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## Transcribed Speech of Professor John D. Blum

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## Transcribed Speech of Professor John D. Blum

PROF. BLUM: Thanks very much, Larry. It's a pleasure to be with you this morning and see so many familiar faces. It's a great feeling to be with all of you. We have been together so many times in the past and are always dealing with these very complicated, difficult issues, all of which we'll wrap up in a couple hours, so we'll have a chance to catch up. So it's my pleasure to be here.

Larry mentioned that I have had the opportunity to travel. Recently I found myself in Malaysia. It was an interesting experience. I was in a place called Penang, which some of you may be familiar with. It's a very old city. I stayed in a hotel that was on top of the city and it was a weird deal because there was nobody else there. So, I was wandering around the hotel and I saw these pictures of the American architect Buckminster Fuller. It turned out that Buckminster Fuller had used this hotel to have a series of conferences and there were quotes from Fuller all over the hotel. There was one quote in particular that I thought, "You know, some day I'm going to use that quote" because I'm always searching for things in articles. The quote is very simple, and it can be applied to virtually anything, so it's the perfect quote: "People should think things out fresh and not just accept conventional terms in the conventional way of doing things."

Well, I thought about that and I thought, "Gee, in terms of health care regulation, what an apropos little quote." In point of fact, I think we're into patterns, we're into ways of looking at regulation. Because most of us are lawyers, we think about rulemaking and we think about certain processes and just assume that's the way it should be. One of the things you think about when you look at these issues we're going to talk about from a global perspective is that, in fact, we ought to be thinking more broadly. [W]e ought to be thinking more creatively. There is no such thing as zero-based regulation, as we will see.

[W]ell, actually, it's funny, because at some point I had to find out where the quote actually came from, which one of his many writings. One of the law schools forced me to get the origin of the quote, so [now] I am on five list serves dealing with Buckminster Fuller. I can't get off the list serves, so each day I get twenty, thirty e-mails about this stuff - stuff I have no understanding of at all! But, it's kind of fun.

In any event, my charge today is to look at quality from an international perspective and to look at value. That's a rather hard thing to do because

there are so many variables. I'm speaking primarily about international issues. But in order to do that, I really have to set the stage domestically.

To really think about regulation in terms of quality raises a number of issues. First of all, there is the perennial issue of what we mean by quality. [I]n reference to what I'm going to talk about this morning, I'm going to take a very broad cut. I think traditionally we looked at quality, at least on the state's side, as something that evolved out of health services research. I think many of you are familiar with the work of late Donabedian, from Michigan, who is the father of the quality assurance movement. He talks about structure, process, and outcome. That's really one way to look at quality. It's a very challenging way. [I]f you have read the recent MedPAC report, you know that we talk a lot about outcome. But there are problems there, and we're in the infancy of this.

[M]y take here is much more [broad]. I want to look at quality from a global perspective equating regulations with quality from a system-wide standpoint. Are we achieving the objectives of creating a strong system and a system that really reflects what we're trying to achieve, namely, value? And, of course, the question of value is a difficult question because there, too, [one may ask,] what do we mean by quality; what do we mean by value?

[I] want to focus on that in two ways. I want to look at the cost-benefit side of the equation in terms of value, which surprisingly is not a side that we focus on nearly as much as we think we do.

[S]econdarily, when I move into the international arena, I want to look at value in terms of public health and in terms of outcome measures - a very global public health outcome measures - [which is] perhaps somewhat different from the way we talk about outcome in the context of American regulation. It's interesting because there is a lot of discussion at the federal level about cost-benefit, but if you look at where that discussion comes from, it's often highly partisan and it is often focused in certain bands. In other words, we can look at the cost benefit of fraud and abuse regulation. If you talk to the people at OIG, we recoup  $x$  number of dollars. If you talk to people at CMS about Medicare auditing, they say for every dollar or less, we recoup ten dollars or more as a standard. And then you can look at some of the literature. There is a very interesting article that was done by Bill Sage, David Hyman, and Warren Greenberg in *Health Affairs* dealing with antitrust and trying to make the argument that antitrust regulation is really a form of quality regulation. It's a very persuasive piece. The problem with the piece, of course, is it is not quantifiable. It's very intuitive, and it's based upon a series of really sophisticated arguments, but there are some quantum leaps. My point is that when we look at cost-benefits, we're really thinking about types of regulation, as opposed to the

entire spectrum of health care regulation generally. I was, however, pleased to find some work that was done which I am going to reference in a moment.

But before I reference that work on cost-benefit, [let me speak about my] intuitive view of this. I have been working in this area for many years and it has taken me a while to come to some of these conclusions. You might look at these conclusions and think, "You are kind of a slow starter." I could have told you that a long time ago about regulation.

Number one: there is no shortage of health regulation. I am absolutely constantly stunned by the volume of regulation that we're dealing with. That is kind of a no-brainer comment, but it is something we need to think about a lot.

Number two: regulation is layered. It is sort of piled on top of each other and I will comment on that in a moment. It is poorly harmonized. When you look at the whole issue of medical error, look at the private sector response, the state response, the federal response [you find] we are all responding in similar but different ways. That is very characteristic. And then the fact is that for every new problem, there is a new regulation. If you go back to 1995 and think about fraud and abuse, which was not on the agenda, then along comes HIPAA, then along comes medical errors, then along comes the recycled med-mal issue, it is almost as though we have the issue of the year. The problem is that all of these become layered on top of each other. We never reach a point where we say, "Maybe we should do some zero-based regulation." We have sunset legislation, but, frankly, most things that sunset rise again. There are few things that die, but basically we continue to layer things on top of one another.

In [2003], the AHA, and some of you may be familiar with this, convened a task force to conduct a very interesting study on regulation. [The AHA] is a trade association, so some of it was somewhat self-serving, but it was really focusing on the MMA and changes in the MMA. But in conjunction with that, it looked at the nature of how we regulate in health care and identified the major sectors of regulation from command and control to market. The conclusion of the report was that we need to go back and rethink all of this. [The task force was] struck by the comments that I just made, how layered and how unharmonized this whole sector is. It is somewhat unique to the American system. It's not totally unique, you see it in other places, but I think that that is a major issue. Certainly on the academic side, it's easier for us to address that than on the practitioner side.

The question is, is there too much regulation? It depends where you sit. I think most people would say, "Absolutely, health is overregulated;" a lot of this is partisan. I mentioned the AHA. You can look at other groups. There are a number of conservative think tanks that do a lot of work on this

issue of overregulation. The Cato Institute is the one I want to focus on for a moment because Cato has sponsored some interesting work. They sponsored the work of the Duke economist, Chris Conover, [who] has been looking at the question of cost-benefit. Even though it's being promoted by a conservative think tank, it is a very thoughtful piece, it is one of the most thorough pieces that I have seen, and a fairly rigorous piece. [With] this kind of analysis, of course, you can drive a truck through a lot of the stuff, but it is better than what we have seen in terms of regulatory cost-benefit analyses inasmuch as what we have seen in the past is kind of the top of the envelope stuff. We have seen analyses where people say, "Well, we don't know how much we spend on health regulation, but we do know how much, interestingly enough, we spend on telecommunications regulation or on energy regulation. It is a certain percentage of the GDP, and health care is a bigger percentage; therefore, we use that as a baseline." [That is] pretty artificial. Well, Conover looked at a number of bands and regulations from facility all the way through the tort system and came up with some conclusions. He concluded, based on [2002] data, that we are spending about \$335 billion on federal and state regulation; that the benefits of this are \$207 billion; and the excess - or really what would be considered a tax - \$128 billion spent on regulatory cost, was a loss. So the cost-benefit analysis is skewed on the loss side and focuses very heavily on malpractice, FDA regulation, and health facility regulation. It is not perfect. [Conover] is continuing to work on it, but at least it has opened up a dialogue at a higher level than what we have seen in the past.

Let me shift gears, then, and talk a little bit about other parts of the world. Is it any better anywhere else? Immediately, of course, those of us who work in regulation, the first thing we think of is, "Wait a minute, we are so different and so unique, it's really very hard for us to draw comparisons to how other systems regulate." Certainly if you look at quality regulation, if you want to focus on it in a broad sense - I mean, we are so introspective - we crank out data in buckets. Nobody else does that quite the same way we do it, so how can we possibly learn anything from other countries? If you look internationally, although this is starting to be addressed, there have been some interesting articles. As a matter of fact, just last week there was an article in *Health Affairs* that did a six-nation comparison. [T]here is a dearth of information and a dearth of data, particularly on the outcome side and at least in the clinical arena; but, I would argue that in spite of that, the interest level internationally in regulation and quality and health systems is growing and is very high. I think the one thing you can argue is that on the cost side, there is a tremendous universality of interest, that virtually every system is interested in increasing efficiency, increasing incentives to limit patient use,

increasing administrative controls, and limiting resources: those are universal issues on the cost side. It can be transposed and talked about on the quality side as well but, clearly, if you talk to people in Germany or the U.K., certainly in the developed countries [there are a lot of parallels. [If] you talk about the developing world, obviously, there is a whole different story about the challenges that it faces.

In terms of regulation and policy, we do see generically parallel areas of development. There is a global interest in I.T. in the developed world. You can look at, I mentioned in my opening remarks, Malaysia. Malaysians have a plan to implement e-health as a national infrastructure development. They are working very hard on telemedicine, at least their version of telemedicine. You can go to India, which is a fascinating country and a very rapidly developing country. They just launched last year a satellite to use for their own telemedicine-based systems. If you look at other developed countries, look at Europe, there's something called e-Europe, [of which] health care is a big part.

Patient safety, we are all aware of that. We are aware of the importance of what JCAHO has been doing for a number of years. JCAHO has now gone international. They are taking their patient safety issues global and there is a considerable amount of interest. We hear them talk about managed care and application and discounted fee for service in other sectors. I'm familiar with those terms in the U.K. If you go to Singapore, which has a very developed medical system, you see similar sorts of terms. The French have created a national agency to evaluate the effectiveness of health care and do similar things to AHRQ [Agency for Healthcare Research and Quality], and so we are seeing parallel developments in the national quality area.

In terms of clinical comparisons, [there is] a lot of work going on. Some of you may be familiar with the Cochrane Collaboration, which is really a global project. I think it is in Boston, but it's had its origins in the U.K. It is global, but [it is] looking at various types of clinical outcomes and clinical guidelines and it is working in conjunction with the National Health Service. So there is a lot of parallel stuff going on in the world. Obviously, it is a trivial comment that the world is a small place, but people are looking over everyone's shoulder to see what the other guy is doing.

With that said, however, I put my big caveats on this and would argue that [while] there are these universal applications and universal things happening, there still are significant differences in terms of ways issues are presented in similar countries. I think of that a lot about Canada because I have spent a fair amount of time there. If ever there were two countries that were similar, much to the chagrin of our neighbor to the north, the U.S. and Canada are about as similar as you can get. And yet if you look at the

Canadian system, which has undergone lots of changes, lots of introspection, they had something called a Romanoff Commission Report, they had a report out of parliament recently, a Senate report, and they're going through lots of economic turmoil, and lots of turmoil about privatization. If you look at some of the big issues they're dealing with, they [seem] quite different, at least at first blush, but they are not all that different.

If you looked at each of these, these are issues that we deal with. They're dealing in Canada with whether or not they should have them. We are dealing with how much co-payments and deductibles should be and how much can we expand the area. They're doing waiting lists. We're dealing with the uninsured. They're dealing with issues [of whether] physicians [should] all be salaried. We're dealing constantly with issues of medical autonomy. That issue about salaried doctors is a big issue for us as well but, granted, it is presented a little bit differently.

Are we spending more on health regulation vis-à-vis other nations? Well, you do not have to be a rocket scientist for this one. No doubt. But I suppose the question is, "Are we spending it effectively?" Some people argue that in spite of the fact that health care is fifteen percent of GDP, maybe that is okay, maybe it should be higher as long as we are meeting our objectives and goals. Are we getting value for the money in terms of health care regulation? [This] continues to be the unanswered question.

If we look globally at what has been done, WHO [World Health Organization] in 2000 did a report where they used some very fundamental public health indices. We got slammed in the report. We fell to number nineteen. France, at least prior to all the issues they are dealing with now, was the number one in the report. But, it's interesting because there was a Harris poll group that did a study in [2004] solely in Europe, and France is not listed as the number one health program. As a matter of fact, Denmark, Austria, Finland, and Luxembourg all ranked higher, but in the WHO report, they were not included. But the French system is still viewed as one that brings a high level of satisfaction.

This is a quote from a great article that was taken from a review of a great book dealing with the uninsured. The article deals with the issue of moral hazard and this book on the uninsured deals significantly [with] how moral hazard has skewed our ability to deal with social policy and social health insurance. ["Americans spend \$5,267 per capita on health care every year, almost two and a half times the industrialized world's median of \$2,193; the extra spending comes to hundreds of billions of dollars a year. What does that extra spending buy us? Americans have fewer doctors per capita than most Western countries. We get admitted to hospitals less frequently than people in other Western countries. We are less satisfied

with our health care than our counterparts in other countries. American life expectancy is lower than the Western average. Childhood immunization rates in the United States are lower than average. Infant mortality rates are in the nineteenth percentile of industrialized nations. Doctors perform more high-end medical procedures, such as coronary angioplasties, than in other countries, but most of the wealthier Western countries have more CT scanners than the United States does, and Switzerland, Japan, Austria, and Finland all have more MRI machines per capita. Nor is our system more efficient. The United States spends more than a thousand dollars per capita per year - or close to four hundred billion dollars - on health-care-related paperwork and administration, whereas Canada, for example, spends only about three hundred dollars per capita.<sup>1]</sup> The point of this rather lengthy quote is to provide some statistics about how we spend \$5000 plus, the rest of the industrialized world spends about \$2000 plus. In point of fact, our outcomes from public health standpoints are worse than what we see in countries that spend significantly less and regulate significantly less.

One of the big indices is life expectancy. This is a broad public health measure. If we look at this, we can look at Japan, which spends \$2139 and has the highest life expectancies in the world. If we look at the U.S., not too bad, 77.2, but we spend a lot more dollars and a lot more of our GDP goes into health. That's a tricky statistic. I do not know if any of you get *National Geographic*. I happened to see the most recent issue where the author talks about Slovenia, Okinawa, and, in the U.S., the Seventh-Day Adventists. All those groups have the highest life expectancies in the world. [This has] very little to do with health care and a lot more to do with red wine and physical activity. Being a shepherd in Slovenia will keep you alive forever. Those are interesting statistics. They need to be correlated with what we are spending in health generally vis-à-vis with what we're spending in regulation.

If you pursue the percentage of public money going into health care - and this is a very frightening statistic - in the U.S. only forty-four percent of the money spent on health care is public money. If you look at other systems, they are spending an awful lot more public money in health care. I found, just as a spurious point, the pharmaceutical spending, which I think is always interesting. Look at Korea, and I think Japan would be similar, spending close to thirty percent on pharmacy. I don't know what to make of that, but I thought it was kind of interesting.

Dealing with resources, with physicians, nurses, acute care beds, and MRI per million, you find that we can't really tout ourselves as having a lot more or having worse problems in these areas. [There are] lots of

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1. Gladwell, Malcolm, *The Moral Hazard Myth*, THE NEW YORKER, August 29, 2005.

similarities. I do not think I'm bright enough to draw conclusions from this data, but I think it is data that you would have to think about in terms of regulatory strategy.

Dealing with health status, [let me] make a counter-argument. If you look at infant mortality, you have some problems there. If you look at adult smoking, that is one area where we have had tremendous success. You could make a counter-argument that regulation works, and some of the things we have done in this area have worked very well. So do not just say no regulation, but regulation has to be targeted in a judicious way.

Of course, we are also fixated on diet issues and if you look at the obesity rates in America, we really have a problem here. These are the sorts of public health issues that we need to grapple with that are highly significant in terms of health status.

Look at sort of another band of international comparison that is evolving: patient satisfaction. Surprisingly enough, this is not just an American passion. We are all familiar - many of us are familiar - with the CAHPS [Consumer Assessment of Healthcare Providers and Systems] survey. CAHPS is focused on managed care and point end-based satisfaction. There is [also] a group in Europe that has sponsored a consumer satisfaction survey. It is interesting because that group has come to some interesting conclusions based upon its data and it is looking at a variety of things. [It is] looking at patient rights and information, waiting time, outcomes, customer friendliness, and pharmaceutical availability. They have come to some interesting conclusions about different systems that I think if you look at the full report, you can get a sense of that. In the interest of time, I won't do that, but it is an attempt to do something comparable to what we are doing in terms of consumer satisfaction.

[Y]ou know who does very poorly on all of this is the U.K. They really got slammed by this group and they are a country [considered] significant in terms of their NHS. But [there is] lots of consumer unhappiness there. Germans tend to be happy but tend to find getting information from the system difficult.

The final thing I want to say, and I apologize because this is a giant issue, is to take away [a lesson] from these international comparisons that it is too easy to argue that we are so different. That seems to be the tone of some people when they look at this. I think one thing you can take away is that we are not alone. There is a universal sense of misery about a lot of these issues. I had some time to talk to some Germans who were involved in their health system and they're very unhappy about the cost, they're very uncertain about the future of their social systems. Everyone is struggling for the magic bullets, which is not unique for us. We need to be cognizant of these other systems.

What we ought to look at is [whether] our regulatory system is too dense. If you look at European systems, they are much more streamlined. They are not perfect, but there is a tradition of private regulation that is much stronger. We do not subscribe to that, but I think it is time to start to think about how we regulate and why we regulate.

Now, I think the whole federalism issue is an interesting one, it is very Jeffersonian to talk about the states as the laboratory, but you need to think about if there are too many. Are there too many laboratories letting people do too many different things in this arena? How do we sort of streamline some of this?

My final point is that we are overwhelmed with data, but I do not always know to what end. I think sometimes we need to be much more cognizant of health status and population measures. I think it's very important that we look at population-based measures and maybe we need to refocus all of our quality efforts to look at end points and not be so consumed with process. Not [to say] that process is not important.

I appreciate the time I have had to spend with you this morning. I look forward to informal chats. [There are] lots of issues to think about, very few answers, but an incredible number of questions. Thanks very much.