ALLIANCE FOR HEALTH REFORM

Pharmaceutical Policy and Pricing: Are Other Countries Getting Greater Value?

Alliance for Health Reform

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[START RECORDING]

ED HOWARD: If I can have your attention, I'd like to get us started if we could. I apologize to some of you who have been here for an hour and a half or something because our outlook section didn't know that it was going to daylight savings time to standard time over the weekend. And so it said better get here at 11:30. But we'll give you an extra brownie if that happened to you. So, thank you for your patience and your persistence and thank you for being here at this program that is designed to look at what we might be able to learn about controlling prescription drug costs from the experience of other countries.

My name's Ed Howard. I'm with the Alliance for Health Reform. And I want to welcome you to this event on behalf of Senator Rockefeller and our board of directors. There've been a lot of discussions around this town lately about restraining government spending. I think you may have heard some of that. And governments, federal and state, spend a lot of money on prescription drugs. And that spending's been growing not only in absolute terms but at least historically as a share of total health spending. It's somewhere between 10 and 15-percent of the total. And it's not just governmental costs that are affected, health plans, employers, hospitals and others

experience the increases even though the increases have lessened as in percentage terms in recent years.

Our desire to get a handle on drug spending is a focus in other countries as well as you might imagine. So with the active leadership of our colleagues at The Commonwealth Fund, we've organized this forum taking advantage of the presence in Washington of a number of top international experts and practitioners in dealing with drug costs. Our partner, as you might infer from that, in sponsoring today's program is The Commonwealth Fund, a philanthropy whose principle aim in recent years has been the promotion of a high performance health system in the U.S. but always with a keen eye on what's going on else where in the world.

And that segues nicely into presenting the Fund's representative on our panel today, Robin Osborn, on my immediate right, who's the Director of its international program on health policy and practice. She also runs the Fund's annual international symposium that's scheduled to begin tomorrow night I guess it is. A more complete bio of Robin and in fact of all of our speakers is included in your folder. And Robin will be sharing the moderator duties with me today and setting a little bit of context for our discussion as well up front. Robin thanks for being here.

ROBIN OSBORN: Thanks very much, Ed. And I'm delighted to join Ed in welcoming all of you here today. I know I'm speaking on behalf of Karen Davis, President of the Fund; Tony Shih, Executive Vice President of the Fund, when I say how pleased we are to convene today's forum. It's a unique opportunity to bring to you a distinguished panel of international experts from the United Kingdom, Germany and France and to be able to share with this broad audience of Washington policy makers a look at the approaches taken in three other industrialized countries to ensure best value in pharmaceutical policy and pricing.

And we're particularly grateful to Ed Howard, the staff at the Alliance for their collaboration in organizing the program. As many of you probably know, the Commonwealth Fund is a private foundation established in 1918 by Anna Harkness with a broad charge to enhance the common good. As Ed mentioned, the mission of the Commonwealth Fund is to promote a high performing healthcare system that achieves better access, improved quality and greater efficiency. And throughout all of our work, we are particularly committed to improving access and care for society's most vulnerable populations; the poor, the uninsured, minority Americans, children and the elderly.

The Fund's international program and health policy

premised on the belief that despite the differences in the ways that healthcare systems are organized and financed, the differences in culture and the political context in which they operate there are valuable lessons that can be drawn when policy makers, researchers, journalists look beyond their own borders at the experiences of other countries. And toward this end since 1998, we've supported international health policy surveys across national comparative research that I think has to some extent dispelled the conventional wisdom in the U.S. And that can operate similarly in other countries that we have the best healthcare system in the world.

Unpeeling all of that, what we see is that we — no country is the best or the worst. Each perform as well on some measures and shows room for improvement on others. And what we hope to do through cross national comparative research, benchmarking and exchanges such as today is share country policy experience and results, highlight innovative strategies and identify where country approaches may be relevant to the U.S. Ensuring access, improving quality of healthcare and efficiency are driving concerns of all industrialized nations commanding the attention of policy makers and the public alike. Similarly they're all concerned with getting value for money.

For the U.S. this theme resonates powerfully as we're

and at the same time challenged by a deficit crisis that makes reining in healthcare spending an imperative. U.S. per capita spending on healthcare was at $7,960 per year, more than twice the OECD median in 2008. In 2008, the U.S. spent more than 16-percent of GDP on healthcare. That too is double the OECD median and was 40-percent more than France, the country spending the next largest share of GDP.

When we look across the 11 core countries in the Fund's international program – the U.S., UK, France, Germany, Switzerland, Canada, the Netherlands, Norway, Sweden, Australia, New Zealand – despite spending more than any of the other countries, the U.S has fewer practicing physicians per capita, few doctor visits among the lowest number of hospital beds and length of stay. So, why are we such an outlier? One of the major reasons is the prices. In a 2004 ***Health Affairs*** article by Uwe Reinhardt and Jerry Anderson, they came to that same conclusion and succinctly titled their article, ***It's the Prices, Stupid***.

And despite our outspending every other country, we often deliver poor performance. In a recent study by Nolte and McKee published in Health Affairs, the U.S. ranked 19th on mortality amenable to healthcare. These are the deaths that could have and should have been prevented by the healthcare

system; bacterial infections, treatable cancers, diabetes deaths before the age of 50.

In The Commonwealth Fund 2008 international survey of chronically ill patients which included France, Germany and the UK, the U.S. ranked lowest on measures of access, patient safety and coordination of care. Patient experiences with pharmaceuticals were a critical area of concern. As integral as drugs are to these chronically ill patients, the majority of whom had two or more chronic conditions, 43-percent of those responding in the U.S., the highest by far of any of the countries in the survey, did not fill a prescription in the past year because of costs.

From our 2010 international survey, we know that U.S. adults were more likely than their counterparts in 10 other countries to have – take one prescription drug regularly and also more likely to take four or more drugs regularly. So not surprisingly given the higher rates of utilization, higher prices in the U.S., spending on pharmaceutics in the U.S. is highest among these 11 countries. In 2009, it was $956 per capita in the U.S. compared to $382 in the UK, $628 in Germany, $640 in France. Pharmaceutical spending per capita in the U.S. also increased at the highest average annual growth rate of the 11 countries between 1998 and 2008.

An analysis of IMS data by Gerard Anderson from John Hopkins, he found that for a basket of the 30 most commonly drug use – commonly used drugs in the U.S., the U.S. paid significantly higher prices than any of the other countries – twice as much as France and the UK, one third more than Germany.

In a 2008 analysis by McKenzie & Company – this is the last data I'll give you – they found that the U.S. annually spends $98 billion more on pharmaceuticals than would be expected based on per capita income relative to other countries. Some of the difference in spending is attributable to higher prices in the U.S., some to the proportion of generic verses brand name drugs, some to formulary decisions, what's going to be covered and some to volume. Infolded into the equation is the fact that the U.S. makes greater use of higher, more expensive drugs.

The historic funding in the American Recovery and Reinvestment Act for comparative effective research and for setting up PCORI, Patient Centered Outcomes Research Institute, offers an opportunity for the U.S. to build the foundation of better evidence for decision makings so that clinicians, patients and payers have better information on comparative efficacy and safety of pharmaceutics, devices and procedures,

This is an investment that other countries have already made. England's National Institute for Health and Clinical Excellence was launched over 10 years ago in 1999. France's National Authority for Health, HAS, has been reviewing comparative effectiveness since 2005. And Germany's Institute for Quality and Efficiency in Healthcare has been operational since 2004.

We'll have the opportunity today to hear the role each agency plays and the impact on pharmaceutical access and spending. In addition to the use of comparative and cost effectiveness review, we've asked our country experts to provide a more in depth understanding overall of pharmaceutical policy in their country and the direction in which it is going and how they're using policy to improve quality and lower drug costs. How, for example, they're promoting competition around generics, using comparative effectiveness and evidence in coverage decisions and what we can learn from their approaches to expensive new cancer and end of life drugs.

These strategies and the need to take advantage of them become increasingly important going forward as the pharmaceutical sector itself is changing dramatically. Pharmaceutical spending growth in the 1990s was highly concentrated in primary care class drugs, drugs for

came to be known as blockbuster medicines. Over the next five years, many of these drugs with combined total global sales volume of 142 billion will lose their patent protection. And the shift to generics and potential for competition creates a real opportunity to control price growth and possibly lower total pharmaceutical spending.

On the other hand, as Steve Morgan reports in the paper that you got in your package, what we see are trends in new drug approvals. It's a transition from these former blockbuster primary care drugs to biotech drugs for specialty markets particularly for cancer drugs. Roughly 30-percent of all new drugs under development are for cancer. And many of these drugs are priced very high. Forbes reported that nine of these new medicines were priced at more than $200,000 per patient per year. So policy makers across countries will face the challenge of decision making about end stage cancer drugs that tens of thousands of dollars but may only extend survival by a few weeks or months.

We are extraordinarily privileged to have with us today a stellar panel of international experts and policy leaders. And with that, I'll turn over to Ed.

ED HOWARD: Great. Thanks Robin. Let me do a little housekeeping before we get started. As Robin alluded to, there

more is online at allhealth.org, our website. And that, as you might imagine, will also include the extent – more extensive speaker biographies that will supplement the meager ones they'll get out of us.

Tomorrow some time you'll be able to look at a Webcast of this briefing on kff.org, thanks to our friends at the Kaiser Family Foundation. And in a few days, there'll be a transcript of the briefing on our website. Call your attention to the blue and the green. The green question cards that you have when we get to the Q&A part of the program, you can fill out and have brought forward. And the blue evaluation forms which we would ask you very sincerely and hopefully to fill out before you leave so that we can improve these programs for your future use.

Now let's get to the program itself. As Robin said, we have a star studded lineup. And we're going to start with Sir Andrew Dillon who's the Founding Executive Director of the UK's National Institute for Health and Clinical Excellence, a very descriptive name that also forms the best acronym in the western world, NICE. The Institute which is part of the National Health Service promotes clinical excellence by making recommendations on the effectiveness of treatments and medical procedures. And Sir Andrew, we're very delighted to have you

SIR ANDREW DILLON: Ed and Robin thanks very much. It's a great privilege to be here. Actually the acronym NICE is good. It's also the name of a biscuit you can buy in the UK. [Laughter] and before the cuts really started to bite, we used to supply these biscuits to our advisory case members as sort of a small token of our appreciation for the free time they give to us.

It is a real privilege to be here. You've got these slides so I'm not going to spend huge amounts of time on each of them. But I just give you a quick overview of pharmaceutical policy in the UK specifically issues around how new drugs get managed into the system and the interaction between pricing control mechanisms and the work that NICE does. On the face of it, it's actually a very simple thing if you're a drug manufacturer. If you've got a license in Europe for your new drug or for your new indication, you can fix the price and you can sell it in the NHS.

In practice, of course, life's a little more complex than that. All sorts of things influence the ability of a company to successfully market a new drug. The work of NICE is one. But local formularies and inevitably the sort of fiscal pressure that's affecting everybody, all healthcare systems, all combine to make it a rather more complex process. The

give you some basic metrics on the amounts of money spent in primary care so prescriptions by general practitioners and drugs dispensed in hospitals. And the graph at the bottom, the bad shot there, is expenditure in primary care over the last 10 years or so. As you can see, it's a flat line for quite a long period during the 2000s but it's starting to creep up again largely, I think, as a result of expensive new treat – some expensive new treatments being introduced into the system.

Since 1957, the governments had a deal with the pharmaceutical industry called the Pharmaceutical Price Regulation Scheme. There are only about three people alive on the planet who know how this system works. I'm asked – somebody who used to work, given it's a voluntary scheme, companies aren't require to enter into it, what the point of being a member is if you can sit outside and do what you want. And she said well it's not that simple. It's a club and it's voluntary. The benefit of being in the club is that you can influence the rules because the rules apply to pharmaceutical companies regardless of whether they're in the PPRS or not.

But it has – it's a scheme since given that it's been in place since 1957 which presumably suits both sides of the bargain. It's helped to set a relationship between the NHS and pharmaceutical companies which generally, I think, work quite

although when I come to the end of the presentation, I'll mention some changes to the system that will have, I think, some impact on the PPRS. And you can see that in the second bullet point, the objectives of the scheme. They're all perfectly reasonable. Naturally I suspect there are objectives that any organized health system would want to sign up to and indeed most actually have those as part of their ambitions.

The extent to which they are achieved though is the issue that's, in a sense, been a feature of the scheme. And it's periodic renegotiations through the whole time that it's been in existence. Delivering value for money critically is very important but equally companies want to make a decent return on the enormous investments that they make in their products.

Encouraging innovation, everybody wants though all of us probably have a slight different definition of what innovation actually means. But it's certainly there to simulate a signal to companies that the NHS is interested in that take forward advance our ability to treat disease and conditions.

Promoting access, I don't say, is also critical. If any of you know anything about doing business in the UK with the NHS, it's an extraordinarily complex and sometimes very

system, it's got a single payer in the UK Government. And it looks like a single managed organization. In practice, it's rather more of a federal system. And decision making particularly on money spent on pharmaceuticals, it's highly distributed in the system and represents a real challenge for companies to engage with.

But it probably has done well achieving the last objective, promoting stability and to some extent, predictability. Companies know the system. They know they've got a big challenge to actually get prescribers to use their pharmaceuticals to get the system — the NHS system to provide the resources. But essentially the system in that way in which they engage with this, the processed they go through in order to set prices has remained pretty much fixed through the whole of that period.

And the numbers that are appearing to show you what happens when every four years; I think it is that this scheme is renegotiated. The last time was in 2009. Essentially there's an attempt by the government to coil back something in overall prices. In this case, companies agree to a 3.9-percent reduction in the portfolio price. In other words, not for individual drugs necessarily but across the whole portfolio of the drugs that they're selling in the UK. And you can see that

reductions, the further reductions and then gradual increases that companies can expect to get again their portfolio prices. They're free to charge for individual drugs within that portfolio price and as they see fit.

What about the relationship between this scheme and the work that NICE does? Well NICE, as I had mentioned, was set up in 1999. Its job is [inaudible] its job is to look at pharmaceuticals. It does lots of other things too. When we look at drugs, we don't look at all of them. We don't look at all new chemical entities. We don't look at all new license indications. What we do is to try and pick those drugs where there's likely to be something significant about them. Are there uncertainty about their benefit to patients or the potential to drive significant resource consumption in either direction either additional cash and the opportunity to make savings.

The link with the PPRS is that companies in the 2009 scheme, if their drug is evaluated by NICE, obviously they'll declare a price. We'll use that in our calculations. But companies can come back again if they get new data that indicates that the drug offers more benefits to patients and might drive and improve price from the company's point of view to seek a price increase. But that would include a further

described as patient access schemes. These are either some varied discount on the published list price of the drug or alternatively some variant patient respond to scheme. So companies or the hospitals, for example, or general practitioners would pay a price based on the benefits – the actual benefits that the drug achieves for individual patients. And a range of those schemes have been put forward and have been used in the processes that NICE has for appraising new treatments.

I'm looking at a couple sides, but specifically how NICE goes about its work. We're not just interested in cost. What we do is to try and bring together and we start with an assessment of the benefits that patients can get from new treatments, the incremental benefit, what more does it bring than treatments that we have already in place. We talk widely to stakeholders including the company. We look costly impacts on the healthcare system. And then we exercise some careful scientific and social value judgments to reach a conclusion about the clinical and cost effectiveness of new treatments. And in assessing cost effectiveness, we use a cost utility analysis called a quality adjusted life year.

When I mention that term, it polarizes the audience immediately. So people who think it's not a bad way of making

it's an appalling way to make judgments about some time — about treatments some of which have the ability to extend life. But it is what we've been using. It does enable consistency over time. And it works this way. You can see the schematic - this green line plots where most of the [inaudible] is the incremental cost effectiveness rations form. If you look at the left hand access one at the top there, almost certain to guarantee that NICE would approve zero almost certainly not in the cost per quality range to [inaudible].

In these areas here, you can see in the green area, our advisory committee would almost certainly approve a drug in the yellow area. There have to be much more testing. And in the red zone, it's unlikely but they can. And you can see here, here are the three cancer treatments that the institute has supported the introduction or the use of in the NHS. And they fall in all zones. So these advisory committees have considerable discretion to make judgments about whether or not to recommend the use of the treatments. There's no ceiling beyond which they have to say no. It is about deciding and making a judgment as a group of individuals on behalf of the NHS and the wider community about whether or not a treatment has sufficient benefits for it to represent a good use of fixed national health system resources.

And if you look at across all of the decisions that NICE has taken, this includes some health technologies that aren't pharmaceuticals. You can see there that if you group together the first two lines there where we've said yes without any restriction to the second row. These optimized decisions where we said well here's something new and it is good. We should use it in these circumstances but keep what we've already got in other circumstances. The great majority of things that NICE looks at we find value in and we recommend the use of something between 80 and 85-percent. So we're certainly not an organizational whose job it is to make it so restrict in some unreasonable way the introduction of new pharmaceuticals or any other kind of technology into the NHS.

And finally, looking forward to the next couple of years or so, the Department of Health, the Government in the UK is very interested in trying to look at ways in which we can just become more specific and broader ranging in the definition of value. That's the critical judgment that the pharmaceutical industry when it looks at NICE would like us to improve on. Taking into account what is the sizable benefits, looking at products that address areas of [inaudible] in new products particularly new products with innovative features are the things that the government's keen to promote the use of. So

uses about essential – the essential importance of making an objective judgment about the benefits that a new treatment brings relative to the cost that the NHS is being asked to pay will continue to be featured the way in which new pharmaceuticals are managed into the healthcare system and their overall cost is controlled. Thanks very much.

ED HOWARD: Thank you very much Andrew. I wonder if I could just ask a couple of quick follow up sort of factual questions. One is who sits on those advisory committees that you were talking about making the recommendations in cost effectiveness?

SIR ANDREW DILLON: They're all – they're independent committees. They're made up of people who are largely physicians who are working in the National Health Service. But we also invite representatives from the organized patient advocacy movement. And each of the committees has two members who are currently employed in the healthcare industries either in the pharmaceutical industry or the medical devices or diagnostics. And there are about 35 people on each committee. And they're entirely independent. And they've worked to processes that NICE sets out. We provide them with the evidence base. But the recommendations that come out of NICE are written unfettered by those independent groups.

ED HOWARD: And on that last chart about the percentage of recommendations being positive, how many recommendations — how many of the requests for recommendations actually get recommendations? That is are we — are we excluding in this chart a bunch of applications that were judged insufficient on the face of it?

SIR ANDREW DILLON: No. What we — companies don't apply to have bad products evaluated by NICE. It would be quite interesting if we went to that process. We approach the companies and say we'd love to look at your product and appraise it because they'd jump at the opportunity. So they come along and put their submission in. I mean what these figures say is what they are. So there's a 100-percent of the things that we look at. You can see how it's distributed there. The things that we don't look at in drugs go into the system and sell or don't sell on the basis of the perception of the wider NHS without any signal from NICE.

ED HOWARD: Okay. Thank you. We turn now to Rainer Hess whose title is Impartial Chairman. We have a few of those in this town. But he is the Impartial Chairman of Germany's Federal Joint Committee. And that committee has authority over the benefit packet for some 70 million German residents and reimbursement levels to providers including pharmaceutical

providers. So we're looking forward to hearing from you about the system that you operate. Mr. Hess.

RAINER HESS: Oh. Thank you very much for inviting me to this interesting conference. And I'm very interesting to take part on the further on the discussion about getting greater value. I can not answer the question if Germany has a greater value than France or Great Britain or your country. I can only ask the question how is the value in Germany we pay for. And, we have a big discussion about this point. Is our system too expensive?

[Inaudible] right instruments to save quality and efficiency special in the pharmaceutically care. And so as — we have these discussions in years. We have very, I think, second or third year we have a reform act in the healthcare system in which specialty pharmaceutical care is in every healthcare reform and it's a point of new regulation. Because in Germany, there's the expenditures of pharmaceutical care are rising steadily over the average. And the reason is — and look please at this chart. As we have in reference prices in Germany since 1997, we have a very good running referenced prices staying in the generic drugs prescription.

The generic drugs prescription has a share of 70-percent of prescription in Germany. It's, I think, one of the

expenditure. So you see it contrasts the – we save money with the generic drugs. It's a reference for our system but we have to pay this drug more than additional for the patented drugs.

And as we have this reference price system in the generic drugs, we have fixed prices under the limit of reference prices. We want to have a rising volume of prescribing generics. We reach it but we can not solve the problem only with the generic solution. We must have a solution on the right end of the slide on the expenditures of patented drugs. And there you can see that the prescribing are decreasing. But expenditure are rising extremely because of the cost for each new drug.

And in Germany, we have no discussion about qualities. We don't accept qualities. If the service is – has costed much money, we have to pay for it if it's necessary. So we are not able to cut the expenditures by qualities and say well this service is too expensive for our system. We can not pay for it. We only make assessments between two possibilities. And we can say well between two possibilities in the same indication we have one which is extremely possible, but has no additional benefit. And we have [inaudible] which is good and it's not so costly. Then we can exclude the more costly possibility.

But we can not say we have the one service which is extreme cost — extreme expenditure and then we cannot say well, we exclude this. And that's why we accepted high costs in the pharmaceutical treatment all in the past years. But we have a big discussion about the question how this [inaudible] earnings - the value this [inaudible] they have. And in this discussion, we come to the results that we in Germany have to me too problem. We have a lot of innovations which have not additional benefits which are morally the same structure than the existing patented drugs.

And that's why our government, this is beginning of this year, starts a new early benefit assessment in which all new medical agents — pharmaceutical agents must be assessed on their additional benefit. And if they have no additional benefit, we have [inaudible] reference price system, an upper limit of reimbursement negotiation. And if they have an additional benefits and the additional benefits is the basis for an additional payment agreement, the payment negotiation between [inaudible] and the pharmaceutical industry.

And to understand this, I must clear or show you a little bit the characteristics of the term healthcare system. In Germany, 90-percent are covered by the Social Health Insurance System. And the membership is based mandatory for

limit of wages. But we have like Great Britain and I think also France, we have a servicing kind system. It is very much a varied co-payment.

In this servicing kind system, the patient has a free choice of sickness funds where you still have 150 sickness funds. You can choose one of these. The patient has a free choice under the providers not only general practitioners but all the specialists. So we have not like Great Britain, a gatekeeper system as Great Britain has. You can go in Germany direct to a specialist. And the specialists are not working in hospitals. They have their office space out patient care. And they also prescribe drugs. And they prescribe the high specialized drugs in Germany. And this makes one of the problems we have is patented drugs.

We have a big competition among sickness funds by directive contracting and as part of selective contracting is discount and negotiating discounts between single sickness funds and pharmaceutical companies. But the main principle is the solid [inaudible] in Germany is the young pay for the old. It helps you pay for the sick. The singles pay for the family.

And that's why the government must guarantee financial stability of our system. If the premium rates are running out of financial stability, people have social problems in Germany

the system running in the existent premium rates and not to raise expenditures by unnecessary expenditure for pharmaceutical care.

And please follow me in the next slide. I fear I am running out a little bit of time. First, [inaudible] to go on the bottom of the slide to the top, the patient has demand for service in kind. I told you the sickness funds are not allowed to operate on hospitals - operate on ambulatories - medical ambulatories. They must contract with the physicians' organization on the one hand and the hospital association on the other hand.

And these contracts are done on state level and on federal level. On the federal level, these main players, they build the federal [inaudible]. And that's why I'm the independent chairman because I am not part one of these main players. I'm independent as a lawyer. I'm moderating the system. [Inaudible] interest come together at one table and they must have compromises as about of the independent chairman makes the decision.

But [inaudible] is not an expert association; he needs the independent scientific advice of an independent institute. And this is the [inaudible]. The institute for quality and efficiency is the basis of our benefit assessments. And we

committee but not – it's the same rights as the other members but they have no right to vote.

The industry, other than in Great Britain, is not our partner with concrete negotiations but they have a big right to bring in the interest in our system. We have to guarantee transparency of assessments with graphs or [inaudible] we have written at our hearings. So we must hear the voice of the industry and their statements. And we have a right to say – they have a right to sue against us and we must justify our decision in published assemblies of our – our assemblies are taken place in public or everybody of us can take part on this. So our decisions always have to be justified in a public meeting.

So what are the – no, I was – then this go to me from the bottom to the top down. And what would you – what do we do in pharmaceutic care. In pharmaceutical care, the Federal Joint Committee decides a pharmaceutical guideline, a pharmaceutical directive. In this directive, all results of the benefit assessment of the [inaudible] are going in as composite directives for each physicians, for each hospital, for each sickness fund. So our directives are compulsory because we have this structure for each physician working in Germany in outpatient or inpatient care for every hospital, for

And on the – if you go a step down then the physician organization and the sickness organizations, they negotiate targets – health targets on the basis of our guidelines which contends volume, an estimated accepted volume of drug prescribing and targets how to reach it, targets to higher quality, targets [inaudible] generic at rock basis of lowering the share of me-toos.

And that's why we have several [inaudible] to us on federal level and on state level. I can only read it because of – I'm run out of time – reference for our setting for comparative drugs including patented drugs, early assessment of new pharmaceutical agents with six months after market access started in 2011, negotiation of setting of reimbursement for 12 months after market access started in 2012, exclusion of drugs in case of inoperativeness compared with [inaudible] alternatives, OTC exemptions if lifestyle [inaudible] framework of negotiations of pharmaceutical care targets.

And on state level, we have also this negotiation of saving goals with measured goals, these measured targets and an IT-based drug prescribing check of physicians in the case of exceeding the [inaudible] advisory board which giving advices to the physician in most cases as a compensation he has to pay out of his own pocket if he's prescribing [inaudible]. And we

pharmaceutical companies based on tending for the insurance including the possibility of risk sharing and price volume, payback agreements and binding of the pharmacist to dispense a discount negotiated drug if the physician does not exclude a similar.

Well this is a new system of early assessment. It starts in the beginning of the year. We have the first case within this early assessment. It's a project of AstraZeneca. We — the pharmaceutical companies must give us a [inaudible] in which they prove an additional benefit if they want to have a higher reimbursement price. And then the Federal Joint Committee orders an early assessment by the IQWiG. And after given this assessment after three months then we have to decide within further three months about an additional benefit. We are now into preparing of a hearing of the pharmaceutical industry and the scientific advisors which take place on the 17th of November. And the decision was made on the 5th of December. After this there's a half year's period for price negotiation.

So, and in the future [inaudible] is running like follows, we have still a free market access of a new pharmaceutical if no false hurdle so every company can bring its products freely in the German market. After market access,

pharmaceutical gets by its own but one year after market success then the reimbursement price negotiation comes into [inaudible]. So we have the early benefit assessment of new pharmaceuticals. We have the possibility of bringing [inaudible] in the reference price system. Then we have these reimbursement price agreements for new pharmaceuticals.

There is a cost benefit assessment only in second line if there is no agreement between the manufacturer and the sickness fund. The policy reimbursement price negotiation, I – my personal opinion, it would be better to bring these in the first line and not in the second line. After the first assessment, if there are subsequent benefit assessments if they're from manufacturer can come back. After each year, he can bring a new dossier if there is a new development with his product. Also the Joint Committee can call up and review authorization. And also they can call up the existing markets to bring its specialty in this early advice system if the existing market is in competition with a new assessed drug.

We can exclude drugs if they are inappropriate if we give [inaudible] advices on the basis of our pharmaceutical guidelines. And so we have a new structure of steering this pharmaceutical course but we must first make the experience visit before we can say it brings higher value. The existence

we have big problem with patented drugs. Thank you very much. And excuse me for speaking too long.

ED HOWARD: It's a complicated system. Thank you very much. Next we hear from Dr. Jean-Luc Harousseau who's a professor of hematology at France's University of Nantes. And since this past February, he's been chairman of the French National Authority for Health. Now the Authority is an independent non-governmental body that assesses for governmental entities the clinical benefit of drugs and medical devices, diagnostic therapeutic procedures that are covered by the National Health Insurance scheme. So we're very pleased to have a chance to hear from you.

JEAN-LUC HAROUSSEAU, M.D.: Thank you very much. Thank you for inviting me to participate in this meeting. I will try to briefly summarize the question but I have to say to start that the problem is really burning and especially currently with the economy crisis in Europe and in France as well. So the government is still discussing the budget for next year. And they have to decrease the expected budget because of say prediction for the gross of the GDP next year. So, it's a difficult problem in France like in other countries.

So the French [inaudible] first, it's at the national level. Second, it's a universal care coverage. Mostly based

which covers more than 80-percent – 90-percent of the population. The rest being covered by what we call CMU universal medical coverage since 2000 and is for insured – uninsured patient and also for supplementary coverage under a certain threshold income.

There is also a system for supplementary health insurance and the 92-percent of the population subscribe entirely to supplementary health insurance. This system covers all medical services, hospital care, ambulatory care and prescription drugs. And as regards to prescription drugs, the co-insurance system depends on their therapeutic value.

What are the rules for drug reimbursement and pricing? First, all drugs have to be assessed by this body, National Authority for Health, before inclusion in the – on the positive list of reimbursed products. The role of the specific commission in the HAS called CITY curiously commission – transparency commission should changed. It should be commission for therapeutic interests. So this role is to give an advice. We don't decide. We give them advice for reimbursement and pricing.

Reimbursement is mostly based on what we call SMR which is the actual benefit for the patients. And there are four levels insufficient, theoretically it’s no reimbursement and it

reimburse a drug whose benefit is insufficient. Weak; it's currently 15-percent but it's currently debated. Moderated; 30-percent reimbursement and important; it's 60-percent reimbursement – used to be 65.

The pricing is based on what we call the added value, ASMR and there are five levels which is, in my opinion, a little bit complicated. The important point is that for 30 chronic diseases what we call ALD; the coverage is 100-percent by the national health insurance. And it's really a great concern for our healthcare system. It's a concern only 13-percent of patient but it's already 68-percent of spendings. The list of reimbursed products is reviewed every five years or earlier in case of new information is available.

Just a word on the special list for innovative and expensive drugs, in addition to the positive list of reimbursed drugs, there is a specific list for coverage of innovating agents and devices in patient care hospital. These drugs or devices are fully covered by the NHI outside the hospital activity-based financial system we call T2A system related to activity and based on the object type information system. This list is mostly for cancer drug or for new biotherapy drugs. And it's important to notice that off level use in authorized and reimbursed if good clinical use according to availability

Finally the budget for this special list is fixed and [inaudible] by the Parliament. So the Parliament plays an important role. It defines every year what we call ONDAM which is the national health spending objective. And the objective for 2012 is an increase of 2.8-percent to be decreased because of the economic crisis. So the role of the HAS, the National Authority for Health is to give an advice to first the Committee for pricing based on the ASMR and second, to the National Health Insurance System for the admission to reimbursement and level of reimbursement. The decision is taken by the minister and the drug is written on the positive list.

Excuse me. So this cartoon is just to indicate how the decision is taken and how we give our advice. We look at the clinical aspects and especially efficacy and effectiveness. And we also look at other aspects especially disease characteristics, severity of disease, target population, impact on public health and impact on the healthcare organization. So as we regard the reimbursement either the benefit is sufficient, the drug is reimbursed at the different level I showed or the benefit is insufficient and the drug is not reimbursed.

If the benefit is sufficient then we discuss the price,

the drug should be reimbursed only if the price is inferior to competitors. If there is an added value, the price is negotiated with pharmaceutical company by the special committee. And if it's an outstanding drug, the company chooses a price and usually it's the European price. So this special pricing, CEPS, is remit – is an agreement with industrial company for provisions for data access, good use and expenditure gross control.

Decision and advice on drug pricing is annual. And there is an annual individual price volume agreement with company. There is monitoring in spending on drugs in relation to the annual budget targets and there are sanctions over shooting volume targets. We rarely use risk sharing agreements.

Besides the pricing, we do a thing in France that what is important is also the prescription by the doctors – by the physicians. So there are incentives for generally prescribing by physician and the substitution and the rights for pharmacists. There is also a regular increase in [inaudible] facts. There are limits on the number of drug reimbursed. And currently many drugs, if there are no real benefit – no actual benefit, are removed from the positive list; 600 in the last few years. This year there will be a decrease in the drug

from 35 to 30-percent. And we have – the government has excluded severe hypertension from the list of chronic diseases to be reimbursed at the 100-percent level.

As we guard the measure for professional, there is a recent low, which pushes professional to enter specific system which is called continuous professional development base and continuous education and evaluation of professional methods. There is also in digital contracting with physician by the NHI. And recently they introduced what we call a cappy which is a contract for improving quality of care and reducing costs. It has been introduced in 2009 and it will be extended to all GP in 2012 and it will base what I call a French P4P introducing a list of quality indicators in specialty including generic prescription. As we got patient, we are late but we try to introduce the gate keeping and we now are what we call the referent doctor. So the result of that is in 2010, we are improving. As you said, we were in the top three for spending as per capita and per GDP. But we are improving. The increase in the 2009 was 1.3-percent while it was 3-percent in the previous five years. And the effort has been made mostly in community pharmacy. We still have the problem of hospital because first prescription of expensive drug is, of course, in the hospital.

I do think that this slowing down of gross is, of course, due to the impact of price management through the impact of measures for rationale prescribing. But it's also due to the lapsing of patents and the growing of generic substitution and unfortunately except in the oncology to the reduced number of new expensive innovative drugs.

So to finish my last slide is the role of HAS in this attempt to reduce the healthcare spendings, we first have the role for a health technology assessments especially for drugs but also for medical devices. And increasing aspect of our remedy is see economic – economic in the public health evaluation. But we have also the promotion of quality of care and safety of patients regarding medical information quality, regarding accreditation of healthcare organization and some physician and of course, regarding clinical guidelines for quality of care and reducing costs. Thank you.

ED HOWARD: Thank you Dr. Harousseau. We turn now – our final speaker is Ian Spatz. Ian's a Senior Advisor in the National Healthcare Practice of Manatt & Phelps and Manatt Health Solutions. And he's a principal in his own policy consulting firm. He's been a vice president for Global Health Policy at Merck & Company. He's been the legislative director for Senator Lautenberg. And today we've asked him to relate

implications for the U.S. healthcare system. Easy enough to do, right, Ian?

IAN SPATZ: Exactly Ed. Well thank you Ed and Robin for inviting me and the staff of the Alliance and The Commonwealth Fund. I very much appreciate it. It's just an amazing panel and I'm honored to be a participant on it.

I think there's one thing that all four of us can agree on from whatever our perspective is that the goal of getting value for money, paying for medicines based on their value is one that we all share. It not only is the right thing for those who are paying for their medicines to only pay for what the value is but it's also the right thing for those who want to innovate and create new medicines because they're getting signals – the right signals to create and invest in the right medicines, the ones that will really have differential value in our healthcare system.

What I'd like to do today is make three points in regard to the presentations that we heard. Three points that I hope you – I can get you to agree with at the end of my talk. The first is the U.S. is different. Seems pretty simple but we'll go into that.

JEAN-LUC HAROUSSEAU, M.D.: Good point.

IAN SPATZ: The second is that the search for value is

that you've heard about will seem very familiar to you if you're a member of a health plan. And the last point I'd like to make is that the success we have in trying to find the value and paying for value will depend on investments in generating data not just investments in analyzing the data that exists today.

So let me start out by making the case why the U.S. is different. And of course why that matters to the discussion we're having today. There's some ways in which the U.S. difference is on the surface not that deep. One, for example, is the difference among the countries that are represented here in consumption of wine. It was fascinating looking up these numbers.

JEAN-LUC HAROUSSEAU, M.D.: Thank you.

IAN SPATZ: We have a winner — a clear winner in this area. [Laughter] another kind of superficial measure may be in the consumption of beer.

RAINER HESS: It's [inaudible].

IAN SPATZ: Yeah [laughter].

SIR ANDREW DILLON: It's [inaudible].

IAN SPATZ: The consumption of beer, we also have a winner in this area although the race is a lot closer in this area with France falling well behind. So some of it is just

that kind of simple and not that important but of course, some of it is a lot more important and relevant to health.

Here's one that is a differentiating point certainly for the United States at the bottom which is the percentage of adults who are obese at least as measured by BMI. That has consequences for how we operate our health system, the value determinations we make and how we look at that.

Another thing is that Robin did an excellent job, perhaps too excellent a job of giving us all the statistics about why pharmaceuticals in the United States may cost more than in other countries. And these are very difficult comparisons to make for some of the reasons I just mentioned but also for other great differences in our distribution systems, how we price things, exchange rates. But in some ways it shouldn't surprise us that much as Americans that these prices are different because the prices of everything are different between the United States and other countries in healthcare. That was the point Uwe Rinehart's article it's the prices.

Here's an example of CT Scans for the abdomen. And these are very large differences. I should note the U.S. price is an average price. It varies a great deal from system to system. Here's another one on bypass surgery. These are the

hospital costs and physician costs. These are radical differences.

So when we look at the fact that pharmaceutical prices are different, I just urge us to look at the context in which these differences occur. Of healthcare systems that pay physicians and hospitals and everyone much less for what they do in this area. So those are just some of the differences.

Another difference though is political. We've heard a lot about health technology assessment, looking at the cost effectiveness of drugs with the UK example of NICE being, I'd say, the most direct in that area. But you may remember a law called the Affordable Care Act that was subject to some debate up here recently. We weren't allowed to use the word cost effectiveness in that legislation. We couldn't talk about it because it was called rationing. In fact we weren't even allowed to use the words comparative effectiveness because those were considered rationing.

So we came up with the term called patient centered outcomes research which no one really knew what it meant including the organization we set up to implement it which who's first task had to be defining patient centered outcomes research. So these are really important differences. So you can not just port ideas from one country to another as much as

And I didn't even go into, of course, the differences that you all know in the healthcare systems that we have. Where in the United States, if you don't like your healthcare plan, you might want to change your healthcare plan. In some of the countries we're talking about here, if you don't like your healthcare plan, you might have to move out of the country. Those are differences. They're not criticisms of those differences. They're just differences.

The second point is that the search for value is already under way in our country. This isn't something new. These ideas have been here before. One of the ways of looking at it is just the size of some of the institutions we have here in the United States that are searching for value that have the ability to use any of the systems that we've talked about to employ health technology assessment, to use reference pricing, to encourage the use of generics.

Some of these are larger than the countries that we have represented here on this panel. So we have institutions that exist that can be very effective. The ones here, of course, are the pharmaceutical benefit managers. This doesn't even include some of the health plans that exist and some of the large employers that are out there.

So what are they using? Well you know some of them.

negotiations within therapeutic classes that have competition. They're forcing generic substitution. That's done by state laws in the United States. It's certainly encouraged. We have the highest rates of generic substitution that we have ever seen, more than any country represented here and the highest actually in Medicare Part D, the prescription drug benefit.

We use prior authorization. We want to know sometimes whether someone really needs a high cost drug. The doctor may have to submit information. It'll have to be remove — reviewed by nurses and physicians. We have plans for trying generics first even when the generic isn't the same as the brand. Seeing if you really will succeed on that and only if you fail on a generic medicine might you take a high cost brand name. We use drug utilization review. We look prospectively and retrospectively about what physicians are doing to see if they're prescribing according to guidelines. And if they're not encouraging them to do a better job in that area.

And then just finally mentioning that these are — there are so many more I could mention. The idea of risk sharing which is increasingly happened in Europe and is now happening in the United States where pharmaceutical companies are sharing the risk with payers on determining whether the outcome that you promise will be the outcome that you get. So for example,

there are products now where if the – if it doesn't work for the patient, the healthcare plan doesn't have to pay for it.

So these are all things that are happening in the context of a U.S. system. It's all possible. And it occurs. And it's actually working. And this is a chart that's taken from IMS Health which adds up all the numbers of drugs sold. And as you'll see the line represents drug trend in the United States. A lot of people just don't even know this how drug trend has plummeted.

Now the tools I just discussed are only one of the reasons they've plummeted. Another has been the emptiness of drug pipelines. All the products now that are also going generic so there's many reasons behind it but this is actually a success story in the U.S. healthcare system right now for a lot of the reasons that I mentioned. Does that mean that every product is priced appropriately? Does that mean the value received from every product? I'm not asserting that. I'm just asserting that these efforts are already under way in the U.S. and are really beginning to add up.

Lastly, want to discuss the issue of data and not just data analysis. I'm going to [inaudible] pick on some things here. One of them out of NICE, one of them actually from a health evaluation done by the Cochran Collaborative just to

give you some idea of what you see in some of these HTA evaluations.

The first and I have changed the name of the products to protect the innocent and also my business. Whether the addition of a product to a chemotherapy regime for this type of cancer improves the health outcome has not been established. And then one from NICE, you can probably know the product. It was not certain whether the product provides enough benefit to patients to justify its high costs. So NICE did not recommend it.

What are these kind of evaluate – these are typical evaluations. What do they really mean? They mean we don't know. We don't know whether something offers differential value. And I want to say that's a very different statement than we know it doesn't help. It doesn't have differential value. Too many times what we're seeing in health technology assessment are not enough good studies, not enough good data, to make these determinations.

Does that mean we shouldn't try? I'm not suggesting that. Again, back to my last point, it's already going on in the U.S. market. But where are we going to generate the good data on which all the authorities represented here and the PBMs and the health plan are going to get to this information?

the United States to make a major commitment in this area which is setting up the patient outcomes research institute. We've committed an amount that's going to reach $500 million annually by 2015 to generate data not just on pharmaceuticals. In fact most of it probably wouldn't be about pharmaceuticals that's not where the money is. But there is some money there and we're going to generate this information.

But I think one of the challenges and I'll be interested in hearing my fellow panelists talk about is what commitment of their governments making to spend the millions and millions of dollars that are necessary to generate this kind of information?

So in conclusion, the U.S. is different. Let's not just port these ideas over from one system to another. Let's remember that some of the really good things that we heard about in this panel today that are going on outside the United States are going on in the United States. They can occur in a system that's pluralistic but it's a system where the government doesn't make one decision that everyone has to follow. It's a decision where there are choices out there. There can be differences of opinion and different ways of looking at the same information.

And last, I just say the challenge is will the United

research that's necessary to generate this information? Some of us feel already that the U.S. is doing more than its share of the research in developing new pharmaceuticals and biotechnology products. Is that the way it's going to be for the research that's necessary to make good health technology assessments? Thank you.

ED HOWARD: Terrific. Thank you Ian. Let me remind you, you have green question cards that you can fill out and someone will bring it forward. Let me make sure that Robin is involved in this aspect as well. You should feel free to jump in with any questions that you have. And, while you are in – I'm looking for microphones. There's one and there's one. Yes. Okay. Feel free to come to those microphones, identify yourself and be as brief as you can, direct the question to a particular panelist if they – that's –

SEAN DONOHUE: Thank you for the presentation. It's Sean Donohue with Eli Lilly & Company. I'm curious to ask our guests from overseas. So much of the medicine today, so much of the research is based on what we call personalized medicine or individualized medicine. And I think the science bears that out increasingly. How do your programs deal with that situation where you have unique patient needs and yet you have kind of a size fits all approach?

JEAN-LUC HAROUSSEAU, M.D.: Yeah. You're right. In many diseases there is a trend towards personalized medicine and specialty in my previous job. You know oncology where we try to determine which drug will be effective in a given patient. What we have done in France is to try and define those markers which are able to indicate which patient will benefit from a given treatment and to reimburse the test which is necessary. This is the case for – except for current cancer in the specific drugs which are active in patient with specific markers.

But to be honest, in my opinion, in France at least, it's not time for a personalized medicine for everybody and especially for primary care. So it's mostly for chronic disease and severe diseases. And our question in France is how can we manage 100-percent coverage of all chronic diseases including cancer? It's really an issue. And we are working on what we call care pass way, trying to define which is the best clinical pass way for a patient.

We are trying to work more on cooperation between the physician, nurses and other professionals which is the case in the United States but which is not the case in many countries in Europe especially France. And we are trying to compare the best clinical pass way to the cost of the different clinical

pass ways. But it's ongoing research and it's not specialized medicine currently.

ED HOWARD: Rainer Hess.

RAINER HESS: Yes, in Germany, we have nearly every month a conference about individual medicine. So it is a big discussion. But the researchers in Germany, they follow you and say well it's not though – we are not so far [interposing] we are not so far that we can bring it in the market in a broad sense. We have two products, cancer products, which have market access. They are combined with pre-diagnosis.

And we have one on the floor on the GBA in this early assessment. So next year, we'll have – we'll make the first decision about pharmaceutical against cancer combined with [inaudible] genetic diagnosis. And so the big question for us as it has a market access, we can not say it has no benefit. And so the question for us is how to deal with the repeat diagnosis costs as a part of the pharmaceutical care or have there been addressed separately?

And in this question, we have a discussion. And in my opinion, we have to include the cost of the pre-diagnosis because they describe the patient group for which this pharmaceutical has an additional benefit. And when we decide an additional benefit we, in the same time, must decide for

And then we can reimburse the negotiated price for this special group and not for the total cancer group of – the total group of patients with the same cancer.

So I think we maybe have make – we have to maybe listen but we are not – we are in a similar stage like you told us from France that this is a maybe future development but it's not as ready as we can bring it in the broad sense in the healthcare market.

ED HOWARD: Okay. Sir Andrew.

SIR ANDREW DILLON: Well I mean companion diagnostics are really exciting prospects. The ability to target therapies on those patients with sickly disease or conditions who we can pretty much guarantee will get the expensive benefits. It's fantastic. It – you can still apply the same evaluative techniques to look at the consumer benefit that the targeted therapy brings. You still have to make the same judgment about whether or not – whatever the system and however it's funded. It has the ability to adopt that new therapy.

But the general concept that we are able to predict ahead of time whose going to get benefits as well as the quantum of benefit puts you in a much better position to make the sort of judgments in our different ways that we do make – have to make about value in order to underpin that decision

ED HOWARD: Yes, I believe you were next.

CAROLINE POPLIN: Yes. I'm Dr. Caroline Poplin. I'm a general internist. And in the interest of full disclosure, I'm also an attorney and I consult with a law firm that brings whistle blower cases against pharmaceutical companies for off label marketing. And my question is mostly for the gentleman from the UK. What makes drugs problem – patent – patented drugs problematic is that there's so little price competition. It's always benefit. My drug is better than yours so I will charge twice as much for it.

I've always thought that NICE would be in a good position to negotiate with the drug companies about price because if you do a cost benefit analysis and the benefit stays the same but the price goes down then they have a better ratio. It sounds like Germany is working towards reference pricing which I think is a great idea. And France also has some kind of system where some drugs get reimbursed less.

We of course, in this capital society, would think of challenging a drug company about what it charges for a drug. But with NICE, it seems to me if I were a drug company making Avastin and you said no. I would say well if you don't like it at $100,000 a dose, how about $80,000 a dose?

SIR ANDREW DILLON: Well companies can say that.

DR. CAROLINE POPLIN: They do?

SIR ANDREW DILLON: Yeah, sometimes and they use different mechanisms. We mentioned — I mentioned these patient access schemes which provide companies with a number of different ways in which they can help the NHS to manage the entry of a new product into the system. There isn't a — NICE isn't responsible for negotiating prices.

DR. CAROLINE POPLIN: I know.

SIR ANDREW DILLON: As I described in the presentation, there is no formal negotiation on a product by product price or individual prices. Companies, themselves, decide to set the price based on their judgment of the market conditions. But they can — but they do exercise that judgment. They know how NICE operates. Most companies have had quite a lot of experience.

They've got people who can, I suspect, do quite a bit of modeling to predict the outcome of an appraisal by NICE. So they can exercise and they probably know ahead of time how close they are to the margin in terms of decisions that we take. And companies will even during the course of a NICE appraisal sometimes make a judgment that there's a different way in which to present the product which has the effects —

So although there's no explicit negotiation, it's entirely up to companies to decide what price they want to present. There are opportunities for companies to exercise judgments about that price both before they go into a NICE appraisal, during it and as I mentioned earlier on, in some circumstances, afterwards too.

ED HOWARD: Can I just ask the audience, how many people do not understand what reference pricing is in the first place? This is very impressive. I withdraw my question. Yes sir, go ahead.

NATHAN DANSKEY: My name is Nathan Dansky. In the United States, we have this entity called the Congressional Budget Office which scores legislation on a — sorry; can you hear me up there?

ED HOWARD: Yes. Start again.

NATHAN DANSKEY: It's a, you know, five years ten years out and the unfortunate thing or challenging thing for healthcare legislation is that prevention is not scored very well and makes it challenging from that aspect. So my question is two fold. One, do you think that affects the amount of money we end up spending on pharmaceuticals in the United States? And then I would also like to know about how prevention is addressed in some of the other healthcare systems

ED HOWARD: You've played stump the band successfully I guess.

JEAN-LUC HAROUSSEAU, M.D.: No.

ED HOWARD: Go ahead.

JEAN-LUC HAROUSSEAU, M.D.: As we got France, of course, prevention is an important part of the policy of the ministry of health especially as regards tobacco and alcohol consumption bringing to show that the French people drunk more than any other country in the world. But [laughter] it's improving. [Laughter] we try to sell our wines in other countries but there is a hot competition as you know [laughter].

There are also prevention campaigns for vaccination, prevention campaigns for early detective of cancer so this is fully covered. And this is part, of course, of the important aspect for the future.

SIR ANDREW DILLON: I'm not quite of the answer of the first question because I thought you were — I thought that was a U.S. specific question. Is that right?

NATHAN DANSKEY: Well it could be both. Like United States, you know it's more difficult to get funding to prevent obesity than it is to pay for someone's diabetes medication for example.

NATHAN DANSKEY: That's what I'm getting at.

SIR ANDREW DILLON: Yeah. Yeah. Yeah. Yeah. I don't think it's that different in the UK. But both countries actually have pretty well organized systems for understanding the benefits which of course are sometimes over very long periods of time of measures to improve our approach to living our lives other things that can be done to change the environment that have a significant impact on length of life and quality of life. We all know all those things. You know them here. We know them in the UK.

The system in the UK in public health is regularly reorganized to help it get better. But the problem still remains. But there's an immediacy of the effect of spending money on people who whether or not their disease or condition is a function of the way they lived their life in the past, the fact is that we want action now. We want something done about it. The problem that we've got and it's extremely difficult to balance that with the enormously attractive but very difficult to argue business case for investing in a much bigger effort to prevent the sorts of diseases and conditions that frankly have the ability to overwhelm the healthcare system.

Big debate at the moment, interesting slide about obesity. I was quite surprised that the UK was number two

then we need to put far more effort into making the investments which are not all about money to change our behaviors now. Because otherwise the health – I mean these conversation we're having now about cost of drugs will be swamped by the impact of the diseases and conditions that flow from obesity and the other problems that we'll face.

IAN SPATZ: I should also make the potentially obvious U.S. point that in the Affordable Care Act, we actually did make a decision to make a major investment in prevention by requiring all health plans to provide prevention services by no cost sharing including prescription medicines if they're part of the U.S. Preventive Task Force list. So, we've made a big – despite maybe the Congressional Budget Office, we've decided to make a major investment.

ED HOWARD: Okay. Good point.

JEAN-LUC HAROUSSEAU, M.D.: Can I just – [interposing]

ED HOWARD: Yes, go right ahead.

JEAN-LUC HAROUSSEAU, M.D.: To be just one second. The problem is not that – it's not easy to be sure that in some instances, prevention will induce economics – will induce or reduce spendings. Just one example, in France, HPV vaccination is covered for young ladies. But we also have a screening of uterine cancer. And first, we don't want the vaccination

best benefit in the long term since uterine cervix cancer does occur at the age of 60. So we still don't know. So we have spent a lot of money for HPV vaccination without knowing whether it's worldwide. So it's sometimes a difficult question.

ED HOWARD: Yes, go ahead. I know.

RAINER HESS: In Germany, we have a program of preventing medicine and starting with a health check.

ED HOWARD: I think he's not on. Is he?

RAINER HESS: Every person –

IAN SPATZ: Microphone?

RAINER HESS: – getting this –

ED HOWARD: Want to try the red light.

RAINER HESS: – with –

ED HOWARD: There you go.

RAINER HESS: Is it? Yes. Oh, in Germany, we have a program for preventive medicine starting with a health check which you get with 35 years and older every second year. Cancer pre-diagnosis for women and men, children's screen diagnosis is a broad program from birth to 18 years. But we have the same problem that you talked as the relationship is between vaccination and early diagnosis especially in cervix cancer norm. And, we pay for a vaccination program in Germany.

pay for preventive medicine as a program to reduce a typical consume [inaudible] consumers as they have the single programs in competition among each other.

ERICK CARRERA: Alright.

MIKE MILLER: Thanks.

ED HOWARD: I think actually this gentleman in the yellow tie was standing in line before the gentleman in the blue tie.

ERICK CARRERA: Thank you.

MIKE MILLER: Should I change my tie?

ERICK CARRERA: Thank you. I'm Erick Carrera with Senator Sander's office. And this question is for Dr. Harousseau and Mr. Hess. It's two parts. So our U.S. trade representative is reportedly seeking a change in U.S. trade policy with respect to preempting states from controlling costs. So it would continue to allow the federal national government to control costs.

So the first question is in France or in Germany, are there any cost control efforts under way at the provincial level or local level or is it all centralized? And the second question would be; does this change in U.S. trade policy raise concerns for those two countries?

JEAN-LUC HAROUSSEAU, M.D.: Well what do you mean by

ERICK CARRERA: Of pharmaceuticals.

JEAN-LUC HAROUSSEAU, M.D.: Yeah. Well we do have a cost control of course. And it's made annually and it induces – it's a decision by the parliament in the annual vote of the law fixing the budget for the next year. And indicating in which part of the budget we have to make efforts so yes, we have an evaluation, of course, not comprehensive but evaluation of the costs annually.

RAINER HESS: And in Germany – thank you. In Germany, I told you that we introduced this early assessment system of drugs but not with the aim of cost control but with the aim of looking of an additional value of a drug which is a typical – which justifies a higher price. So in Germany, the benefit of the drug – the medical benefit of the drug is as a first position, we have to make. And not the costs and if we have no additional benefit then we reduce the costs on the level of the existing [inaudible] therapy maybe a reference price group.

If it has an additional cost, we will introduce the same added value system France has with the three steps; enormous additional benefit, important or small additional benefit. And on this level, there will be, beginning this next year, this reimbursement price negotiation between sickness funds and the manufacturer on federal level.

On state level, each sickness fund is allowed to negotiate discounts also for reference prices. So the real costs of the drug may be below the reference price system because its sickness funds negotiate in a tendering way these manufacturers to lower their reimbursement price with this sickness fund. Also combined with a volume negotiations or a scale downs negotiations. So we have a competitive system of reducing costs on the state level.

Not on the federal level, on the state level beyond the limitations we decide on the federal level with the reimburse in price negotiations starting next year. But we have not quality cost control system like Great Britain has it. So in first line, we look is it — has it a benefit? If it has a benefit, additional costs are possible. They must be paid by the sickness funds. And the real costs are negotiated on a state level with which each sickness fund and the manufacturer. So we have a difference in costs in a competitive contract way.

ED HOWARD: I might clarify that the -- and there is a sheet in your materials about this. A story from ***Health Watch*** detailing the potential problems that some consumer groups see in this trade negotiation with a number of Asian and Latin American countries that might prevent them from restraining prices in ways that they thought that they were able to before

So, it's probably not applicable to the countries represented on our panel but it is an issue that clearly a lot of people are interested in.

ERICK CARRERA: I appreciate that. And that's another concern also for the Senator. But there is one provision that would affect, for example, the 340B Program and other state programs which aim to reduce prices for consumers. And so I was wondering particularly with the German case now where it's the German states' sickness funds that enter into negotiations with pharmaceuticals if there would be any concern that a similar type of provision, which admittedly we haven't seen the final text for, would – expending to other countries' trade agreements whether this change in U.S. policy raises concerns.

ED HOWARD: You may have – well I'm not going to speak for our panel members but it doesn't look like a lot of familiarity with that trade issue at this stage at any rate. Yes, go ahead. Mike.

MIKE MILLER: Hi Mike Miller. I'm a health policy consultant physician. And I want to ask a question that gets back to a little bit of the value prevention issue. The Commonwealth Fund about two or three weeks ago came out with a great report called *Why Not the Best*? They've done it a series of – it really demonstrated some of the problems of the U.S.

But one of the bright spots was how in the United States for the last 10 - 15 years they've increased the percentage of people with serious chronic conditions like diabetes and high blood pressure who are actually getting the recommended treatment. They're getting the proper treatment for those conditions.

Because I know in the pharmaceutical industry one thing that drives people crazy is there can be no value for – if there's great medicines out there but people aren't getting them prescribed or used or anything else. So I mean I guess it's a good thing that we're now at about 50-percent of the United States of people who have diabetes and high blood pressure are getting adequately treated.

I just wondered if there was – any of our panelists had any thoughts or data about what the situation is like in other countries in providing the actual clinical value of the use of medicines to – for these chronic conditions. And thanks for liking my tie, Ed, too.

JEAN-LUC HAROUSSEAU, M.D.: Maybe I can start. It's a difficult question is how to push most of the general practitioners to prescribe the right treatments for chronic diseases. And it's part of our role in the HAS to write guidelines. So we write many guidelines with many questions.

So the question is how to push doctors and we tried in the past sanctions in case of the doctors do not follow the good clinical use prescribe the drug of [inaudible] prescribe too many anti-depressive agent or do not follow the diabetic patients. So, it was not a success in France. So we try the other way to have incentive in the financial incentives for the doctors. That was I called the cap[inaudible] for limited number of GP in France, 15,000. And they had a limited number of indicators to fit in. And they have – I don't remember exactly but it might be something 15,000 euro if – so then the – this objective.

So since it was a positive experience, it has been extended for all GP and for larger number of indicators including control of hypertension, including [inaudible] for glycemia, including different quality indicators regarding prescriptions. So we will see. It's just new and we will see whether it's sort of P4P for GP will be worthwhile.

ED HOWARD: Sir Andrew go ahead.

SIR ANDREW DILLON: Yes, and the same challenge exists in the UK, this veritably in the access to treatments, people living with chronic conditions, variability in the organization of systems locally to support people to effectively manage their conditions over time. And as in France, the UK's shift

interventions undertaken by primary care physicians in specific chronic diseases. Diabetes is one. In order to signal the importance of both registering patients who are living particular chronic conditions and then delivering care interventions and organizing services effectively around them.

NICE has responsibility for identifying those key indicators. The Department of Health negotiates with the medical professions on the monetary value associated with achieving those indicators locally. And we back that up with our evidence based clinical guidelines and the new quality standards that we're putting out.

And a quick word on that because it isn't just about the money that's offered to health professionals to incentivize their practice. It certainly isn't just about the existence of evidence based guidance. It's critically important to energize the patient communities so they're clear about what the offer is from the NHS in the UK's case.

And with that noise, they're empowered to go along and talk to their local primary care physicians and say this is what I should be getting. There's the quality standards. How about it? And the quality standards that we're producing being used that way. Diabetes UK have just done a 10,000 patient survey using the quality standards of diabetes that NICE

I haven't seen the results of that yet but what it signals is that if you produce something simple enough, something that ties back to the evidence base and something which is also being used to incentivize physicians in the healthcare system, you've got almost a virtuous circle there. If you can close that then I think we have the ability to improve our stride race at getting the right interventions to people when they need them.

ED HOWARD: Okay be [interposing] I'm sorry. Go ahead. Mr. Hess.

RAINER HESS: In Germany, we have disease management programs for diabetes and for cardio vascular diseases designed by the Joint Committee which lay down the clinical pathway how to treat diabetes patients and how to treat cardio vascular patients. And they also – they include pharmaceutical guidelines. But we also have a competition between general practitioners and specialists treating diabetes patients. And there is a different feeling or not – a different level of treating diabetes patients between general practitioners which are not so strong in bringing diabetes patient up to the level of [inaudible]. And so the specialists will say well we need to bringing on this level because otherwise there is a big risk.

So we have [inaudible] of physicians. What is the good, best care of diabetes patients in the pharmaceutical treatment? Must it be very strong and strict or isn't it better to let the patient more lifestyle – more live quality? And we have – we didn't solve these problems yet. But, so I think as we have no regulated system, we have a free choice system. We must give this decision to the patient. He is within this diabetes program as a patient is in registered. He has several – he has fixed contacts with physicians. And so he must decide by himself, I – will I go to a general practitioner or will I go to a specialist for this drug prescribing?

ED HOWARD: Thank you. Anybody else? Thank you. Go ahead. Robin, go ahead.

ROBIN OSBORN: I wanted to take a slightly different tact in terms of a question prompted by some of the comments that Ian made about the data and understanding the data and being able to use it. And one of the issues that I think all of the countries here are struggling with is having the really most useful data available from trials in order to make decisions about the comparative effectiveness of different drugs, having the right comparators and then ultimately having patient outcomes.

And so I guess what I'm wondering about is what are the

needs, do you see, for agents in each country to be working more closely? The agents that are making decisions about coverage and the payers with the regulators to get the pretrial data that's really going to be most useful for decision making. But similarly across countries, what are the opportunities or the benefits of collaboration on standards for the data and the kind of expectations and early involvement with the industry? Earlier involvement in terms of saying this is what we all want to have and this is what you're going to need in order for us to make decisions.

JEAN-LUC HAROUSSEAU, M.D.: I think it's a very important question. In France, we had the very difficult problem with the use of anti-diabetic agent called benfluorex which was responsible for a hundred of deaths because [inaudible] vigilance issues. So we have a new load regarding security related to drug use and misuse.

And one of the aspects of this load is even for drug approval to look at comparative drugs, to have clinical studies even for approval, it's not currently admitted at the European level. The EMA doesn't need comparative trial to prove a drug that we would like to have comparative drug – comparative trials to approve new drugs.

But we guard [inaudible] technology assessment and the

trial the new drugs verses standard of care. Of course when there is no standard of care, it's an [inaudible] drug it's probably easier. But when there are — there is a standard of care, we seldomly need comparative trials in the future.

So the question you address is how could we work all together in order to have a better cooperation with pharmaceutical companies and help them in defining which trials would be necessary to obtain not only approval but also reimbursement and good pricing.

They ask that to me. The pharmaceutical company ask early discussion prior to licensing and prior to discussion regarding reimbursement. In the past, we didn't accept that. But now which is done in the United States and which is done for approval in EMA in Europe, I think it is very important. So, would it be possible since many drugs are developed at the international level to have the same discussion? I think certainly it would be useful.

In Europe, we are trying to set up a network which is called a unit - unit HTA European Network for HTA. Not that easy. We also work with the German and the British for comparing our jobs — our different jobs which is very pleasant. We meet twice a year. But I think it should be more organized in order to have the same rules in all countries and to have

ED HOWARD: Go ahead.

SIR ANDREW DILLON: This is the big thing. This is the big thing we have to get sorted out. Because it is not good enough for healthcare systems, for organizations like NICE to say well wouldn't it be nice if you'd have done it this way? And we have this data. It's not enough. It may be true. And we can do something about it.

We can actually talk to companies and say well if you're developing – if this is what you're developing, if this is the mode of action then the sort of data that an advisory committee is going to be looking for, making judgments about, comparative value is this. It's the same conversation that companies have had with regulation bodies, the FDA and others, in the world for a long time. And there's no reason why you can't have the same conversation with organizations like HAS or IQWiG or NICE to get a sense of what those evaluative bodies want.

So about three years ago, we set up a scientific advice program that'll ask companies to do just that. And companies come along in complete confidence and talk about a product. There's a firewall between that conversation and what happens downstream and in the evaluation of that product eventually comes to NICE. And it's a real win win. It helps us learn

Hopefully if the company finds some new value and they weave that into the development process then downstream we'll get a better submission than would otherwise be in the case or a more appropriate submission. And the win for the company is that if they can do that then their chances of getting a positive assessment increase as well.

So it's absolutely right, the point Ian made right in the beginning about evaluation's not enough. We've got to get the data right. And one of the things that we can do to contribute isn't about the generation of data itself. It's about making sure the data that does get generated, whether it's in the U.S. or the UK or somewhere else, is the right data.

And we think we can go further upstream too for those decisions that are taking particularly for the new biotech products by investment, by venture capitalists for example. They too can benefit from a conversation with a variety of agencies to inform the decisions they make really only decisions about whether or not to invest or whether to put their money somewhere else.

And at a recent meeting that we had with about 75 [inaudible] community based in the UK, it was just extraordinary how enthusiastic those companies are to strike a

couple of pilot projects with venture capitalists as they're looking to make those decisions. And it's all about getting that win win. It's all about making sure that the right facet comes so the right decision can be made.

ED HOWARD: Mr. Hess and then Mr. Spatz.

RAINER HESS: The Germany early assessment system basis on comparable price. And this is one of the difficulties we have starting this system the beginning of this year and forcing the industry to give us comparable price. And if they don't have them maybe they have no additional benefit. They are in the market. They have benefit but not additional benefit. And then they are reimbursement right is limited on the level of the standards therapies — existing standard therapy.

And so we have a big quarrel with some companies fix — deciding the comparator. And if the comparer is a generic, we have an additional problem because the price level of the generic is very low so the additional benefit may also very low. That's why some companies say don't bring their product in the German [inaudible] market. Because they fear a low reimbursement price which influences the bulk mark price.

And that's why we are high interest in an early advice to the industry. And it's also part of our legal act that we

companies who ask for early advice together with the assessment bodies [inaudible]. And we started also an early advice [inaudible] to solve these problems of comparable price, seeking the right comparator.

And I think that our institutes IQWiG, NICE, and [inaudible] are working together in this topic to come closer together in this assessment system and find the right level to decide what must a company show as initial – additional benefit and what basis it must show it. On what trial it must show the additional benefit.

ED HOWARD: Very good. Ian.

IAN SPATZ: Just continuing my theme, I mean these discussions are also going on in the U.S. market where companies in designing their pivotal trials to bring a product to market are consulting with payers about the kind of evidence that they want. They're consulting with you and you and you but also U.S. payers to begin to do that.

But I want to point out the real limitations of doing that. You may be asked to compare yourself with a product that isn't on the market and you can't do that. You can't test a product against your product if it's not yet on the market. And most pharmaceutical development is a race to the finish line; things coming out within months of each other or maybe a

year of each other. It may not even be practical to do the right comparative trials.

And also those are trials. They're done in a clinical trial setting. And there's lots of discussion about how we need to have real world evidence to look at these things. So we're going to make these health technology assist — assessments before the product gets on the market or within a year of it getting on the market. We can make some substantial mistakes. We need the evidence when it's actually there on the market.

Now can we wait 10 or 20 years? No. but we have to find a reasonable period of time to give a product a chance to be on the market, give a reasonable time to have comparative trials done, have public funding as we do in the United States. So we're not just relying on the drug sponsor to do the trial. And then we can do a better job evaluating.

ED HOWARD: Let me just say we have some folks at the microphones. We have a very limited period of time left. Before I go on to entreaty you to be brief, I will be brief in saying that as you listen to these last few conversations, we'd very much appreciate your filling out the evaluation form while you're doing it. And I would ask the folks at the microphone to be as brief as they can and I ask our panelists to be brief

SAHIL KAPUR: Hi. Sahil Kapur. I'm a — sorry — reporter for *Inside Health Policy*. Thanks for doing this panel. My question is for Sir Andrew but the rest of you feel free to weigh in as well. You talked about some of the comparative effectiveness research that happens at NICE. And I was wondering if you have any thoughts about our stab at that concept in the Affordable Care Act with the patient centered outcomes research institute that Ian mentioned. Do you think that it can have an impact without looking at costs or do you think there can't be impar — sorry, meaningful comparative effectiveness research without looking at costs?

SIR ANDREW DILLON: I know because — no, it's very — can have a big impact just by looking — just by better informing. That's judgment about the incremental clinical benefit that a new treatment brings over — kind of standard practice. That's the start point in any judgment. It's certainly the start point in NICE.

The business about — the judgment about whether the price the health system's being asked to price is worth that incremental benefit. It's a separate distinctive downstream judgment from the first and most important assessment which is just what additional benefit a new treatment brings. So, that comparative factor is going to be done with new organizations,

hugely important, based here in the U.S. and presumably is the public domain to the rest of the world too.

ED HOWARD: Okay. Yes sir.

DAVID HOGBURG: David Hogburg, *Investor's Business Daily*. Also thank you for doing this panel. One of the things I noticed in the presentations, there was a fair amount of talk of social value but not necessarily individual value. And I want to know what role – can you talk to me a little bit about what role do individual values of drugs play in your process? That is, you know, if the patient values it. And if a patient values a drug but your agency does not, you know, what are the patient's alternatives? What are their options after that?

JEAN-LUC HAROUSSEAU, M.D.: Maybe I wasn't clear enough but in France, if the assessment is based on the individual value currently. And in the future, we will look at more general arguments regarding collective value in health economics. But currently the role at HAS is mostly to address the question of the effectiveness – the clinical effectiveness, clinical efficacy and it's mostly the benefit for the patients.

So next question which will be addressed but it's rarely addressed currently is; what is the value for the health economics and the policy of healthcare in France? Say, the question we address is; is a drug good enough for a patient to

be reimbursed by the national health insurance. So it's really based on the patient benefit.

ED HOWARD: Right. Rainer Hess.

RAINER HESS: In Germany, we have a free market access of drugs. They are all paid by the sickness funds. So we have big entrance [inaudible] in the German pharmaceutical market. And it is in the responsibility of the physician what drugs he is prescribing his patient. And he is free in physician. So, I think we guarantee individual pharmaceutical care either by specialist or general practitioners. It's their responsibility. But maybe if physician only prescribes costly drugs, he gets in the danger of paying compensation. And that's the problem for the physicians in Germany and maybe also the patients.

But I think that in our system, it's – I think it's much too liberal and too individual. And the problem is can we pay this system in the future with a growing aging population with this individual medicine which is more costly than the existing medicine. So I think it's – we have individual drug prescribing but the question is can we afford it in the future.

ED HOWARD: Yes Sir Andrew.

SIR ANDREW DILLON: Well a default position for all of us as patients is probably in most circumstances, they want to

potential benefit. And depending on the disease or condition we've got, we may be more or less enthusiastic about doing so. Of course the data that anybody has access to individual patients, physicians, organizations like NICE doesn't tell you in the great majority of cases how an individual patient's going to respond. So we have to deal with that data as a population level. And we have to make our decisions as a population level.

And for the point you're making, I know is well what happens when the decision is to restrict in some way access to a treatment as it does sometimes in NICE. And therefore individual patients who would like to try it who use the NHS system don't have the ability to do so. Well that is as it is. For an individual patient, it will be disappointing, unsatisfactory. Individual patients in those circumstances and remember that table, it's by no means – this is very much a minority can get very angry and very frustrated and very upset.

And as a human level, I understand [inaudible] of the organization. But I also understand that the cost of that treatment is drawn from a pool to which we all contribute as citizens in the UK. And we all expect the NHS to do as much as it possibly can. So at some point, somewhere in the system, a judgment has to be made about whether individual treatments

purchase them and to use them set against what we could otherwise use that money for. It's very difficult.

And in the UK, you don't have to leave the country if you want a different health plan. You can buy health insurance. 10-percent of the population does usually for elective surgery. So there are ways in which you can get access to treatments if you want. But again I know in some circumstances that's just not a possible option for many people simply because of the price of these treatments. It's a difficult situation [inaudible].

IAN SPATZ: Well your question related to certainly one of the great fears of health technology assessment. That it's population based, as you were saying. It's based on an average patient where we haven't met an average patient. I think the challenge that is for those who conduct comparative effectiveness studies for this product sponsor and others is to have them sufficiently large enough that you can present information on variability and response. And then perhaps decisions can be made based on that variability to identify patients we had in the personalized medicine way who might benefit or not benefit. But that's very difficult to do a product launch given the size in clinical trials and the lack of comparative experience.

So again, you know there's ways of using health technology assessment that's good. And there's ways, I think, that can be quite harmful to patients.

SIR ANDREW DILLON: You know the thing is not to be a slave to the data. You need to use the data to inform a judgment but that judgment needs to be made in a context of what the health system as a whole is trying to achieve. And I think the neat thing about the way NICE has evolved over the last 12 years or as it's demonstrated is I think that particular schematic I showed in my presentation illustrates that you can get very high cost treatments with relatively low cost effectiveness but still make the judgment that it's right for the health system to adopt those.

Explaining that, codifying it and being consist; all these things are very important. But they all demonstrate their good quality decision making goes beyond the data to make the judgments in the interests of the community people use the health system.

ED HOWARD: And I would commend to you the statements of Carolyn Clancy who's the head of the association or the Agency for Healthcare Research and Quality and probably the key player in the PCORI machinery even though she's not head of that. Because she does make nuanced observations about what use

question and one that I think is getting a fair amount of attention.

The lady behind you has been waiting very patiently to ask what is the last question.

RACHEL NUSBAUM: I'll be very brief. I promise. My name is Rachel Nusbaum and I'm an intern in Congressman Oliver's office. My question is about drug shortages. You have probably heard we're having some problems with drugs that have gone off patent and so are not profitable and are not being produced. We're having some shortages of the generic versions. I was wondering if this is a problem we've had in your countries and how you've dealt with it.

ED HOWARD: Good question. You're off the hook but our three gentleman — let me rephrase it. In the United States, there have been some generics that have become in very short supply because they're off patent and therefore not as profitable. And the question is whether that's unique to our situation.

JEAN-LUC HAROUSSEAU, M.D.: No, we do have shortage of drug as well. And that is one of the reasons why we wouldn't like to reimburse only a superior drug. We would like to reimburse also me-toos or drug with the same benefit for the patient. In other words, we have two or three drugs not 12,

shortage. It's one of the ways. There are, of course, other ways. But this is mostly true for all drugs which are very cheap and the company doesn't want to continue the manufacturing of these very cheap drugs. So that is a serious question.

RAINER HESS: So we exclude drugs only if they are in the relationship to the standard therapy inappropriate. They have maybe higher risks or they have a lower benefit and higher costs. And otherwise, we in this early assessment system, we don't exclude any drug. We only lay down the basis for price negotiations. The — and in the further development of the drugs then we check what is the drug, what has it — what is the value of the drug against its competitors. And if there is a similar value, maybe we only make a price level decreasing and excluding of cheap drugs, if I understand the question correct, we don't do it.

ED HOWARD: Sir Andrew.

SIR ANDREW DILLON: I'm not that close to the — you know the general issue about access to generics to be certain about whether or not there have been major setting not conscious in the UK that they've been any major issues. But what's interesting about the patent cliff and the fact that they presumably develop a proportion of drugs consumed anyways.

different kind of market dynamics coming into play. And it's about – it makes sense it becomes about supply and demand.

If there's a demand for older drugs that have gone off patent, become generics then over time there may be a lack capacity we put in place. And it may not be in the country of consumption. It may not be in the conventional drug manufacturing countries. It may be in India or it may be in China where it becomes economic to produce very cheap generic treatments. Quality is an issue I know. [Inaudible] can be resolved them maybe that's the direction in which it's going to go. But I'm not quite sure it's a major issue in the UK.

ED HOWARD: Alright. I think we've come – actually – we've all been generous with our time. Thank you for staying with this. As you're filling out your evaluation forms, you can listen to my last remarks. That is that you've really made an effort and thank you very much to learn lessons from a wide range of experience as represented on this panel today.

I had a whole page of questions prepared to fire at our panelists but I never got to them because you were so active in putting the questions to them. And I want to thank you for that. Thanks also to The Commonwealth Fund, particularly to Robin and her colleagues, who've working very hard to put this program together in a way that would maximize its value to you.

And finally I'd ask you to join me in thanking our panel for an incredibly important conversation about drug policy not only where they're operating but its implications for where we're operating right here. Thank you very much. [Applause].

[END RECORDING]