in the market in Canada and I'm sure it's the case here in the United States – our drugs that are comparable to other drugs on the market. So we have the opportunity to make comparisons. And I think through that opportunity we have the ability to pursue value for money by fostering and innovative form of competition, which is competition in terms of price per proven quality adjusted life year or some other measure of outcomes. Without rigorous evaluation, however, we are going to have a market

that's dominated by marketing and not science, and I think that's important to bear in mind.

If we could develop, simply put, some information that is independent and rigorous with respect to the impact on health status and the impact on health system costs, both the drug budget and others, we could put together effectively a matrix that would make a lot of decision makers decide should we or should we not cover a medicine. This basic information is lacking in many countries, mine included, and certainly it's difficult to find en masse here in the United States, although there are a number of initiatives that are pushing towards this direction of providing such information. I'll just throw this up and you can read through it, but really if we could get some decent information, comparative data on cost and outcomes, coverage policy actually becomes much more simple. And I'd encourage any of you who wish to pursue this line of reasoning to read a Health Affairs paper colleagues of mine and I from British Columbia had written a couple of years ago called "Outcomes-based Drug Coverage in British Columbia". And it lays this framework out in somewhat more detail.

I want to just get onto the paper that's in your folder. If it's the same as mine it's in green paper. And that's the paper actually that Libby, Panos, myself and a

number of other colleagues from around the world put together about centralized drug review processes. I put this terrible slide up, and I won't go through the details, but just to highlight a couple of things. First of all these systems are complex. It's extremely complex. There's about three points I want you to take away from this, however, one of which is that almost all of these centralized evaluation systems or drug-review processes are independent from the licensing process. This is not should a drug be on the market or not. This is should public or private payers fund a drug or not. So it's a different question, different agencies involved.

The other thing to note here is that economic and clinical evaluations in most of the agencies that we've reviewed and in fact other agencies I've looked at since doing that study, economic and clinical evaluations are separated, and I think that's a good point to remember. There's dialogue between the economists and the clinical experts, but the functions are distinct.

And lastly there some issues around the degree to which agencies correspond or communicate with both the industry patient groups and then the general public – the degree to which there's public representation. In the paper that's in your handouts there we separate the functions into assessment of scientific evidence, including the science with

respect to cost. And then there's that tricky bit of appraisal – what do you make of the evidence going from the "is" to "ought"? We know that this is what will happen if we use one drug or another. The questions that are most difficult are ought we fund that drug – going from the positive to the normative. And different countries have different processes for doing that.

Quickly reviewing, and I'm sure Libby can provide tremendous more detail here on Australia's system. It's a template for us to just look at the other countries. A couple of things I've noticed – that Australia has a national system for drug coverage. It has a national formulary. That's going to be distinct from both the United States and my home country of Canada. Reviews are required for national funding. To get onto that formulary you must be reviewed by the pharmaceutical benefits advisory committee, the PBAC. That's an important step in their process. The minister cannot approve and fund a drug without a yes from the PBAC, another very important lock step or connection between appraisal and the actual coverage process.

This process is very pragmatic. PBAC reviews approximately 100 drug per year including generics. Generic reviews would be much faster than new molecular entities, but nevertheless, many, many reviews. It's a timely process. I

believe it's a 17-week cycle and Libby can correct me on that in a moment. And the rationale are published on the Internet. So there is some degree of public disclosure here. Prices are negotiated. It's part of the ultimate process, although it's not negotiated by the PBAC. It's a separate body that does that. So it's all tied together in an interesting national and comprehensive set here in Australia.

New Zealand resembles that to some degree, although there's a slight difference in New Zealand in that they have a universal coverage, but it's not technically national. They actually have regional funding bodies who have agreed to tie their coverage to the national review process. So effectively, these regional bodies, almost the equivalent of state Medicaid programs, have decided that they were actually going to have a national formulary and that they would tie their hands to that in order to gain some of the efficiencies that come with the purchasing power associated. Otherwise it's a similar process in many respects to Australia.

England's is a unique process. They don't have a national formulary. It's a universal program of coverage, but they have what's called a negative formulary. And that's basically a blacklist. If you're on that blacklist you're not to be covered or you don't necessarily have to be covered by public funders in the UK or England and Wales in

particular. But all other medicines effectively are de facto covered.

The NICE, the National Institute for Clinical and Health Excellence in the UK reviews only controversial medicines. So it does far fewer drugs than, say, the PBAC in Australia or the PTAC in New Zealand. It's an exhaustive process. I would call it a Cadillac version of drug review. It's got an incredible process that takes into account a number of different dimensions, and it reviews about 11 drugs per year. It takes about a year plus per drug. There are no price negotiations in the United Kingdom, and Panos can talk more about how prices and profits are regulated in the UK.

Finally Canada – Canada is a mixed model of coverage. It's probably one of the biggest misunderstood segments of Canada's healthcare system. Unlike insurance for hospitals and doctors' services, drugs are a patchwork of both private and public coverage, with many, many Canadians receiving no coverage at all. So in some sense, Canada's drug coverage system resembles that of the United States in a way that North Americans are alone in the world because both Canada and the United States rely tremendously on private insurance and have a tremendous population uninsured. In Canada however, our 16 or so public drug plans have agreed to a single drug review process. This is the assessment and

appraisal process, that is that they basically engage in the technical assessment of evidence on efficacy and cost effectiveness – two separate reviews. And then they put together a recommendation. However it's important to note that the recommendation of Canada's centralized drug review process called the Common Drug Review is not compulsory. Every province or every other jurisdiction that's partaking in the program has the ability to cover or not as they wish, but they are effectively held accountable to this publicly disseminated guidance from the national process. There is no price negotiation involved in this process in Canada.

The impact of findings – you'll see some information in the published study that I've given you, that's in your sheets there. It's important to know that review processes that are tied to coverage have impact on use and costs. And review processes that are tied to national coverage policies are that much more powerful. That's the no-brainer statement. Just this past February, we convened a meeting in Canada, which brought together the heads of the review agencies of these four countries I've just described to talk about some of the challenges that they've faced. And it was fascinating to think that we are all struggling with major challenges, just as you are in the United States. Some of those include the use of surrogate measures at licensing

stage to bring a product to market when we don't know whether or not that surrogate measure that is that sort of sub-clinical measure of what it does to the biological processes of the body. We don't know if that's connected to clinically meaningful outcomes in quality of life, and that's a major challenge for all review processes. Transparency is a major challenge, and lastly, once a drug is approved to coverage, the indication can be a challenge for funders because you approve a Cox-2 inhibitor for at risk patients, but suddenly everybody's at risk – at least so the market believes.

Why is transparent review important in the United States? I threw this slide out just to provoke a little bit. This is the direct to consumer advertising expenditure in the United States measured in billions of dollars. In 2005 manufacturers spent 4.25 or 4.24 billion dollars marketing products directly to consumers. In some sense this is the marketing side of driving utilization here in America, and to give you indication of that I provide this slide. This has been changed slightly from the slide in your set because I realized there was an error in that slide. On the left-hand scale, if you will, is the difference between Canada and the United States in terms of per capita expenditure on prescription drugs measured in US dollars. You can see – this is the blue line from 1975 to 1995 US and Canada

basically were spending the same amount on prescription drugs per capita. And then that shoots up from a difference of under $20 to a difference that's now nearly $300 per capita. On the right side is a scale of per capita investment by manufacturers in direct to consumer advertising. That's the red line. It almost walks lock step with the difference between Canada and the United States. It's notable that direct to consumer advertising is illegal in Canada. We are, in some sense, your control to see what the impact of DTCA has spending here and the United States. That figure represents a $75 billion annual additional expenditure on top of what you would have been spending if you had kept pace with Canada over the last decade.

Now Canada's spending per capita has more than doubled over that decade. It's just that it's gone up that much faster in the United States. That $75 billion – I'm sorry for taking so much time here – the $75 billion can hire, at a minimum approximately 150,000 physicians to provide care for the underserved. It could hire nearly 500,000 nurses or approximately a million early childhood educators.

I know you're probably thinking, well what's the comparative value, money on drugs or money on these other services? That's exactly the point is that we seldom have

comparative value even within drugs, let alone drugs across other social services, so I would encourage Americans to consider investing that much more in processes here to compare one drug to another because there are orders of magnitude of costs and oftentimes just minor differences in outcomes between medicines, if you can rationalize your drug policy in a way that spends money prudently and forces competition in terms of value for money – that is dollars per quality adjusted life year or dollars per proven outcome – you're certainly going to have billions of dollars more to spend on other important healthcare priorities.

You can read through these recommendations I've got for the US, and you can see them in our paper as well. So thank you very much.

[Applause]

ED HOWARD: Thank you Steven. Next we're going to hear from Libby Roughead. She gets the award for having come the farthest distance. She's on the faculty at the University of South Australia in their School of Pharmacy and Medical Sciences. She's done a great deal of high-level work evaluating the use of prescription drugs and drug safety in Australia. And in 2003/2004 I think it's worth noting she was a Harkness Fellow at Harvard Medical School in a program

administered by the Commonwealth Fund. So we're very pleased to have you with us, and thanks for joining us.

LIBBY ROUGHEAD: Thank you. Australia began thinking about coverage decisions way back in the 1940s when we were worried about our people not having access to penicillin. Coverage decisions for us are now part of something called our national medicines policy because we came to realize that thinking about coverage alone, without the context of the whole national medicines policy was a bit silly. So I want to today explain to you what goes on in terms of our national medicines policy, what it is, and then look at some questions, particularly some issues that arise in this country, about some of the things that go on overseas.

While we started in the 1940s it took us until the year 2000 to actually get this national medicines policy a formal policy document. It has as it's goal to make medication and related service needs so that both optimal health outcomes and economic objectives can be achieved. The thing to notice about that statement is that it holds tension. It holds the tension between economic objectives and health outcomes, holds the tension between medication and related service needs. That's our challenge.

Within that we have four objectives. They are objectives that most developed countries want. We want

timely access to medicines that Australians need, at a cost individuals and the community can afford. We want medicines that meet appropriate standards of quality, safety and efficacy. We want those medicines used well, and in Australia we say that we also want a responsible and viable medicines industry.

I'll just go quickly on how we get there. No – this was the one thing I meant to put in first. The one thing in Australia that we recognize is that we think these things are interdependent. You can't have one without the other. So we worry about them all. And we depicted in this graphic to show that interdependence. At the center is what we all want – healthy consumers. It's the common journey. Industry wants it, governments want it, health professionals want it, consumers want it.

Surrounding that we have to have those medicines used well, but we then need these other access points. And why that graphic is important – if any one of those things isn't there, the whole thing falls over. So when we're thinking about coverage we also need to think about industry. But when we're thinking about industry we also need to think about equitable access and about quality use of medicines. Everyone wants the common goal.

Quickly – safety, quality and efficacy. We have the equivalent of the FDA. It's called the Therapeutic Goods Administration. We register prescription and over-the-counter medicines, but we also do complementary medicines, which I don't think you do here in the US. We're currently harmonizing our regulations with New Zealand.

In terms of the pharmaceutical industry, we've had an industry development program for the last 20 years just about. It's currently known as the pharmaceutical partnership program. The federal government in Australia invests $150 million into research and development activities to assist the industry in research and development in Australia. And it's enabled the Australian industry to achieve a growth of 11-percent over the last five years and increase our exports in this area. So exports for pharmaceuticals are Australia's second largest manufacturing export. But our big exports, like you, are agriculture and mining.

We actually have a national program for quality use of medicines. We started this in 1992, and we did it because consumers said to us, "You haven't got it right. We're suffering." In 1992 we virtually had nothing in Australia. We had antibiotic guidelines. We had a national therapeutics bulletin. We put this document together, which was the dream

of what we wanted. It identifies everybody who needs to be on board, the resources we wanted and the framework for working.

The federal government invested two million dollars annually and initiated research, and I'm very pleased to say that today in Australia we have an awful lot that's gone and been translated into practice. We have the national prescribing service, which was established in 1998. It provides newsletters and prescribing feedback to every GP in the country. It runs a new drugs program. It funds people in geographical areas across the country and provides academic detailing, case studies and clinical audits, and over 50-percent of our GPs voluntarily participate in those interactive activities. It also funds a consumer program, which has been going since 2003. It has campaigns, small group education, resources for consumers. It runs telephone lines for both health professionals and consumers and is involved in curricular development. It has funding of over $100 million over the next four years.

We also fund medication review services. We have them for community care where pharmacists go into homes. We also have them for aged care, and they cover every bed in the country. We have a national medication disposal service, and I'm embarrassed to say that we collect 250 metric tons of

unwanted medicines each year. But we can now dispose of them in an environmentally appropriate way. We have national therapeutic guidelines which cover every major organ system that's available. They cover more than 2,600 diseases. We have the Australian medicines handbook, which provides comparative drug-to-drug information, and we now have consumer medicines information for every registered product in the country.

Our system for ensuring equitable access, as Steve talked to you, is the pharmaceutical benefits scheme. We started it in 1950. Today it has about 600 medicines on the list, 1,500 formulations and 2,600 products. There's a very small private prescription market in Australian, but this scheme accounts for 90-percent of our drug use.

Of those products, 298 of them require what you would call prior authorization. And as you can see the consumers pay a portion of the cost. If you're a social security beneficiary it's $4.70. If you're a general beneficiary it's $29.50. We do have a safety net system, and the safety net operates at a family level. So if you're a social security beneficiary you pay $253.80 per family per year, and then the medicines are free. For everybody else it's $960 per family per year, and then they're provided at $4.70.

So the Pharmaceutical Benefits Advisory Committee does decide what goes on the list or had to provide a recommendation. Ultimate responsibility lies with the Health minister. It's statutory committee established under legislation, the *National Health Act*.

How does the medicine get on the list? The sponsor – it can be anybody, but it's most commonly industry – makes a request, including the type of request. So the industry actually requests if it's generally available or restricted.

In assessing medicines – on the legislation it says that the PBAC must consider comparative efficacy, comparative safety and cost effectiveness. We began trialing cost effectiveness in 1990, and it's been mandatory for every product listed since 1993. The cost effectiveness takes in whole of healthcare costs.

So some questions – and these are questions that are often put to my country primarily by yours. What about these access policies; do they restrict industry R&D? Isn't that the big fear that everybody has? And I just want to show you what's going on in my country, remembering that we operate in this national medicines policy framework, so we try and address both. But industry R&D in Australia has grown at a rate of 16-percent per annum over three years, '98 to 2000. And that compares with a background rate of research and

development in Australia of 3.5-percent. Now you can say to me, “But it’s the global issue. It’s the global R&D that we’re interested in, isn’t it?” Well I wonder if global R&D is not increasing as a proportion of all heath R&D. This is the figures from the USA, Canada, Germany, France and Japan in 1998. So pharmaceutical R&D accounted for 37-percent of all health R&D. By 1997 in those same countries it had risen to 46-percent. It had grown. What you should remember or take note of is that in your country you spend 13-percent of your health budget on pharmaceuticals. In my country we spend 15-percent of our health budget on pharmaceuticals. We invest much more on pharmaceutical R&D as a percentage of the health expenditure on R&D.

What about our cost effectiveness assessments? Aren’t they a form of price control or price constraint? We hear that a lot. Well we might argue maybe they reflect value for money and innovation for health gain. And I want to show you some things. This is the list of medicines that the FDA fast-tracked or that the Canadians labeled as innovative because of health gain. This list comes from 1994 to 2004, and I’ve had to cut off the ones that aren’t funded in Australia or aren’t registered. There’s a number that aren’t registered in Australia. But effectively, this list

of medicines is a list of medicines that have significant health gain.

This slide here shows you the federal supply scheme process, the big four process, and the Australian process in May of this year in US dollars. These are ex-manufacturer[ph] prices. This is the first have of the list. The bold or the purple color is where the price is higher, so you can see that for some products the US federal supply scheme price is highest. And for some Australia is highest. And sometimes it's significant. The Australian price is almost double what you have on the federal supply scheme price.

If I go to all 22 products what we find is that the Australian prices were higher on 64-percent of occasions, up to 73-percent of occasions when I included the big four prices. And on average, they were 38-percent higher than the FFS prices and 52-percent higher than the big four prices.

What about reference pricing; does it restrict access? So we have this interesting phenomenon in Australia where because we work on cost minimization and on the word for reference pricing, the PBAC can't actually reject a medicine that comes in as cost equivalent. So you don't see in my country what you're observing here, where you might only get two medicines in a class on a list or three

medicines in a class. You actually get them all. If one's come in they all come on. And so we have all of the NSAIDS that are registered in the country on the scheme, all of the SSRIs on the scheme. We don't tender for lowest priced products.

And just to also give you a sense of whether a new medicine's missing out in my country, this graphic here – and I'm sorry it's hard to see – but this is the share of the pharmaceutical market that's accounted for by new molecular entities launched between 1996 and 2001. So your about 33, 34-percent of the market is accounted for by those new molecular entities. This is Australia, so we're actually not much different. And this panel here is showing the change in the share of national market by new molecular entity in terms of the growth across that same time period. This is Australia here. And you see Australia had a higher growth in uptake of new molecular entities than the US, which is down here.

So just to conclude, I think National Medicines Policies offer us one way forward for thinking about holding all aspects of the system and holding the balance. It's certainly the challenge that we're faced with in Australia, but it's both a local and a global challenge. And I'd like you leave you with some words of some friends of mine that in

the final analysis medicinal drug policies are concerned with more than drugs. They're fundamentally about people and their relationships with one another. And they are concerned with achieving a balance, a balance with many things: between economic growth and social justice, wealth and poverty, regulation and freedom, risk and certainty, incentives and sanctions, costs and benefits, suspicion and trust, isolation and involvement. This is the challenge for us all. Thank you.

[Applause]

ED HOWARD: Libby is congratulating herself because first she negotiated an additional time and then she came in under it. [Laughter] Actually I'd like to take advantage of that situation if I could. I saw some scratching of heads at the term "reference price", and I wonder if you could just explain briefly what it means and I assume how it works a little bit in Australia.

LIBBY ROUGHEAD: So effectively in Australia we have what we call cost minimization approach that if something is of equivalent efficacy or safety as an existing product, we won't pay a higher price. So by default the existing product on the market becomes the reference price, and the other products we will not pay a higher price. And so if a company

wants to list it they need to agree to come into the market at that price.

ED HOWARD: Yes, go ahead Steve.

STEVEN MORGAN, PhD: I just wanted to speak to that as well because in British Columbia, which is my home province in Canada, we've applied reference pricing for just a little over a decade now. And in our circumstance what the government does is it'll actually reimburse at the rate of the reference price, and if the consumer wishes to purchase anything else it's their choice. They will get a subsidy equal to the reference price, and they pay the difference. It's not unlike a tiered formulary or tiered co-payment. Only in this case the tiers are exactly equal to the price difference between products.

LIBBY ROUGHEAD: And now we'll go right over time because effectively in my country that could happen too. But Australian consumers won't pay, effectively. So what happens is the biggest difference you ever see is about a dollar, maybe two dollars. Australian consumers just say, "No, not paying more."

ED HOWARD: That's very helpful – both of you. Thank you very much.

Next we're going to hear from Panos Kanavos, who's a research fellow in pharmaceutical economics and a lecturer in

international health policy both at the London School of Economics. He's advised more countries on health policy than I've ever visited as a tourist. He's also advised the World Bank, the World Health Organization, other international institutions, and now he's going to advise all of us. Panos.

PANOS KANAVOS: Thank you very much. I'm here to listen as well. Thank you very much to the Commonwealth Fund and the Alliance for Health Reform for inviting me here. It's a pleasure and delight, and I'm hoping to give you some of the mindset of decision makers in Europe, how policy makers think about drug policy in the European Union, the European Union of 25 member states – it used to be 12 a long time ago. We have expanded recently and the coverage is in principle, there are a lot of things about Europe, which in principle happen, in practice they don't. One of them is universal coverage because I can think of several occasions and several types of services which are not fully funded. And another principle of course is equity, which is in the status of most healthcare laws, but I can think of several occasions where equity is not observed.

So let me give you the mindset very briefly, and the mindset translates into that sort of equation that you see there – namely that if you are to contain costs in medicines, if you're to improve efficiency and resource allocation you

essentially need to target two very important variables. One is the price of medicines, if we're talking about medicines. The other one is the volume of medicines. And there are many ways you can actually target these two variables: one that essentially addresses the price is what we call, obviously, supply side measures affecting the price of medications that pharmaceutical manufacturers charge health insurance. And volume – there's a panoply of measures there and the policies that European nations have implemented and are in the process of implementing and relate to physician prescribing, pharmacy dispensing and also, to a certain extent but very little, patient co-payments.

Just to tease your interest this is sort of a map of Europe by default – essentially looks at the 25 member states and some of the types of supply side regulatory policies that they have on medicines, both in patent medicines, branded medicines, but also off-patent medicines. And you can see measures such as price control, international price comparison, average price, reference price that Libby and Steve talked about earlier on, and also profit control. And these methodologies are used par excellence, particularly reference pricing in the majority of member states to set sort of a ceiling on reimbursement and beyond that the consumer, the patient, can make a choice and pay the co-

payment. So it's a fairly complex process and a fairly complicated map.

If we're looking at it from a regulator's perspective then the type of criteria that regulators apply to do policy, these relate to how good the science is, tells the story. Then we're looking at the process of excise in price control. Is it by virtue of one or another methodology? And there are at least a dozen methodologies that control prices. But we have control over budget, or something called payback. In other words, a pre-agreed budget ceiling beyond which the key stakeholder, the industry in this particular case, will pay health insurance back. And of course there are also issues such as cost effectiveness, budgeting pattern analysis, but also industrial policy considerations. That is the good citizenship approach, whether you contribute to a country's R&D, the kind of issues that Libby mentioned earlier on. So it's a fairly complex function.

What type of regulation? Well if you look at the Europe of 25 then price regulation can be summarized into two bullets, either profit control as it applies in the UK or price regulation as it applies to the other 24 member states one way or another.

And if we look at rate of return or profit control regulation, then as I said, it applies to the United Kingdom

through the pharmaceutical price regulation scheme, essentially under rights, relative free prices for medicines. But if you look at cost containment, it is not necessarily the key variable in controlling costs in the UK. It is the control over the demand side and physician prescribing and dispensing that controls, or helps control, the drug budget. And if you ask the question about accessing innovation and leading to relatively good access to innovation, the PPS does nothing of the sort. It is really the National Institute for Health and Clinical Excellence, particularly in new medicines that contributes – or doesn't – to accessing innovation.

If you look at price setting in the other 24 member states, you probably realize that there is more methodologies than you can even think of. And it's probably a minefield to get into this type of issue at this point in time because each country has got its own type of regulation. The fact of the matter is that most nations in Europe have had these types of regulations for over three or four decades now, and they still do.

If we're looking at reimbursement and the policies on reimbursement, then you'll realize the multiplicity of criteria are used. Of course the tool to set reimbursement is always the positive list, with the exception of course the UK because we like to be different in the UK, and therefore

we have a negative list only. We don't have a positive list. And there's a multiplicity of criteria – whether the science of the other product is good, whether we have cost effectiveness analysis and health economics. We have budget impact analysis and so on and so forth. Last but not least of course, we do have reference pricing, or again, the maximum reimbursement per product.

A great deal of emphasis has been placed in recent years and continues to do so nowadays on the proxy demand and the demand side. And the key feature there is policies[ph] the word physicians. And this is something that European nations have actually discovered in the course of the last 10 to 15 years. And some of the European nations have just about discovered it. So a physician prescribing did not attract a great deal of attention until very recently, but we do now have the means, increasingly, to control prescribing, to provide guidance, to monitor and audit prescribing decisions and so on and so forth. And you can look, at your leisure, at the types of policies of different nations have in place.

Now let's look at a few trends from a European perspective. The first one is really that the regulatory practice is intensified and together with traditional focus that European nations have had on the supply side, there's

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the additional focus on the demand side, particularly physician prescribing and to a certain extent pharmacy dispensing with extension of substitution rights and changing the type of margins that pharmacies receive upon dispensing a particular type of medication.

The second trend relates to defining eligibility because it is not necessarily the cast that if a drug goes through the marketing authorization process, it will be allowed to be prescribed in general practice. And here we have different types of policies, one through NICE. If you do a meta-analysis of the NICE type evaluations you'll realize that the majority of these evaluations make new treatments, second, third or fourth line treatments for patients. So essentially NICE de facto defines the type of patient that is likely to benefit most of a new intervention. And of course there are other schemes, such as risk sharing programs, particularly those related to targeted treatments.

The third trend is really cost effectiveness, and of course the criterion of cost effectiveness or health economic evaluation is applied differently in the countries that you see on the slide. It can be applied as a supply side or a demand side measure. The fact of the matter is that in the majority of countries in the European Union it is a criterion that essentially allows medicines to be including in

formularies. In other words, if not cost effective, no listing or significant limitations in reimbursement.

The fourth trend relates to what I call flexible pricing arrangements in return for controlled use. And I have in mind here the types of targeted treatments that we have witnessed coming out in the last seven or eight years. We did a small analysis of medicines that you see on the top left hand side, like [inaudible], and you'll see that member states, individual countries, have different types of regulations in return for controlled use. It is not the physician but it's the specialist in hospital that has a license and is allowed to prescribe such medications. Of course, in return for all that there's the issue of industrial policy in return for innovation, some countries reward this. For example in France these medicines are reimbursed in hospital over and above the DIG rate. Or in Germany they're allowed to be prescribed without physicians having to face budgets and budgetary restrictions. Of course in the UK sometimes we make them second, third or fourth line treatments. But that obviously may vary according to the type of medication and the type of patient.

The issue of fragmentation that we mentioned earlier, especially in what concerns prices has led to something on which we've had a long discussion here in the US as well –

drug re-importation, and we've witnessed the phenomenon in Europe. And essentially it says that drugs from lower priced countries go to high priced countries and there's some kind of arbitrage taking place.

The sixth trend relates to a peculiar phenomenon, which is European in nature and relates to margins of the key stakeholders. And here I have in mind – and you can see that on the top left hand side – the type of margins that wholesalers and pharmacists get out of distributing medicines. The average wholesale margin in the EU 25 is 8½ to 9-percent. The average retail margin is about 25 to 27, sometimes 30-percent. And of course on top of that you have the tax. So essentially what the manufacturer gets and what the wholesaler gets and what the pharmacy gets is a different story here. There's a different procedure that rewards all stakeholders as well as the Ministry of Finance, which closed back BAT[ph] on medications.

And last but not least, there's the issue of generics, and generic prices are significantly higher in Europe than they are in the US.

So overall what does that tell us about the magical world of the EU 25? First that we do have regulation and both supply side and demand side, and demand side has been intensified in recent years. And there is therefore

increased emphasis on the demand side. Secondly, that there is an attempt to introduce some kind of rationality in the decision making process through cost effectiveness analysis and health economics, particularly in new medicine and new medicine evaluation. I would argue that there are significant inefficiencies in the value chain for medicines. And in a nutshell, balancing what we call cost containment, efficiency and resource allocation is still something of a conundrum on our side of things. Thank you very much.

[Applause]

ED HOWARD: Thank you, Panos. We're going to hear now from Tanisha Carino who is the director of the Center on Evidence-Based Medicine at Avalere Health – in Washington, DC I should point out. She's been in key positions at CMS. She's been a research fellow at AHRQ. She's been a Fulbright scholar. She's the author of an article in an upcoming Health Affairs article that came to my attention a couple of days ago about how Medicare decides coverage of colorectal cancer drugs. In other words she is an expert on what the US policies are in this area. And today she'll give us a US frame of reference on how the new Medicare Part D prescription drug benefit operates and especially how coverage decisions are made. Thanks very much for being with us Tanisha.

TANISHA CARINO: Thank you Ed, and thank you my esteemed international colleagues. I think that Robin really put our goal up in front of us when she said that in the passage of Medicare Part D that Medicare strives to be a more prudent purchaser of pharmacy care and medications in the country. And I think that the values that were underscored by each of our presenters previously talking about how we make these decisions and how we can make them more rationally is something that this country is also grappling with.

So I want to keep my presentation pretty short and sweet because I expect that there are many more of you that are experts in Medicare Part D than even me, and go on to talk about the contrast and the differences of what we face here in the United States. I'd like to just also point out that this is just one way that even pharmaceuticals are assessed and appraised and reimbursed in the country. There are different ways of doing it. And even Medicare, with Medicare Part D products state Medicaid agencies have a different way of approaching pharmaceutical reimbursement. And as you know, the commercial factor, which is as similar as it gets to Medicare Part D, has a different way of approaching this as well.

So just to start off I think that we have the same goals as our international counterparts, but we have a

different approach. And the approach reflects the values of the United States. In trying to first find market-based solutions to the healthcare problems facing the country. And when we think about the key aspects of the Medicare program, the first is of course there is voluntary enrollment into the Medicare Part D program. The second, which is the facet of being market based, is it was a decentralized program. It's decentralized in key areas that are different than what we've seen from our colleagues. First there was no uniform, standardized benefit structure set forth by either congress or CMS. So, for example, Medicare beneficiaries pay a wide variety of premiums and cost sharing. Not all beneficiaries paid the average $35. Second there was no standard benefit package. There's no one drug list or national formularies you might see in other countries and in also the VA here in the United States. The government chose not to allow Medicare to have direct negotiations on drug prices. And then finally a point that is subtle, but very important if you compare us to other countries is that the Medicare Part D program has no centralized process for systematically reviewing clinical or cost effectiveness information.

And so this market-based process, or the decentralized process has resulted in plans competing on premiums, on expected out-of-pocket costs for beneficiaries,

on the benefit packages that they put out in the marketplace and on their reputation. And based on what we've seen to date, there's been a lot of interest in Medicare Part D, with only 4.4 million beneficiaries still lacking coverage.

So ultimately the role of the federal government and the role of CMS in Part D is to provide oversight with the goal of managing Medicare's budget and also to provide appropriate access to medications for beneficiaries.

I want to make certain that even though we have a market based approach, and even though we have decentralization in many key facets of the program, the federal government and Medicare does maintain distinct roles in influencing the development of Part D formularies. And many of these roles that you can see are trying to define either a process or a structure. So for example, congress put forth in the statute that the United States pharmacopeia would define a therapeutic classification system, which is essentially a structure for a formulary.

So CMS in both regulation and guidance provides the plans should be reviewed based on the drugs that are listed, their use of utilization management tools, like prior authorization and dosing limitations, and should also be reviewed based on their cost sharing. So for example, CMS said that there are classes of drugs specifically that they

expected most plans to cover at least substantially all or if not all of the drugs that are approved on the market. And these classes include key areas such as age drugs, immunosuppressants, cancer drugs and mental health drugs. All of these classes being important to Medicare beneficiaries in maintaining their stability. Also CMS ensured the role of the P&T committee for Part D should follow at minimum commercial best practices. And in that, Medicare Part D plans are required to identify members of their committee that are free from conflict, have independent members who have also clinical specialty in areas that are relevant for the Medicare population. And they also said that Medicare Part D pharmacy and therapeutic committees should also look at a drug's therapeutic advantage and follow commercial best practices of using the best available evidence to conclude whether a drug has therapeutic advantage. And this includes pharmacoeconomic information. And finally the government ensures that beneficiaries have recourse for drugs that are either too expensive or for drugs they can't get on formularies by defining a process for appeals and grievances.

So what did this result in? We see that Medicare Part D is a wide range of options. And this slide is a recent analysis of our database that we have at Avalere,

which is a proprietary database on Medicare Part D. And it shows the top six plans in which beneficiaries have been enrolled and the lowest premium options for the top six plans across the country. And as you can see from the slide here, the premium levels range from the lowest offered by Humana, which is the Medicare Advantage plan, from $1.87 a month for Part D coverage to $34.88, which is a plan offered by Pacific Care, a stand-alone prescription drug plan. Many of the most popular plans chose to offer no deductibles, and the top six plans varied in some cases pretty widely in their coverage of drugs and their use of prior authorizations, and then in the construction of beneficiary cost-sharing tiers. And it was interesting to note that when Libby showed her slides about Australia, if I read those correctly, if Australia has 600 drugs on their list and 288 of them are prior authorized, then that's significantly higher than what we have here. Is that –

LIBBY ROUGHEAD: 600 drugs, 2,600 products – 288 products would be prior authorized. But most of those products would be single … so it's a bit tricky. I'd have to get you a different number.

TANISHA CARINO: It'd be interesting to understand those types of differences in what we see. But the short of it is to say that there are many choices. And at least in

2006 the benefit structures and the premiums that were offered were enough for beneficiaries to be interested in enrolling in Part D.

But the tradeoff here with the market-based approach is one that I think can't be missed, which is to say that there is a lack of transparency in terms of how the private market makes their decision. And presumably individual plans use the same level of systematic reviews and the same independent reviews as what you've just heard from other countries. However, this is a main point that as we look and explore the Medicare Part D program, we'll have to come to terms with to try to understand how these decisions are actually made and how the value of the medication, how they value medication, whether it's the price or their clinical superiority, and the needs of beneficiaries are really measured.

But the federal government has a lot of different ways to – the proverb of more ways to skin a cat. And the federal government has established a very interesting program with the agency for healthcare research and quality, which is the establishment of the effective healthcare program. So CMS, in partnership with AHRQ is defining a research agenda, which is of many interests to Medicare Part D plans, many payers, physicians and patients. In the first year it

received $15 million, and I think that you have a handout of some of the information on this effective healthcare program.

But CMS and others were able to prioritize a research agenda to meet the needs of the new Medicare Part D program, which included looking at the drug comparative effectiveness information on key Medicare conditions such as diabetes, cardiovascular disease, depression and asthma. And this information is going to be actively translated by AHRQ to different payers, patients and physicians. So moving forward in the future it'll be interesting to see how many Part D plans use these reports.

Second, with the coming of Part D means, as a researcher, there's just a wealth of information on Medicare Part D, drug use and how this interacts with the beneficiary's medical costs. So Medicare Part D in this new data can be used to evaluate the different benefit designs out there, evaluate them for how much cost savings they bring to the beneficiary, but also their impact on beneficiary health. The new Medicare Part D data can be used to understand the benefits and the use of drugs by the Medicare beneficiary population and the data can be used to both measure and report on the quality of Part D plan performance and the quality of pharmacy care.

And so finally, Medicare as its new image of a public health agency can also begin to directly communicate some information to beneficiaries about appropriate medication use, about comparative and clinical comparative and cost effective information. So it'll be interesting to see the options that CMS and Medicare choose to go down in the future.

[Applause]

ED HOWARD: Thanks very much, Tanisha. By the way there is information – Tanisha mentioned the AHRQ effective healthcare program. There's information in your packets about the program and a copy at least of a summary of the first report in that program having to do with drugs for osteoporosis.

The experts from outside, both outside congress and outside the country have spoken. And now we want to get reaction from the folks who are here on the hill and have to continue to shape the US prescription drug policy for Part D. And we're very pleased to have back with us two senior staffers who can offer some observations from both sides of the isle, from both houses of congress. Mark Hayes is the chief health policy advisor for the Senate Finance Committee under Senator Chuck Grassley, and of course as you know the

finance committee has responsibility for the Medicare program.

Cybele Bjorklund directs the democratic staff of the House Ways and Means subcommittee on health under the direction of ranking member Pete Stark. And I think they have jurisdiction over Medicare too don't they? Although some of my friends in the commerce committee who take issue with some parts of that. We're very pleased to have you both with us. And maybe Mark can lead off with some comments in response and maybe some observations about what steps that the finance committee have in mind. Mark?

MARK HAYES: Thank you very much. And thank you to all the presenters. This has been a very valuable comparison of how different countries approach these complex issues of drug pricing.

And I think the observations that I have are that the situation we have in the United States is so different for a number of very different reasons I think. But I want to mention a few things about the impact of Part D. The first thing is that the price increases in the United States have actually been lower in the last two years since the implementation of Part D compared to the years prior to that. Part D is a big new piece of the marketplace. It's not the entire market place, but it may be having some effect there.

The Part D plans prices themselves in the last six months went up less than the prices in the rest of the marketplace. So the Part D plans themselves have been more successful at negotiating lower prices than the marketplace overall. And we've also seen that Medicare beneficiaries are using generic drugs to a greater degree than they did prior to enrolling in Medicare Part D. And that's because a lot of them were cash paying customers. They bought their prescriptions at the pharmacy counter with cash, and as a result they were not as sensitive maybe to alternative therapies that were available, and I think the formularies that Part D plans present to beneficiaries for the first time have probably affected that quite a bit. And the price – it's been shown that the average prices for the premiums have been a lot lower than what anybody anticipated. The average price that beneficiaries are paying to enroll in Part D is about $23 compared to what was projected around $35 or $37 a month, which is quite a bit lower. So not only has the competition between plans been working, but seniors have demonstrated that they can look across these different plans and be very cost-conscious. And they've chosen these lower priced plans to a much greater degree than anyone anticipated.

But what have we heard though about beneficiaries' reactions to Part D? And I think this is really instructive

for us in the policy-making world in terms of the political salability of some of the efforts that other countries that are represented here have taken to manage their drug spending in ways that the United States has not done. One of the areas where we have heard a lot of criticism about Part D is in the area of formularies. And while there are some very important national standards for those formularies that all the plans have to meet – there's a formulary review process, there's a national standard for those categories and classes as was pointed out, the P&T committees and so on. And even if you're in a formulary, if you're in a Part D plan and the plan does not cover your drug, there's a very extensive grievance exceptions and appeals process. And there's different cost sharing depending on whether you're talking a preferred drug or a non-preferred drug.

This is really different from what we're hearing about what other countries do. If you have a positive formulary that says here are the drugs that are covered, the other drugs simply are not covered. That doesn't mean that you could get them and pay higher cost sharing, they're just not covered. And when we look at the chart of the number of covered drugs between the different plans, there's a big difference. And we hear from beneficiaries. I've gone out to all these town-hall meetings with Senator Grassley, and

one of the things we frequently hear are people saying, "I went into this plan and my drug's not covered under the formulary. So then I wanted to switch to a different plan." And the fact that they can switch plans is a good thing because they can then find the formulary that best meets their needs. If there was a national formulary they wouldn't have any other choice. And the process by which that formulary is decided upon is also really different.

And I often, in those conversations, contrast Part D with the VA. And when I do that I find that I get sour looks on the faces of people looking at me when I say well we could have a system like the VA. But the VA has one national formulary, so if your drug isn't on the formulary you can't change to another plan. You just probably won't be able to get the drug. And there is kind of a process in the VA. It's very hard to get off-formulary drugs. Only about 2-percent of the drugs in the VA system that are dispensed are off-formulary drugs. They really stick to their formulary.

Plus they have a very restrictive distribution network. You have to go to VA or you do what most people do in the VA is they get their prescriptions mailed to them. And I happen to have a little personal experience with this because my wonderful mother-in-law has moved in with us. She is fortunate enough to get her medications through the VA,

and so whenever I'm checking the mailbox I see these packages come in from the VA. Four in five of the prescriptions filled in the VA system are through mail order. But what have we heard from Medicare beneficiaries? They're concerned about formularies and their ability for their doctors to go through the exceptions process to get something that's not on the formulary and their ability to get their prescriptions filled at their local pharmacy and a really kind of a resistance to using mail order pharmacy.

And I think that presents for us a real challenge if we're even going to think about using some of the price control mechanisms that are used in other countries. And I think the sort of backlash that we might get from the electorate here would be substantial. The electorate here are really repulsed by the idea of a national formulary, by more out-of-pocket costs for off-formulary drugs or for non-formulary drugs. And they're really not thrilled about formularies to begin with. And I think that is a real challenge for us, and Part D represents really a balance then, and a number of the presenters mentioned that balance. And I think the balance that's in Part D reflects really the willingness of the public to accept the kinds of things that are in Part D to steer people toward those more cost effective drugs and to control that access.

Now we have done a few things then also besides Part D that I want to mention really quickly. One is that just this past February congress passed a reconciliation bill. The reconciliation bill provides to Medicaid, for the first time, the ability to have preferred and non-preferred drug [inaudible] in a way that it hasn't done before. This will allow states to have more of a private-sector-like formulary than they've been able to do in the past. That was very controversial to a lot of folks who did not believe that higher cost sharing should be applied in the Medicaid program. But again I want to say that's far different from saying the drug is not covered at all. If the drug is not covered at all in a national formulary they have no other choice. This is just saying that there would be some differential between that cost sharing.

And then I want to make one interesting observation about reference pricing – in the 16 seconds that I've already gone over – and that is that in reference pricing, by saying here is if all these drugs are equivalent we're going to pay the lowest price, and the consumer pays the difference. I think we're also experimenting with something very similar to that in the United States in consumer directed healthcare, by making consumers much more price sensitive so that their own out-of-pocket spending drives those decisions that they can

make on their own about which drug that they want to take or which therapy they want to access. So that's all I'll say. I'm sure, knowing Cybele and the panels we've been on before, I know she will have many things to say in response to what I've just said and no doubt generate a lot of other discussion. Thank you.

ED HOWARD: Cybele you agree with all that don't you? [Applause]

CYBELE BJORKLUND: Thank you Ed. And thanks to the Commonwealth Fund also for inviting me to participate. It's always fun to be on a panel with such impressive experts, especially from other countries because I think they often can go home feeling very good about their system. And for me it validates my concerns about ours. Because no matter what problems you have in your various other universal coverage systems. They pale in comparison to the problems we have here.

I will say that much of my prepared comments were going to focus on – and hopefully we'll still have some time for this – to talking about the need for us to get into some cost effectiveness and cost-benefit analysis research here and the positive influence it could have, both in our public and private programs. But we've turned into such a Part D discussion, we'll probably have to have a little bit of

response to some of that if I can read my chicken scratch. And I think it is clear that if we want to get pharmaceutical spending under control in this country we'll have to use both supply and demand side policy to get there. However as others have pointed out, it's very tough to do in our fractured environment.

And the beauty of studying these other countries is that they have universal coverage that in most cases relies entirely or predominantly on public programs. And with that comes the ability to make the decisions that need to be made. Sometimes tough – often tough – because of the competing interests, but when you also look at research funded by Commonwealth and others that make international comparisons, you find satisfaction in those countries much higher generally with some blips in UK than in the US.

And one thing I would like to clarify right now because there's been an assertion both by Mark and another panelist that Part D is a reflection of the sentiments of the American people and a reflection of our values, and our tolerance and our preference for a market-driven approach to healthcare. And I don't think that's exactly a fair characterization of the evolution of Part D or even necessarily the sentiments about it. Without wanting to retread a fight that started three years ago too much, it's

far from universal. And in fact the program was put together with a small privileged few. It did not reflect – it passed a bare majority of the congress in both chambers in its ultimate form. I haven't seen any surveys about whether people would prefer this approach or a system that promised universal access at an affordable price. There's a lot left to be desired, and I think we just need to get through it. I'm not going to go into the price disputes. What we have seen are that the prices and the plans this year have risen commensurate with the AWP price listings indicating that the plans aren't doing any better job at coming off of the pharma list price increases that are predictable. I think the fact that beneficiaries are choosing lower-premium plans is an artifact of two things. One there was tremendous confusion about what plan choices to make. And so generally it appears, from the limited data that CMS has released, that people have flocked to names that they trust and know, and that accounts for a large enrollment in United and AARP, irrespective of necessarily the price. The price is important, but they also want to know that the plan's going to be there for them and that they trust them and to cheap plans, hence the enrollment in a lot of Humana. So they are looking for a cheap plan regardless of whether it necessarily

meets their needs. We're still trying to find out whether these plans are meeting people's needs.

The initial few months there was a holiday on a lot of what passes for cost-control on these plans, which is really utilization access. And now they're starting to faze those things back in. We're hearing in a lot of congressional offices a lot of complaints about how to get through the exceptions and appeals process. And there was a last minute scramble by CMS and the plans to come up with a unified form. But they haven't required that everybody use that form yet. So it remains to be seen really how well this is working. And one of the key problems there is that CMS is not releasing a lot of the data, including some of the data that Tanisha mentioned, which would be useful in allowing people to compare plans as they approach the open season on how well they're meeting beneficiaries' needs. Call center response time may have been collecting I think on a monthly or bi-weekly basis for months. We have asked for it several times when Mark McClellan testified before our committee. And

we've asked for it in writing twice now. We've asked for some of the other quarterly data that – I think the first quarter came in May 31st – trying to assess how many appeals and exceptions are being filed per 1,000 beneficiaries and

the disposition of those and some other things. And we hope that they will release that prior to November so people can take that into consideration.

So I think that there's a lot we can do to improve research and practice and acquisition on prescription drugs, but we're really hampered until and unless we make systemic health reform changes in the US that bring us to a more unified system. Part D again is the case study as to the difficulty we have regulating a government program and extracting the value that taxpayers really deserve. We're projected to spend nearly a trillion dollars over the next 10 years but have no control over that spending. It's all been outsourced to the private companies. And furthermore because the statute prohibited price negotiation from the government, and broke up the largest group of purchasers that we have, and including those who are disproportionate users, so we could extract the most in a negotiation position, we've crippled the ability of the government to materially reduce prices or control spending.

I'm averse, frankly, to changing the FDA process in terms of safety and efficacy reviews. It's not my jurisdiction, so I don't want to get in a food fight with Energy and Commerce or my former colleagues from Senator Kenny's staff, but I do think we need another government or

quasi-governmental agency, whether via AHRQ, a new agency or another avenue to get more into cost effectiveness and cost-benefit analysis for the greater good. We're spending too much, both in terms of per capita spending and as a percent of GDP on all health, not just drugs, to not step forward to generate unbiased expert advice that public and private payers can use to evaluate the value of current and new treatments.

MMA – some of this has been mentioned – did contain a provision to start some of this research. There was lots of ballyhoo, including from certain republic corners, but the funding has fallen far short of its promise in need. DERP – which is mentioned in some of the written materials, but I don't know that we've talked about it here – out in Oregon is doing some interesting work. But there is surprisingly little discussion of that out here, and again I think that this is a national priority and something we need and would value for our public and private programs. We should start getting on the ball with it. And I would say where is the Office of Technology assessment when we need it. Many of you may not remember that agency because it was abolished with the GOP contract with America revolution in 1994. But it would be a handy agency to have around at this point.

[1] kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

I do think it's also important, as several panelists, Panos among others, had raised – physician and prescriber impact. Again, in our system, we have little control over that. Special interests really will get in the middle of our being able to regulate it because of it where I think GTC is an insidious[ph] contributor to our increased spending, the detailing practices of the pharma companies as well as a proxy for what you could do to control that. You can look at the VA or Kaiser Permanente, two large, close systems that have aggressive policies, at least on detailing, and they have physicians that are invested in those systems to resist the [inaudible] that come in the door.

It'd be nice to be able to address this in a bi-partisan fashion and I think we could generate some support from physicians and payers, but most of those are too timid to step forward on their own because they have day-to-day reimbursement issues that they're facing and they don't really want to play up against pharma and others.

So I think that there's no doubt that we want a thriving pharmaceutical industry that's producing new medicines, which can do a great good for a number of folks, but we need to really recognize that not everyone needs the once daily version or the pink verses the purple pill. And the key is finding out what works best for whom and the

actual value of a new benefit in successor drugs while having a viable, simple rational exceptions and appeals process that ensures access to drugs. And it's a balance that is exceptionally difficult for us to achieve in the Part D environment we've created where we have really very little direct tie. There's very little oversight. There are words in the statute. They're not enforced very well in the broader system, so I think we could benefit from some research that some payers will be incentivised to put to good use, but we're a long way from being able to replicate some of the systems in other countries.

ED HOWARD: Thank you very much Cybele.

[Applause]

Because we've had such a rich collection of information to transmit to you we have a somewhat truncated Q&A session, but I want to invite you to pull out those green cards and fill them out. Probably with the short time we have you ought to use the microphones to ask your questions, and we would ask you to do that in an expeditious way. Get to the microphone, state your question as briefly as you can, and we'll go from there.

While we're waiting for that to happen, let me just jump in here. Cybele mentioned it, and I think Steve was talking about the drug effectiveness review project, DERP.

What is that? Do people know about it think it's worth doing? Is it contributing one way or another to usefulness?

STEVEN MORGAN, PhD: I'll take that because I'd like to contrast Medicare Part D against the DERP, although it's related in some sense because AHRQ is funding some of the work that DERP does. DERP is a collaboration between multiple kinds of funders, both public and private here in the United States to sponsor the ongoing review of drug classes to look for best in class or best in show kind of performance for pharmaceuticals. And it provides assessment and then leaves it up to the payers to use that to make the appraisal and coverage decisions. The comparison I want to make is just the industry and public response to Part D verses DERP. I think – at the risk of never being invited again back to speak here – when Part D was brought on the industry was applauding. And I think that sent a message to everyone including states, consumers unions and independent experts as to what the likely impact on costs would be. Whereas DERP now is being applauded by states, consumer unions and independent experts, but the industry is not beginning to attack it, which would suggest that it is in fact the kind of thing that would raise the evidentiary bar allowing states and other payers to effectively force that kind of competition that we want to see. And it can happen

in a multi-payer system like the United States, as it can happen in Canada, which is a multi-payer system for drugs. If you raise the evidentiary bar in terms of establishing what is the best in class, what is the best drug for treatment, consumers will understand better why it is a given drug plan restricts choice, so to speak, to that particular product. And they may be willing to vote with their dollars if they want a particular brand they saw on television, but the information or raising the evidentiary bar is essential for forcing the kind of competition that would keep prices in check.

ED HOWARD: Yes, Cybele.

CYBELE BJORKLUND: The only thing I was just thinking as you laid it out that way [inaudible] is that now that we've called attention to DERP in this environment, I suspect their funding will be jeopardized.

MARK HAYES: I'd like to make a comment.

ED HOWARD: Go ahead, Mark.

MARK HAYES: We looked at DERP last year as a model that we could use in the Medicaid program because that's part of what participates in Oregon as you are no doubt aware. And part of the emphasis behind the cost-sharing program in the reconciliation bill around Medicaid was focused on the fact that DERP exists and it's working for a lot of states.

But states didn't have a way to apply any kind of formulary restrictions in the Medicaid program. So we changed that in the DRA, so that states can use and participate in DERP. It's a volunteer program. Any state can participate. And they have the ability to use a formulary process in Medicaid.

Now I also want to add too that I actually think there's a lot of support on both sides of the isle for comparative effectiveness research. I don't believe at all that it's a partisan thing. The money has been smaller than we would like as well. And Senator Grassley and others have written letters to the appropriations committee asking for more funding to be provided for that process. But I don't think you necessarily need a centralized formulary process in order for comparative effectiveness research to be of benefit. In fact Canada itself I think, it was mentioned, doesn't have a centralized formulary process, but nevertheless does comparative effectiveness review type of measures. So I don't think these ideas have to go hand in hand, and there's no reason why we shouldn't be funding comparative effectiveness research and make that available to Part D plans and other payers to state Medicaid programs and anybody who will use it. Whether it will convince beneficiaries that formularies are a good idea or not is a different question.

STEVEN MORGAN, PhD: I just want to reiterate or just make clear – I'm not calling for a national formulary here in the United States. I have argued for it in Canada because I think our willingness to trade off the individual verses the collective is slightly different in the two countries, as it relates particularly to health. But I absolutely am not calling for a national formulary here in the United States. I just think disseminating good evidence and let everyone make informed decisions – that's where we want to be. And I think both sides of the isle would agree on that.

ED HOWARD: Robin?

ROBIN OSBORN, MBA: I just wanted to pick up on that and ask just a follow-on question. In addition to agreeing that there's a real benefit to doing more comparative effectiveness review, one of the contrasts that seems to be between some of the other country approaches is that the information on coverage decisions actually is made much more public, is much more transparent, and consumers have access to it and rationales are given. And I'm just wondering the extent to which some of that is transferable to how Medicare Part D operates here and whether consumers are going to actually be demanding more of that.

MARK HAYES: I would at least say from my boss's standpoint – I mean if Senator Grassley stands for anything

he stands for transparency in government. And the idea of making that process transparent is something that we actually had in the senate bill S1 that did pass with a much broader bi-partisan vote than the final bill did. And so we wouldn't see a problem with that at all.

CYBELE BJORKLUND: I would never want to speak for the republicans on my committee, but when we have talked to them about this issue and the need for transparency, there is tremendous opposition from the PBMs and insurers from the pharmaceutical industry, and there's a lot of discussion in the nomenclature of consumer-driven healthcare about the need for transparency and CMS is moving forward with some hospital disclosures, which is sort of irrelevant because hospital choice is dictated by your physician and, for the most part, more complicated situation. We think you've got Part D on the table, we could start with transparency there. But I'd be really surprised if we see it anytime soon coming out of the House.

ED HOWARD: I'm sorry – go ahead.

DIANA DENNIT[ph]: Thank you very much. I have a question –

ED HOWARD: Do you want to identify yourself?

DIANA DENNIT: Sorry, Diana Dennit, America's Health Insurance Plan. I have a question on the European situation.

I got from the presentation that they were a lot of things sort of on a range of things happening in Europe. I was wondering what role, if any, the EU is taking to look at any kind of efficiency in trying to pull together some of those countries. I noticed New Zealand and Australia are working together, and I just wondered if the EU or any of the countries are working more collectively. And I hope I didn't misunderstand the presentation in that question. Thank you.

ED HOWARD: Go ahead.

PANOS KANAVOS: The member states are responsible for organizing, financing and delivering their own healthcare, and that includes pharmaceutical care. Therefore the role of the European Union is limited – the European Union bodies. Having said that, we do have a centralized review process through the European Medicines Evaluation Agency, but this is largely where things stop. There initiatives on public health. There are initiatives on rare diseases and [inaudible] drugs. They're for providing a sort of pan-European framework for research and support into conducting research in rare diseases, but in terms of finance, organization and delivery, the member states have the financial responsibility and, obviously, the burden of care. That rests on the principle of subsidiarity, which says that

because of fiscal issues, the member states decide how to cover, where to cover and where to stop.

Having said that, we do observe trends over time related to cross-border healthcare, the insurance directive and the portability of health insurance, and insurance across member states. But I think we are very far away from a common European health policy or a single European health insurance coverage. I think not in my generation.

CYBELE BJORKLUND: Diane you raised an interesting point that I'd meant to mention, especially after Libby's presentation. It's different but somewhat related. And that is the other interesting thing that's happening as we have our own issues here at home, we are using trade negotiations to try to upset the systems in other countries. USTR is going into these negotiations, often at the behest of pharma and trying to affect the coverage and pricing strategies in other countries. So it's not enough to have it be affecting us here at home. We're going abroad and trying to upend their systems, and it's a disturbing facet that seems to be with us in perpetuity now. We're getting ready to start another negotiation soon.

ED HOWARD: Panos?

PANOS KANAVOS: Following on from that, and I think Libby also mentioned the point, it does not necessarily

follow that US prices are the highest in the world. In fact as our research from the LSE, which will come out in the next few weeks will suggest it may be the other way around. And in fact it is the other way around. If you look at the top 70 or top 75 products which are common across the two continents, and when we look at some of the top European countries, Germany, UK, France, Italy, Spain and compare their prices with the US, it is the way around. It may be the case – in fact it is the case – that UK and German reimbursed prices are certainly higher than reimbursed prices in the United States. The common mistake we make and perhaps the USDR is making is the fallacy of comparing list prices in the US with list prices in Europe. And the list prices in Europe are reimbursed. List prices in the US, as you very well know, are never reimbursed. There is process of negotiation and discounting.

MARK HAYES: And if I can even just add to that one second more, it's further compounded by the fact that even the data we do have does not necessarily reflect all the price discounts that are happening in the United States. Because a lot of times we don't know what other rebates and price concessions are going back to the payer in this country – speaking of the need for more transparency.

Female Speaker: The surprising thing around that, and I'm looking forward to the LSE study, there's been some US ITA studies on the same thing. But if there were not very real fear and threats to the pharmaceutical industry for using an international benchmark pricing strategy as a benchmark for here, I don't think we'd see quite the opposition that we see. So while it may be true for some of the top drugs because of universal coverage systems those drugs are less preferred and therefore reimbursed higher rates when you can get to them, I suspect overall it would have a material effect on our spending here or we wouldn't see such opposition from Pharma for doing it.

ED HOWARD: We've got time for a couple of questions from cards, one of which asks "Have the healthcare systems in the respective countries yielded other non-productive side effects that the US doesn't currently deal with, such as weakened economic conditions?"

STEVEN MORGAN, PhD: No.

ED HOWARD: Okay. [Laughter] A one-armed economist.

STEVEN MORGAN, PhD: I'm going to throw into this because I mean Canada, we are your closest neighbor I suppose and certainly largest trading partner. If anything the Canadian economic advantage in terms of manufacturing is the fact that we have a universal public health insurance system.

A lot of automotive manufacturers choose to make vehicles in Ontario now as opposed to the United States because they know that the total cost of labor includes the cost of health insurance premiums. And Canada's universal public insurer is a lot cheaper than the multi-payer system here. So in some sense the economic benefits of a well-run health system, not withstanding the fact that our pharmaceutical sector is not particularly well run, but the rest of the healthcare system is reasonably well run and very efficient in terms of output per dollar spent. We actually gain a competitive advantage for that, and I think the Americans would do so as well if you could one day get to that point of having a universal system that was better managed.

PANOS KANAVOS: Of course I hear what Steve said and I quite agree. That doesn't necessarily mean to say that where you have a regulation, that doesn't necessarily lead to distortion. For example, and I have in mind reference pricing, which we have studied and we actually show that prices, for example, generics in European countries are significantly higher, particularly in reference pricing systems than they are in non-reference pricing systems, and I have in mind here both the UK, which doesn't have reference price, but also the US where there's an open competition system. So if that leads to – as the question says –

weakened economic conditions, I don't know. But I suspect we're looking at potential waste and inefficiencies which we can root out if we start thinking collectively and creatively as policy makers.

ED HOWARD: Robin has picked out a couple of related questions and we're going to make them the last ones, which you can listen to me read while you fill out your blue evaluation forms, if you will.

The first one is addressed to Panos and Steven. "In the UK, the National Health Service accounts for well over half of the prescription drug market on the demand side. Given this near monopsony market power, the National Health Service has leverage to negotiate lower priced drugs. (1) Could you comment on how this works? (2) What lessons could this provide to the US where the federal government is prohibited from negotiating price discounts?"

And we don't want our congressional folks to be left out. Mark Hayes is being asked, "How about the Families USA report, which clearly shows that price negotiation works to drive down prescription drug costs? So how come we can't do it in Part D?"

Shall we start with Steve or Panos?

STEVEN MORGAN, PhD: I guess my answer would be that Canada doesn't do it either. We're just as bad as the United

States in terms of using national leveraging to get a lower price. I mean there's all this talk about Canada verses US prices and it's somehow miraculously cheaper in Canada – it's not. We don't have these hidden discounts that occur between purchaser and the manufacturer. So we do a terrible job on this front. And we look to Australia, New Zealand, Europe – anywhere else but, frankly, the United States for guidance. So I'm looking forward to hearing Panos's answer.

PANOS KANAVOS: With me lies the burden of proof. No proof though, Steve. Back to the question – we don't have lower drug prices in the United Kingdom. I would strongly dispute that because we have a free pricing system, or a relative free pricing system. And these prices are reimbursed by the National Health Service. It is an actual monopsony. There's nothing else. I mean the private market is a tiny fraction. The secret of the UK's success I think is two-fold: one on the supply side there are about 10 people in the Department of Health running the pharmaceutical price regulation scheme, which is a scheme that controls the profits of the industry, but also looks at prices and runs industrial policy for the country. And therefore we pull investment into the country. And I think that's a big, big achievement and a big asset to have. The second of course being the demand side regulation, and I think there in terms

of physician prescribing I think we are fairly effective, but in terms of, for example, generic pricing there's a lot of work that we could do. We did another study, which is about to come in the next – well it has come out and was recorded in the Financial Times the other day – and shows that the wholesalers are essentially to a certain extent reaping off the NHS to the degree of 80-percent in the sense that they're buying $20 and they're charging the NHS $100. So that discount does not go to the NHS, and I think the US is doing a much better job at keeping the discount in the system as opposed to basically looking at benefiting some of the stakeholders. So I think positive lessons and negative lessons, but I think overall we're doing a reasonably good job in terms of controlling healthcare spent. But I would like a bit more access in the cutting edge medical technologies, for example, where we seem to be making most of them as second or third line treatment.

ED HOWARD: Libby, you had something to add to this?

LIBBY ROUGHEAD: Just a quick comment. In the 1970s Australia had one of the lowest prices in the world. We were 50-percent less than the OECD. We used our monopsony power to incredible effect down there. And so you can – you can use it and you can bring prices down. I think though the real question is – back to this question of balance – we

changed our policy because the industry all started to move offshore and we were in a bit of a spot. So there is this question of what sort of research and development to we want? And we don't necessarily want all of it. My country is belabored at the moment by this free-riding idea that the rest of the world is free-riding on the R&D that comes out of America. Why I showed you the prices that we pay for those drugs that have considerable health gain is that we're quite prepared to pay high prices for drugs that give us considerable health gain. And we will pay more than your country. But we won't pay for some of the drugs that we think the research and development wasn't worth the effort. And sorry the industry made the mistake, and so I think this question is not just about price control or cost containment. But in Australia we've stopped using that language. We talk about value for money and buying health outcomes. And so the question is about what sort of health outcomes do we want, and so what sort of price are we prepared to pay for that? And how do we work together to get there?

ED HOWARD: Thank you Libby. Mark, do you want to take a crack at the other half of that?

MARK HAYES: Sure, I'd be glad to. The Families USA study, if you'd call it that is about comparing Medicare prices to VA prices, and as I mentioned earlier, the VA

system is really, really entirely different. And I would challenge whoever asked that question to go to your boss and ask them if they want to introduce a bill to convert the Medicare Part D program into a program that works like the VA and then come talk to me. But in the meantime, the negotiating that is happening in Part D is working. The prices, the Part D plans are negotiating. The prices are growing at a slower rate than the rest of the market, and I think that we're going to see, as we go through another bidding cycle that my prediction would be that a lot of the plans who did not pick up a lot of enrollment may drop out. And you're going to see more market power than in the plans that will be left in that marketplace. They'll have even more leverage than they do now, over those pricing negotiations, and know you have an even greater impact in those negotiations. But if someone wants to have their boss introduce the VA bill – even the Gephart[ph] and Dingle bill or the Dashell[ph] bill that was introduced and debated in 2003 – none of those bills and President Clinton's bills didn't propose having the Medicare system work like the VA. But I'm always willing to look at new ideas, and if a member is willing to introduce that and give it a try I would be glad to talk to them.

ED HOWARD: How about Mr. Stark[ph]?

CYBELE BJORKLUND: Those bills may not – I can't speak to the Dashell bill – but in the house they may not have said let's slam everybody into the VA system, but they did use PBMs and others as contractors. They required price negotiation by both the PBM and the secretary with a double insurance policy to get a better price. So I suspect that we could do a lot better than we're doing today if we would unshackle [inaudible] the government.

MARK HAYES: I'm sorry Cybele. Both of those bills, and I know the Dashell bill had exactly the same non-interference clause that is in current law that prohibits interference in those negotiations.

CYBELE BJORKLUND: I said I can't speak to the senate bill, but the house bill did not have that language. It had the opposite. I'll send it to you later today.

MARK HAYES: I'd be glad to look at it.

ED HOWARD: Well we're beginning the negotiations right here. [Laughter] We've come to the end of our appointed time. This has been just incredibly useful I think. I want to first of all thank you for staying with it. This has been tough sledding. You stayed with us through DERP and monopsony and reference pricing and a lot of other terms that most of us don't use in our coffee conversation. I want to thank the Commonwealth Fund, and Robin in

particular for putting together, I think, just a cracker-jack program. And most of all I want to ask you to join me in thanking the panel for a wonderful set of presentations and comments on one of the toughest subjects we're going to deal with. Thank you very much.

[Applause]

[END RECORDING]