Forum: What is the Truth About the Cost of Utilization of Medical Technology in Europe vs. the U.S.?: Keynote 1 December 3, 2004

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

[START RECORDING]

DR. CATHARINA MAULBECKER: Some of the points raised in the last session, one being the lack of data and the need for HTAs to provide data to look at the efficiencies of some of those new technologies. I would also like to differentiate and I've asked my speaker, Jennifer Erredge [misspelled?], to look at medical technology a little bit from the perspective of the spectrum because we have large apparatuses and we have personalized care and remote care is something that Wendy talked about in the last session and that's something that can actually impact hospital days a lot.

Also I'd like to take up the cost part. If you think about Germany's spending about 10% of its GFP on health care and we here spending 17%. That's a German car produced has about 10% health care cost and a U.S. car 17%. And what that means for employers, and I really liked the last panel and having an employer's perspective, Marriott's perspective in the inability to continue paying for the health care for the employees.

So I think a lot of interesting points raised for my panel here and without further adieu, I'd like to introduce Jennifer Eredge. I'm really excited about having her here, because not only is she the Director of Economics and Reimbursement for Medtronic Europe, but she is a truly

international health care citizen. She lives in France, she works in Switzerland. She works in Europe but she spent 15 years as a professor at the University of Washington, publishing more than 30 papers on outcomes research in health care. So, she combines basically the American perspective and the European perspective. That is why I am very excited about having her here and if you could please give us your presentation.

JENNIFER EREDGE: It's a pleasure to be here and I want to thank the organizers of the GMF for inviting me to talk on a topic that is very dear to my heart and I feel quite passionate about. The only downside is I only have about 15 minutes to talk about it and I could talk all day.

I was asked to talk about what we can learn from these two systems, Europe versus the United States. And first I would have to say that Europe is 25 countries. There are 25 different systems, that's not to say that you can't learn something from Europe for the United States, it's that in fact you could learn 25 different things. Living in Europe is like living in the middle of an experiment on health care financing. We can learn about reform, about how to change our system. Europe is learning, right now, from the United States specifically, I think the biggest change in Europe, is the move to the DRG system. There have been countries in Europe that

have used the DRG system for as long as 15 years, but right now the largest and most populist countries in Europe are moving and adopting to a system somewhat like our system here in the United States and is certainly based on the DRG.

Another area that I think there's a lot of room for learning, and this is maybe that the U.S. can learn from Europe has to do with health technology assessment. I will speak a bit more about that as I go along.

I think the third area has to do with looking at the impact of funding mechanisms. And not thinking, "Oh can we adopt a socialist system versus a capitalist system?" But look a level beneath that into the actual mechanisms that we try to use to make changes for reform. We can look at the anticipated effects versus the unanticipated effects. In Europe there are many different aspects of these funding mechanisms that have been in place, going into place that we can learn from. I think a good example is in the U.K. we recently had a health technology assessment from the NICE and I know we'll have a speaker, Andrew Dillon, I know from the NICE later on this. It was an assessment about insulin pumps. It looked at the cost effectiveness of insulin pumps and when you do that in the formula for evaluating cost effectiveness, patients who had the highest cost will end up showing the most benefit in terms of cost. If you reduce the cost of a high cost patient, that will

be better than reducing the cost of a low cost patient. From that deduction, or example, pumps were not recommended for children, because children – even diabetic children – are relatively less ill than older people. The anticipated effect of that is, of course, that pumps will be rationed in a way to provide the pumps to those people that are the high cost people, more elderly people. What is an unanticipated effect? An unanticipated effect is that if a child wants a pump he could go out and not take his insulin correctly to have side effects associated with the insulin in order to qualify to have a pump. That's an unanticipated effect. Those are the kinds of things I mean when I say I think we can learn from each other I think a little more deeply.

We can also learn about what factors might make a particular funding mechanism work. When I first moved to Europe, which was over 8 years ago, I was often asked, "Well why is that the U.S. spends so much more, we spend so much less, how do you explain that?" I'm here 8 years later and I hear the same thing. I don't think we've changed that. I've reflected on how to explain this primarily to Europeans. This is a slide that, in my mind, hopes to explain a little bit of both the similarities and the differences. I particularly split out the Western Europe versus Eastern Europe because in Europe it's important that we have these 10 new Eastern

European countries that have joined the union and it has a lot of effects on the movement of goods. So, setting those aside, if you compare Western Europe to Europe to the U.S. you'll see that there's about the same number of people, a few more people in Europe, but roughly comparable. You can also see on this slide that the public spending in the U.S. and the public spending, meaning government direct spending in Europe, is also roughly comparable and I think most people don't recognize that. The big difference is the private spending. In my mind that is a lot of what drives the kinds of services and the differences in the services that are used between the U.S. and Europe and I'll talk more about those differences.

My conclusions today are going to be, that in fact, we have similarities; similarities such as both Europe and the U.S. accept scientific, understanding science as it's known in the kinds of studies that we do. The expectations that people have about what is good medicine are roughly the same. If you talk to doctors in Europe they're quite familiar with the studies that go on in the U.S. and vice versa and I think amongst doctors and if you look at guidelines, they aren't significantly different.

But there are differences primarily in 3 areas. There are difference in resources, there are actually differences in medical need, I will argue, and there are differences in

structure. The rest of my talk is going to be about these three areas with respect to medical technology.

Now, I said there are resource differences. One myth I feel, and I also had it before I lived in Europe, was that Europe is roughly the same as the U.S. with respect to resources and if you want to use GDP per capita this graph shows that in fact Europe is not quite, it's about two-thirds of the U.S. with respect to resources per capita. I think that's important because if you think about, if you are an American and you go over to Europe, you tend to go over on vacation, you enjoy the museums, you sit in the cafes and you seems opulent, you look at the buildings, they're beautiful. It's an opulent environment in some ways. The history is overwhelming. The fact of the matter is Europe is still building from the Second World War basically. It is still recuperating and the resources that they have for day-to-day operations, you know for living are not the level that you have in the U.S. And in my mind that's an important factor explaining the differences that I hear when the Americans say, "We're spending so much on health care. What can we do like the Europeans?" Now, I'm using an economic term when I say health care is a luxury good. What I mean by that is the wealthier, from economics we know this, the wealthier a society is the more likely that that society or person is willing to

spend a larger proportion of their available budget. What I mean by that, again, is not that having a medical device is a luxury but that we could predict that if Europe GDP per capita becomes the level that it is in the U.S. that the resource uses for health care are also going to be at that level. That are part of that difference is just a function of resources available. This is a graph that shows the same thing. It basically shows that the more you have the more you will spend, I used pacemaker use, but look at where the U.S. is. It's a little bit off that line in comparison with the other countries. So, I'm going to qualify what I said, to say that that explains some of it, but it clearly doesn't explain all of the differences.

The second point that I mentioned at the beginning was to talk about medical needs. And if you compare the U.S. to Western Europe with respect to something that's commonly used as medical needs in a population over 65, you see that Europeans, in fact, have a more elderly population and therefore the demand for health care services is a bit in advance of the U.S. because the trend is just a bit in advance. So of course, if you are in an environment of a more government and going back to one of my earlier slides showing that the government pays a lot more of the healthcare services you can imagine the impact and the pressures on the governments within

Europe to cover the needs in which in fact the demands were greater than in the U.S.

Now, we've been talking about medical technology and the earlier discussion, I thought, talked quite a bit about pharmaceuticals. I am not going to talk about pharmaceuticals because I think the dynamics with medical technology are significantly different, especially in Europe the processes for getting reimbursement, et cetera are quite different. And when we listened to the earlier speakers talking about the processes that people went through to get access to products in Germany, keep in mind that entire process that she described occurs after, what the equivalent to the FDA approval occurs in Europe. In the U.S. you get FDA approval and the product is available. In Europe you get a European level approval called the CE Mark and then each country goes through a process different from, each process is different, but not significantly less than the process that was explained earlier for Germany. That has also a big impact on the acceptance and the adoption of new technology.

Another thing I wanted to say about the medical devices, is we often here about MRIs, we were talking about it earlier, the big machines that you a buy few of them, CAT scanners, PET scanners, et cetera, in hospitals but the vast majority of medical technology is personal. It's pacemakers,

it's deep brain stimulators, it's insulin pumps, things like that. That's where the vast majority both of expenses for medical technology and for innovation occurs. But I've noticed in comparing Europe to the U.S. is that if the technology is older you actually see not much difference between the Europe and U.S. This slide takes hip replacements, which is an older technology, and if you look at the use of this older technology in comparison with Europe versus U.S. again it's roughly the same. So if there is a technology that has been around awhile, I can pull up quite a few others, it's pretty much the same.

Where the issues lie, I think, are in getting acceptance of new technology. And therefore I'd like to talk more around new technology and the adoption of new technology and those differences. Again, I'm going to focus on health technology assessment, which was discussed briefly earlier, and a little bit on DRG. Europe has, there are quite a few structural differences, this is the third part. The European budgets are more constrained because the GDP per capita is lower in Europe. There are specific constraints on private insurance. Don't think that when you hear, "Oh well there is private insurance and therefore people could opt to take that versus public insurance." There are quite a few constraints on what and how private insurance works that you don't have in the U.S. So it's not the same thing. In Europe you have much more

constrictions on direct to consumer communications, therefore patients are less involved in the decision-making. And of course we don't have the issues in Europe of product liability like you have here in the U.S.

It seems to me that Americans are particularly interested in the health technology aspect of what's going on in Europe and I have to say it is very different. Most countries in Europe have government sponsored health technology. Their main focus and to some extent it has to do with legal constrictions, it is whether the technology is cost effective. I heard earlier comments that well, "I don't know in the U.S. whether that's really an option here." But that is a big part of what the analysis is for health technology. The issues around doing health technology are really dealing with real world data. When you do health technology for the purposes of how is it going to be in your country, it's not sufficient to look at randomized control because you have to look at how the technology is used in life and getting those data are not easy.

The second big issue is when you do the health technology some of the countries require a health technology assessment looking at cost effectiveness before you get access to the market at all. But at that point the technology, I don't care what it is whether it's computers or telephones

whatever, it's always more expensive when it's first introduced. So you run the risk, if you do the technology at entrance, of cutting off a potentially cost effectiveness therapy after use over time. Some countries it isn't quite like that and I'm happy to see, actually, a representative from the NICE which doesn't take that approach in doing their health technology and will be interested in hearing more about that. A positive assessment does not guarantee funding, a negative assessment will guarantee that you don't get access to the market. I'm being told to speed up here so I'm going to go quickly through the slides. What we do know and there was actually a very recent study presented a month ago looking at the relationship between health technology assessment and access to the market which showed that countries that use more stringent health technology assessment are slower adopters to new technology.

I was going to say that on the other side, if I'm talking about the European environment Europe again is adopting from the U.S. pretty much the DRG system. And I'll skip over that to talk more about the impact of technology.

Again, if you look at older technology and here I chose an MRI because we talked about it earlier, you'll see that Europe uses less than the U.S. but if you compare that to a newer technology like angiographies it's significantly less.

You can take a whole set of products like this and you will see that the newer technology the bigger the gap is between the U.S. and Europe. Now you can say, “Well maybe that’s a good thing. Maybe we need to slow down the adoption of new technology and that will help reduce health care expenditures.” But if you think of it more personally are you willing to not have access or wait two years for access for something that you just read in the medical journals actually makes a huge difference in your health care? Personal experience, for example, that I can give you is that I was hear a day early for the conference to see my mother who was suffering from fainting spells to a atriofibrillation. She was in Florida and she just had an ablation therapy done. A tube went into her heart and they used radio frequency to stop the problem. I met with her to see how she was, she was feeling great. The curious thing for me, was that on Thanksgiving I had a Thanksgiving dinner and I invited my son-in-law who is German. His parents were also German. His mother suffers from the same thing my mother from and I was relating just last week at Thanksgiving what my mother had gone through and his mother had never heard of this. She’s on Coumadin but had never been given an option for a therapy that basically had cured this. Coming to this conference and having that just happen last week I think is a good example of the cost we pay in Europe for not having access

to the newer technology. However, in Europe we were talking about the German situation you can see that there's a huge difference in the adoption within Europe. That's why I think we can learn, in the U.S., from Europe. We can look at country by country at different strategies and see what works and doesn't work, because clearly it's not one place. You have a huge variety of strategies, Germany being a actually being a pretty good adopter of health care technology.

My leanings are that between Europe and the U.S. we share a good understanding of what medicine is. The U.S. definitely spends more on new technology and Europe has broader access to all technology because of the socialized system, but barriers to the new technology. We also know that if those barriers are lifted in Europe people choose to use more technology.

DR. CATHARINA MAULBECKER: Thank you very much for your presentation [applause]. I think we heard a very nice, kind of different perspective from a European, granted, but who also represents an international organization towards the restriction on medical devices has for Europeans. One thing that I would like to urge us not to do in this panel is dive into the differences between the 25 different European health care systems, this is not a system discussion. But it's rather, I'd like my panel through, are the Europeans better

purchasers and users of technology? How do they deal with the additive effect versus moth-balling the old machine? Different aspects of medical devices? Wendy talked about the remote care aspect of medical devices, let's think about that and juxtapose that with [inaudible].

Let me introduce my panel, quickly. Dr. Murray Ross is the Director of Health Policy Research at Kaiser Permanente and he is looking at technology assessment quality of care. So I'm very interested in getting their perspective. Kaiser is very interesting also because of all the players in the U.S. it's probably the most European in that the average length of stay with the system is 14 years as I learned yesterday while on the average here in the U.S. it's two and a half to three years. In the European system it's often times for life or at least for ten years. So when Anne Haas talked about AOK, she has her life, her people there for a long time, which has an impact in terms of how you look at technology spending and what you do. So, I'd like Murray Ross to talk a little bit about how Kaiser deals with technology.

Then we have Chip here, Chip Doordan is the President of the Anne Arundel Health System in Maryland. He is an actual and I think Mary or somebody said earlier, he has the grease on his hands. Which is he has to manage a hospital system, manage the doctors, and make those very tough decisions on what to spend his money on and how to budget for technology.

And last, I have Steven Howe [misspelled?] here, who is the Vice President Global Strategy and Analysis of Advermed [misspelled?] the medical device association of the industry and he, as Jennifer, is able to give us the global perspective looking across the Atlantic, what's going on Europe and what's going on the U.S.

With no further delay, I'd like to give the word to Murray to talk about his perspective on what Jennifer just presented.

DR. MURRAY ROSS, PhD: Thank you, you gave me sort of some open-ended questions here so I'll try to answer as a good economist by giving a very blurb answer to it.

I want to offer, I think, two sort of framing thoughts. First of all there is a lot of ways to address the, the sort of who's better on a macro level but one of the statistics that particularly calls out to me, is that despite the fact that the U.S. is so much higher in its health spending as a fraction GDP, the trend over time over the past couple of decades has been remarkably similar in the U.S. and in Europe in terms of the, if you will, the excess growth of health spending above GDP growth. That leads me to conclude we're all facing the same issue. None of us have found the magic bullet. I think one of the thoughts that came out of the presentation is that is there a fundamental difference or is there just sort of a lag here and that Europe will eventually catch up when we eventually, if we eventually flatten out.

Just as it is difficult to generalize across Europe, it's very difficult to generalize across the U.S. and I think difficult

also to separate technology acquisition and management by itself from the larger in environment in which we operate. My organization is fairly unique in this country as both a health plan and a delivery system. That gives us some real advantages. Our partnership with our physicians gives us better purchasing power and an ability to designate preferred suppliers. A focus on evidence based medicine and technology allows, I think, to give guidelines and less inappropriate care and more appropriate care on both pharmacy and technology. And as a philosophy of stewardship both patients and populations are under consideration. And then as Catharina mentioned the loyalty of members with a very long average tenure, we can take an investment frame of mind that many other insurers cannot. All this said, we don't really face an internal arms race the way some others might, but we still operate in the same kind of environment and it's an environment that always pushes for more and not for less.

I just wanted to identify a couple of those factors that I think are important as we try to isolate on technology assessment. We do have to think of the structural pieces in which it's operating. First of all there's public expectation. This is a country where anything is believed to be possible and many of us feel we're entitled to it. There's a legal environment where inaction is much harder to defend than action or over-action. There are financing mechanisms, particularly in commercial insurance, where employees' premiums do not fully reflect differences in the cost of their insurance. We have an entrepreneurial technology

industry that has a pipeline of gee whiz products, I never cease to be amazed at the things that are out there. It is one that has benefited from the stand that has said not why, but instead why not? And you alluded to the technology assessment profess. This is a country where we have lots of entities using lots of different methods. There's proprietary information that's not necessarily shared and I think the best technology assessment process that we have touches on a part of the flow of new technology into use doesn't even begin to touch the base of what we are currently using. So I guess my point here is that you can have all of the pieces in place as I think we do at Kaiser, how successful you are then still depends on the environment, you know, the ocean in which you're swimming. As we think about sort of how to improve technology assessment in this country there's the old adage about you eat an elephant one bite at a time. I don't think we can eat the whole elephant at once but we may need to think about taking bigger bites and asking not just the technology assessment question but in addition what are the kinds of changes that have to accompany that. I'll stop there.

MR. MARTIN "CHIP" DOORDAN: First of all let me say that I'm – when Bob asked me to be part of this panel I was very humbled to be thought of in this way. And looking at the other panel members I guess that I am unique in a way, Catharina mentioned that I perhaps had grease on my hands. Somebody in the audience when they mentioned that earlier, I think perhaps a better analogy blood

and it’s not from practicing medicine it’s from trying to work in a system that does practice medicine.

Many of you do make policy and I’d like to just take a minute if I could to give you a perspective. I come from about an hour in beautiful Annapolis, Maryland, which is the only state that has a cost control system left, the Health Services Cost Review Commission. So the way we’re reimbursed is different than the other states. Second, we have I think a very effective certificate a needs system, Pat was talking in Alabama that perhaps it doesn’t work well, I know in the state of Maryland to a large extent it does work. Some of us who would like to have open heart programs and can’t get them are dismayed by the fact that we can’t, when our next door neighbor Delaware, where any hospital from five beds up can get an open heart program and we’re right next door to each other as you will. So there is some unique things.

I’m probably you’re worst enemy in some ways as well because three years ago we were fortunate enough to complete and open a brand new hospital. A labor of my love for a number of years that has resulted in an incredible facility. We are a corporate partner with General Electric. We have just been named the first see and treat facility in the world that is a combination, that was put together between Verion [misspelled?] and General Electric. So folks now come and will come from all over the world to see a cancer center in a regional facility that technology obviously is incredible but behind that of course is the incentive of the companies to want to sell more to regional facilities. We do

appreciate that. We were the number twelve Novalis [misspelled?] System to be put in in this country, which is a stereotactic non-evasive brain types of surgery that's not available for several organs in the body. So in many ways we've had an interesting situation to deal with and it's fascinating to me to hear about technology in Europe and what's happening to the specific question is that a better system or does it work? I say perhaps. You indicated, Jennifer, that some of the issues that you are dealing with in Europe. I just had a very similar situation; personally with a mother-in-law that the exact same thing is happening as we speak that in Europe today would not be happening. At 84 does that make sense? I think that's part of the ethical question that we all have to deal with. It's hard to compare, I believe. You didn't want to get into comparing between states or countries, we have differences between my friend in Kaiser and what he's able to do in California and what he's able to do in the state of Maryland given the circumstances. My whole feeling is that you have to put it in perspective and that perspective will make a determination as to how far we're going to go in this country in changing policy. The state of Maryland is a showplace to many in regards to cost control and access for the poor. And given the fact that it's what, 42,000,000 I guess now in our country that don't have health care, perhaps policy may want to take more of a look at that system.

STEVEN HOWE: Thank you and I'd like to thank Jennifer and the other speakers for their excellent points. I think I would be doing very well to simply reiterate some of the points that they

have made. I will actually make one of those right away and then add a few others. Context is absolutely critical in a debate about medical technology and also the role of HTA. We're talking about 6 to 8% in terms of the portion of health care that is attributed to medical technology in this country. You actually find similar figures in a number of important European markets including Germany. How that results in sky-rocketing health care costs across the population is a very difficult calculus and I think it's quite obvious that there are many other things going on in each of these systems, in some cases the same factors and in other cases not.

In a market like Germany, labor is overwhelmingly the largest health care expenditure and it continues to be and it continues to be protected in the reimbursement solutions that are put forth to quote unquote reform that system. We see extreme price pressure in a number of European markets for key technologies. And what I'm hearing from companies on the ground is that in some cases it is a market-destroying scenario. That's the sort of business parliament for a scenario where they will no longer bring their most innovative solutions to certain markets, certainly not first and if at all, because the reimbursement levels are simply not there.

It seems to be not a factor of formalized HTA done with a scientific methodology; rather it seems to be a factor of payment. The payment amounts are simply too low and are calibrated not at the median level but at the lowest denominator in certain technology groups. I met recently several, three, medium sized technology manufacturers who have been doing business in Germany and they see

themselves either leaving, one of them has already left, or leaving very soon. One of them said to me that the good news about that is my greatest competitor globally happens to be a German company and I know that they will be out of business within three to five years. So there is another point here in that if a society does not foster innovation and r & d in their home market it's unlikely to exist there. This is something we have seen in some of the Europeans with the industries that they have driven out. That has an impact on access to technology and innovation, medical progress in that home market if you are depending on an overseas market. Adevermed, my association, represents 1,100 manufacturers of medical technology and that means everything, just about everything in the doctor's office except for the physician himself and the chair. A full range of technology. What it is interesting to me about this debate is that we talk foremost and consistently about imaging technologies. That is an important sector and we're very proud of its contribution, it is a small fraction of the broad spectrum of products that we bring to serve patients around the world.

DR. CATHARINA MAULBECKER: Steven, let me butt in just briefly, we had last year at this time an event here where we talked about pharmaceuticals and pricing and how Germany is hurting from not paying enough for prescription pharmaceuticals and r & d is leaving. Then we had a very interesting debate about well is the me toos that we are furthering by high prices or aren't the Europeans paying as much as Americans for truly innovative drugs. And aren't we creating a disincentive for

pharmaceutical to be truly innovative and I'd like to draw the analogy to technology if I may at this point because in pharmaceuticals you have pharma for economics and I think Wendy made the point is there something like medical device economics that actually proves the value and how it very nicely showed the health technology assessment that the [inaudible] funds are doing together with the physicians and the government in Germany to see what it is the impact of that new technology for the benefit and for the cost side. And shouldn't we rather look at that, across the board the Europeans aren't paying enough and r & d is leaving Europe. I'd like to get away from that and look at isn't there medical technology here in the U.S. and in Europe that are worthwhile to pay for, that actually save hospital days, and where a pharma economic type equation would be rather positive. And then the question is wouldn't the Germans then not only also pay the same amount as you would be paying at Kaiser or you would be purchasing in Europe?

JENNIFER EREDGE: [Inaudible] cost effectiveness in health technology. Having worked with, since you've mentioned pharmaceuticals and I used to work with a pharmaceutical company. What I found interesting in moving to medical devices is the difference in cost effectiveness evaluation because for medical devices, the vast majority of them are these little

things, these little physical things you know whether it's a pump or a stint or a pacemaker, there's a little computer in your body or whatever. You either turn it on or you turn it off a lot of the times, it isn't one of the issues with pharmaceuticals is that you can make a great statin but the patient has to take it every day and compliance is another issue when you start looking at cost effectiveness, by the time you get compliance and side-effects, et cetera involved it's not quite so clear. But in medical devices when I looked at the devices my company makes, I was stunned at how cost effective they were and I think it was primarily driven, even though the prices are higher, it was primarily driven by the fact that like or not it works. The patient has no choice about it. It's a dramatic effect if you look at pacemakers in the heart, it makes the heart beat. So using that a little better to understand where to put your resources is probably a particularly good idea in the area of medical technology.

DR. CATHARINA MAULBECKER: I mean if we had a process like that in the U.S. wouldn't it make it easier for employers, and with Jill from Marriott to defend kind of the process and say, we've done our homework and this is what we do. I'd like the panel to react to is the process that Anne described that the Germans are going through something that we should think about? Could we do it? Why aren't we doing that? I know that

there are structural issues like litigation, like a lot more marketing or so that may hamper the process but wouldn't it make sense to have that?

DR. MURRAY ROSS, PhD: It's hard to argue against better science and better information the question is sort of and what do you do with that information once you have it? Is it voluntary? Is it mandatory? In a multi-faceted system how do you take advice and have it filter through that? In our system right now we have many points of entry for technology, you get coverage in the public sector and that's used to argue private payers that they too should cover it. You can have fee for service who start to begin to cover something and then create an impetus for a managed care plan. In the Medicare if you can't get coverage nationally, you can get covered locally and then sort of return to fray to bring it into the process. And there are sort of the end runs that when you can't get something covered through, for example through the Medicare program because of the technicians and the bureaucrats it hasn't passed their muster, well you go to your member of congress and you sit next to him on the airplane and you explain the wonders of your device and you do an end run. If it's a private health plan and you are having difficulties getting coverage you take your case to the press. There are lots of different ways to go through this, I ask, given a

scientific assessment of things how does one make that fit, is kind of the question.

DR. CATHARINA MAULBECKER: Or shouldn't we rather have a more formalized process like what Anne just described instead of the lobbying and be the kind of one on one type?

DR. MURRAY ROSS, PhD: I guess my question is and maybe I would put that question to you is, how in other countries do they avoid the end run that we have in this country. Everyone likes evidence-based medicine and scientific technology assessments in the abstract and at the population level. They just don't like it for themselves, their employees, and their family members. My sense is that other countries are dealing with this better in some respects, but I'm not quite sure how.

JENNIFER ERREDGE: Control it. Go back to this bar graph I had in which you've got the government, how much is the government paying. Well if the government is basically the monopolistic card, they can write the laws. Understand that in some countries if something is provided by the government you can have it, if it isn't you can't go out and buy it. Some countries restrict that option so your other choice is to leave the question. That may work to get a drug but if you leave the country to get deep brain stimulation that means you have to leave the country to get adjusted when you need to, you don't have access to it. Medical technology has a lot of other

support structures with doctors and other equipment. It's not as easy to get around it. When the government comes along and says this is what we are going to pay for, they have the power in those systems to enforce that.

STEVEN HOWE: In all markets, including this one, there's a tension between the science and the bureaucratic process. I don't think any of the companies in our industry disagree that scientific methods to evaluate their products are a bad thing as long as they're applied appropriately and they're not based on a model designed for drugs, which is something you see consistently around the world. How you implement that in the context of a bureaucracy in such a way that doesn't cut off access for the 18-month period in which the decision is pending, that is true consistently in many markets. The one where it may not be is in the U.K. where the NICE process actually seems aimed at increasing the utilization of technology and that's an interesting model to look at I think.

MR. MARTIN "CHIP" DOORDAN: I would go back to the basic premise, I think. We, as a country we are very spoiled, we expect a lot. We have terribly inconsistent policies even between states or within states, the COM process I just mentioned so there are ways. Most hospitals are open medical staffs there if I can't get what I want at one hospital, I'll

go to the other. Or if I can't get the surgery time and so there's a very competitive piece there. I can't believe I'm saying this but I really do believe that the only way we we've got to get a controlled system that is uniform throughout the country if we're going to be consistent and if we're really going to start to get a handle on cost.

DR. CATHARINA MAULBECKER: That's a good comment to close the discussion with that should raise some questions. I would like to take questions from the audience now, if you could state who you are and what organization you are with that would be very helpful.

BARBARA CALBERT: Barbara Calbert [misspelled?] from Skydent [misspelled?] Corporation. I think the discussion of HTA in the U.S. versus Europe has been very interesting. As I see it, one big difference is in Europe most of the governments appear to have one HTA process with one decision maker usually government controlled whereas in the U.S. we have lots of people doing HTA, we have government agencies, we have private payers, we have various profit and non-profit groups. So my question to the panel members is what are the pros and cons of these different approaches. Having one HTA function that is the ultimate decider or having more of a range of different things to express.

JENNIFER ERREDGE: I think there's an advantage, I have to say, to having a variety of HTAs because it's a dialogue about it. If you have an HTA agency and you have no other opportunity to do the evaluation but through that evaluation, it can be a good evaluation or it can be a not so good evaluation. On the one hand having five or six evaluations, taking different perspectives and if you are the payer, the insurance company, the government, whatever and you have all these to look at. Some of them may be done by industry, I heard a concern about industry doing some of them. It may be done by other parties involved, then I think you get more reasoned evaluation. That's on one side. On the other side, it's true that if you have an agency in the government that is doing this evaluation that whatever comes out of that agency is going to have a bigger impact because it's the only one town and therefore if you want to use that in order to control access you certainly have more opportunity to do that with one agency. That may not be the best HTA.

DR. MURRAY ROSS, PhD: I think I'm in agreement in much of that if you're going to put all of your eggs in one basket you want to be sure that you're getting, a that you're resourcing that basket sufficiently to do the kind of assessments that you want to do and that you're willing to live with just one assessment. I guess one solution that I see to

the myriad of assessments and processes that are going on there now is to try and encourage if not a greater standardization of methods, more transparency of methods, more transparency of measurements so that people can be free to use different samples, they can be free to use assumptions and techniques, but someday lets convert them all into the same measurement currency so that we can stand one up against the other and decide if they're saying the same thing or if it is something different.

MR. MARTIN "CHIP" DOORDAN: My only comment is, again, I think that we need to find best practice. Whether it's in Europe or here, wherever standardized to the extent we can but make sure that we have a way to insure that it always stays best practice.

STEVEN HOWE: I think it's fairly known as an industry, that all of us are open to admit this that we struggle as an industry to find a unified single methodology for evaluating medical technologies and I think we've reached a point where everyone is starting to recognize there is no such thing. From a fairness perspective that's also difficult when you have governmental agencies with a centralized process. To my mind it makes a ton of sense to have a diversified process across many different providers of HTA evaluation.

DR. CATHARINA MAULBECKER: The only thing and having lived in Europe for a long time is it aides the implementation of the findings and you see that across European countries. So that would be the draw back if you had one central organization and AOK can implement that to the 25,000,000 lives very easily. Whereas here we may have a more richer source of information but it's harder to then to get it spread out. Next question.

TAD CAMPION: Tad Campion [misspelled]from The New England Journal of Medicine. I'd like to ask about information technology which I think in this day and age should be connected to the use of all medical technologies as well as old fashioned medical care and perhaps has some opportunities for improving quality of care and perhaps even control over the use of devices, high-cost medications, et cetera. What's been the experience in Europe and in the view of the others too, about the prospects of better use of information technology in medical care?

JENNIFER ERREDGE: Information technology is a broad subject so let me take a little bit of it. If you mean information technology, web access to what treatment is there, anyone in Europe can access and use and does use that kind of technology like the U.S.

TAD CAMPION: Let me just clarify a little bit then. I'm not thinking of information technology so much as a magic

solution to make decisions about who should being do what. But starting with the basics, records, who is getting what care, when how, who has been vaccinated, who has not, electronic medical records and basic communication within hospital and between doctor, nurse, patient.

JENNIFER ERREDGE: That's a great question for me because one of my interests when I moved professionally to Europe was that I assumed in a socialized system they would have population-based data. They would be monitoring what is happening to these populations because they are providing care in a population. And what do I find? In Europe we use U.S. data and try to adapt it to Europe. The investment hasn't been there in the past. However, we do have some pretty exciting new initiatives in this area. France, for example, has just passed a law that every citizen is going to be having a card that's machine readable that will then tie to the system with their care. In the U.K. there are actually a couple initiatives like that and we do have some systems that are developing those kinds of patient records, tracking systems, but I'm afraid we're kind of in the same boat with the U.S. on that.

DR. CATHARINA MAULBECKER: I'd like to give opportunities to another question.

DR. MURRAY ROSS PhD: I have a little bit of a plug for Kaiser Permanente we're in the process of rolling out our electronic health record and spending several dollars over the next years and the promise that that holds in having an electronic health records for an eight plus million patient base where we have people around for many, many years will really allow us to do a lot of studies in health services research that won't be able to be replicated anywhere else. I think the issue is going to be how do you convert all this data into information and how do you begin to think about which questions you should be asking, but we will have a lot of the pieces that [inaudible] on these questions.

DR. CATHARINA MAULBECKER: More questions?

MALE SPEAKER: [Inaudible] Associates. The question that I have is regarding not does the technology get approved but what does the technology get approved for? My memory is escaping me here but it seems that about 30 years ago the federal government approved the use on an experimental basis of MRI machines here in the United States for certain discrete very specific tests, and what happened is MRI machines are now used for everything in the world, and in fact were back then and the growth of that technology exploded. So technology is put in place for a specific purpose or a set of defined purposes and then I think what we've seen is that is sort of

expands to be used for any number of different procedures. So I'm wondering in the area of HTA is there the possibility of defining not only what technology is accepted, what it's accepted for. And then more importantly defining what reimbursement occurs after that to eliminate off label use of technology?

DR. CATHARINA MAULBECKER: Chip, could you answer that?

MR. MARTIN "CHIP" DOORDAN: I'm reminded of, and I know we're not talking about the drug industry, but I'm reminded of a situation that's occurring right now in the state of Maryland around approval through the FDA if you will, or of a drug that was used in a different way because it became the standard of care and a huge lawsuit and the litigation that's resulting from that. If you take that whole mentality to equipment I think you start run into the same type of issues, technology changes and does it the – Novalis system for example that I mentioned, was primarily initially for the brain. It's now been found to be very effective for prostate and a couple other organs. The issue then becomes do you withhold access to technology that is there and that has proven to have value? That's the catch 22 I think you run into. I don't know what answer except to say that we are going to reimburse for certain things as my friends in the insurance industry have to and not for others and leave it at that.

DR. CATHARINA MAULBECKER: You'd like to make a comment from the European perspective on that.

JENNIFER ERREDGE: In fact the health technology assessment in most of the countries actually try to look at sub-group populations. That is a big part of the process and again I keep referring to the NICE, my colleague is here but I think that is one of the best HTA assessments in which that is part of the goal to say which groups are cost effective. They may be good for all but which groups are cost effective. What does that mean? It can mean that based on cost that you are deciding to providing care or encouraging people to provide care whereas from a physical or medical point of view it may be perfectly good with another patient population. But it's more enforceable for the country that uses these agencies for that reason. I'm thinking in terms of impact and in fact you'd get a new indication you tend to have to have another health technology assessment on that indication. The downside is because the calculations are you'd have someone who is old and very sick, goes to a hospital maybe three times a year and you can reduce that 50% you're give that or do you want to give it to someone who is young and you could avoid them because of the technology they wouldn't get old and very sick. Do you give it to them earlier and 50% reduction of their hospitalization isn't as high. The health technology assessment would

encourage you to do it to the elderly people. I think we have to beware of that.

DR. CATHARINA MAULBECKER: Unfortunately we are running out of time with this panel, but we have lunch and you will have the opportunity to talk to all of us over lunch. Lunch will be at the Haight Adams Hotel [misspelled?], which is just around the corner, and it will be served there. We will be resuming here at 1:30 sharp for the next session. Thank you very much.

[Applause]

[END RECORDING]