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EURO-ATLANTIC ACTION COMMISSION

**ROUNDTABLE SESSION ON INNOVATION AND HIGH
TECHNOLOGY COOPERATION BETWEEN HUNGARY AND THE
UNITED STATES**

TRANSCRIPT

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WELCOME AND INTRODUCTION OF PARTICIPANTS

George W. Handy, Director, International Actions Commissions, CSIS

Ladies and gentlemen, good morning. I'm pleased to have this opportunity to open this cooperative session between the United States and Hungary. On behalf of Dr. Marburger, Dr. Atkinson, and the distinguished Americans who have joined us today, it is my privilege to welcome the Hungarian delegation. We were honored that Hungary's outstanding scientist, Professor Norbert Kroó suggested almost a year ago that this exchange take place.

We've watched with admiration as the Hungarian government has taken decisive steps to strengthen its approach for high tech development and innovation and we've watched with equal admiration the selection of Dr. Miklós Boda to be the lightning rod leader of this effort. My thanks to State Secretary Jambrik and to all of the members of the Hungarian delegation for making time in your busy schedule to join us today.

Today's roundtable is not a single event, its part of a process, the beginning of added US-Hungarian cooperation on top of an already rich foundation. The presence of the head of the Hungarian High Tech Center, Dr. Földesi, is particularly appreciated. With friends like Mark Brzezinski and partners like Dr. Gene Block and Dr. Gerry Gordon, who joins us later today, the HTEC will certainly be a valuable element in the future of practical cooperation that we hope will follow from today's session.

This session would not be possible at all were it not for the outstanding leadership of Hungary's ambassador. Ambassador Simonyi will join us at lunch today and it would

not have been possible without the expert management of Dr. István Takács. We at CSIS would not have attempted this effort were it not for the generous and expert leadership of Eli-Lilly Corporation. They have provided the energy and vision for not just today's effort, but also the work that we'll do in the months to come.

Our purpose for today is sharing the experience from US innovation process and financing approaches for high tech with Hungary, and taking the step towards organizing four cooperative teams that will share ideas and develop opportunities in the month's ahead. We'll have a follow-up session around March at the call of the Hungarian side in Budapest. We'll also present a white paper from this effort that will take general lessons learned in high tech development and share them with neighboring countries within the central and eastern European region.

It's a pleasure for me to pass the floor to Dr. Marburger. Before his appointment to the executive office of the president, he served as the director of Brookhaven National Laboratory. He was the third president of the State University of New York at Stony Brook and he has a distinguished career, as a physicist, which occurred principally at the University of Southern California, where he was a department head, professor, publisher, and speaker of some significant reputation. We're delighted Dr. Marburger, that you would agree to be here and to open this morning's session.

**DISCRIMINATORS DEFINING DEVELOPMENT OF HIGH TECHNOLOGY – US EXPERIENCE
Dr. John H. Marburger, Director/Senior Advisor to the President, Office of Science
and Technology Policy**

Thank you very much George. I am pleased to be here. Of course physicists particularly in the US are very conscious of the long history of the excellence of Hungarian science and we have a great deal of respect for these intellectual assets that Hungary can bring to bear on this technology intensive economy - an economy which is growing rapidly around us and rapidly becoming globalized.

The title for my talk, I'm not sure how we pieced together this title, "Discriminators Defining Development of High Technology – US experience," but I can tell you a little bit about my own experience and there are others around the table, who know more than I do about how this works in detail. But I have been part of a technology transfer machinery in the US and I would like to talk about it from the federal point of view, particularly from the perspective of federal funding and federal priorities.

Let me talk first of all about these priorities. The fact is that, as you all know, the US does not possess a single science agency that has a big budget that is dispersed. We have a number of different agencies and departments. The tradition in this country is for science to be funded through agencies that have missions relevant to societal needs. So by far the largest amount of research and development in this country is through the Department of Defense. About half of our current budget of \$130 billion per year is expended through the Department of Defense and much of this is on development of systems associated with national defense.

Some people in the science community have criticized us for spending so much on development or perhaps bragging about all of the money and increases in this area but it is a major investment in the technology infrastructure of the US. Whether its basic or applied, the more than \$60 billion per year that goes through the Department of Defense is a major sustaining investment in the technology infrastructure. It leads to new ideas concerning intellectual property that diffuses through the industry and helps support it.

The other half of our investment of \$130 billion is distributed in a way that I would like to make sure that you're aware of. Although there are more than two-dozen different agencies and departments that have science part of their portfolio, there are five big agencies that do this work. By far the largest, I'm talking about non-military R&D, is the National Institutes of Health. NIH consumes 47% of the non-military science budget. In this administration, an effort to double the budget for the National Institutes of Health was consummated in 2003, and investments in NIH have flattened out, but it is still funded at a rate of increase larger than most of the other agencies.

Second, largest on the budget is in NASA. Of course NASA has responsibility for providing access to space, that is necessary to the programs of many other agencies. For example, the National Science Foundation, the Department of Energy, the US Geological Survey, the National Oceanographic and Atmospheric Administration all rely on NASA space launch/satellite launch capabilities to carry out their programs as well. But NASA has 15% of the non-military budget.

Next, in third place are three agencies of roughly the same size, the National Science Foundation, the Department of Energy, and the basic research part of the Department of Defense. All have between 9% and 10% of the non-military R&D budget. No other agency has more than a few percent; the US Department of Agriculture is next largest with about 3% of the budget.

Again there are many other smaller agencies that are important, such as the Geological Survey or the National Institute of Standards and Technology, which play important roles in our system of technology transfer, but their budgets are very small. These budgets are appropriated through Congress. Congress has thirteen appropriations committees, ten of which are responsible for the science budget. So there is no one committee in Congress; in no case does the budget that is appropriated by one of these committees consist largely of science. In other words, science does not dominate any of the Congressional appropriations committees. So it is always in competition with other missions.

Despite that, the percentage of the domestic budget, we call it the domestic discretionary budget, the percentage devoted to non-military science, is practically constant year after year - about 11%. So the US devotes about 11% of its discretionary budget each year to science. In this administration it is somewhat higher, it is about 13%, but it fluctuates around 11%. This is how the funds are distributed with respect to the specific programs within each agency.

Of course there is some need for coordination. The manner of technology, for example, is a very broad area of current interest that is carried out in 13 different agencies

coordinated by interagency committees that are staffed by my office. My office of Science and Technology Policy is the primary coordination office in the Executive Office of the President for pulling together the contributions of all of these different agencies into a national program. We operate interagency committees under an umbrella in the cabinet called the National Science and Technology Council and that cabinet umbrella authorizes the participation of each agency in these interagency working groups.

From these groups we assemble, each year, a list of priorities and priority areas, that are published in a memo and signed by myself and the director of the Office of Management and Budget, that identify the areas of science and technology that will receive special attention in the budget process. So each agency makes budget proposals to a central Office of Management and Budget and at that point my office participates with the Office of Management and Budget to try and ensure that the proposals are consistent with the overall priorities. Then the budget is assembled into a single request to Congress. Congress then takes it all apart and appropriates it piece by piece to the agencies and then the agencies do their work.

The priorities are no surprise. They include things like nanotechnology, information technology, biotechnology, and certain areas in energy that are important to us such as, a search for alternatives to petrochemical, to petroleum, and to carbon based sources of energy and also environmental issues that are important to us. So, energy and environment, public health, are high priority areas of investment for this country. These priorities are very similar to heavy-developed countries as far as I can tell. I think the reason for that is that the scientific community has much more cohesion than government and we listen to the science community for advice on what the most important areas are to invest in, and all countries are talking to the same side.

But, truly we are engaged in a global enterprise and we're very conscious of the priorities in other countries as we select our own and try to compliment work done elsewhere. We do of course participate in international science. We are a major partner in construction of the new accelerator at CERN [Large Hadron Collider project], for example, in Europe. This administration decided to participate in, once again, the international fusion program, which we hope can resolve its impasse about where to site the project. But we think it's important for us to invest in it wherever it is ultimately located. These are just some generalities about the way our process works for identifying priorities and spending money; and the money indicates our priorities to some extent.

Now, I would like to say a few words about the US innovation process. One of the interesting features about research and development in the US is how much we rely on research universities. We have significant investment for basic research in a large number of universities distributed through the US. In order to encourage the application of the research results in universities, about 25 years ago Congress passed laws that give ownership to intellectual property developed with federal funds back to the universities where the work was done.

We have a process that transfers ownership from the federal government to the research performers in universities, whether they're public or private, that we think has had a very

important impact on the desire of universities to make use of this intellectual property, as well as the ideas and research results developed in their institutions. Most universities arrange for a very generous allowance for the faculty members who participate in the research and indeed faculty professors who have developed intellectual property are often able to participate very substantially in royalties and licensing fees.

This ability to participate in profits and revenues from intellectual property that the universities have was extended to operators of national laboratories about the same time, so that wherever the research is done there is an incentive for developing it, applying for and developing the patents, and licensing the processes or discoveries to private industry. This has been quite successful. In fact, the patent disclosures increased very rapidly after this legislation was introduced. There was a major [change in] activity, just before the law was passed in 1980. There were only 250 patents issued to universities per year before the passage. Just a few years ago, 1998, the most recent year that I have figures for, there were approximately 3,200 patents awarded to universities; an enormous increase in patent and licensing activity. There are others here who can answer detail questions about this, but in my experience the ability to profit from intellectual property developed with federal funds has been a major incentive for getting these products out of the laboratory and into industry.

There are other opportunities as well. There is a mechanism called, Cooperative Research and Development Agreement (CRADA) where it's possible for industries to work together with federal laboratories on projects that use the resources at the federal laboratories. There are a significant number of these CRADAs today. I think the number of active CRADAs in 1996 was something like 3,500. This is the number of specific projects that were jointly sponsored by industry and federal laboratories. This just gives you a flavor for the kinds of things that we try to do, to not only support basic research, but also to make sure that its products become available to industry and reach our economy. I'd be glad to answer other questions in the discussion period but this at least gives you a feeling for the general picture. Thank you.

INNOVATION ENVIRONMENT AND DECISION-MAKING FOR HIGH TECHNOLOGY DEVELOPMENT IN HUNGARY

Dr. Miklós Boda, President, National Office of Research and Technology

Thank you very much ladies and gentlemen. We are here today, because we have the same common interests in possibilities of cooperation between Hungary and the US. That is why I think it is important for you to understand the environment in Hungary. With my presentation I hope to highlight the main features of the environment and possible opportunities Hungary may offer for you.

Let us start with the environment. This year the new Hungarian innovation system has been built in order to promote a cooperative economy. This goal can be realized if the research and development is driven by the present and future needs of the economy. You may all know this but it's something new in Hungary. This means that our main task is to provide a new framework for innovative activities in the country. To this end the government has established a new government agency, the National Office for Research

and Technology. This office is responsible for implementing the science and technology policy of the government. The major government institutions of reform reflect the commercialization-oriented government R&D policy. The separation of policy-making and funding management resulted in a more sufficient and clear distribution of the task. The setup of the government level science technology policy board and the IT advisory board and other development research and technology and innovation, assure a strong leadership for the operation of the system.

Challenges for our innovation system. Two related challenges shown in the slide. First, a break through is needed in cooperative R&D activities. Unlike in the US, the challenges are largest for SMEs in Hungary. We need to create a new set of small innovative firms. In order to grow, they also need to have access to seed and venture capital.

Second, companies need a strong academic background to rely on. After my presentation Professor Kroó will surely convince you about the strong impact the Hungarian scientists have made on the global development. Let me just mention from my office the main job is to provide a linkage between academic and industry in Hungary that has much room to improve.

In order to restate the main problem in the Hungarian innovation system let me show you the breakdown of Hungarian R&D spending. The real problem is shown in the blue in the low figures of industrial R&D. During the transition to the market economy in the '90s robust industrial funding for R&D was low. We have not fully recovered from this event by today. There is a large reserve of highly qualified researchers available for this challenging new task. Now overall, the spending of the country increased after the bottom of '96, but by 2001 again had reached 1% of the GDP. This is still a very low figure compared to global leaders. Other challenges are to change the structure of the expenditures. Business expenditures are still, in order, only 30% of the total spending. The share of public funding, shown in purple, still remains nominal. Our goal is having it the other way around.

What we are doing to tackle those challenges is quite simple. First we have taken measures to boost corporate innovations. Secondly, to promote connections between the academic and the business world it is time now to put this declaration into effect. We are not just dedicated to those goals but match our commitment with action and science. Funding is made for the foremost and high input drivers towards those goals.

How are we doing that? We are introducing strong incentives to boost R&D activities. We have implemented indirect incentives like large R&D tax allowances. As you can see, the amount multiplied the deduction for the R&D costs from the corporate tax bases. Those are complimented by large-scale corporation PPP funding schemes. The most important point about those strong focusing of researchers, the goal is to create a critical mass and concentration of priority fields. Through competitive goals we are aiming to create regular incentives of excellence in the key technology fields. Those can grow and become regular focal points of innovation through cooperating investment and create a strong demand for a marketable R&D results coming from the public research institution.

Public sector innovation has long been hindered by strict and prohibitive regulations. That made the commercialization of R&D results too difficult. We are in the process of changing that, for example, new IPR rules for public-private partnership will give both partners incentives to cooperate. The obstructions of establishing universities spin-offs are being removed.

What more can we offer? Let me give you some evidence about the qualities of our workforce. The regulation system in Hungary is definitely not bad. But let me make another important point, I think the culture and the history contribution, like independent solution finding and innovative thinking, are the key competitive advantages of Hungary. This is true not only for the science and engineering professionals but for the total workforce. Those qualities are used for any company or corporation, and I mention that because such people are available in large numbers.

I have a win-win proposal for you. Hungary can certainly learn and benefit from the vast American experience on how to commercialize R&D results. We can learn about what makes America the most successful innovating country in the world. In return, we believe there is an excellent opportunity for American companies and venture capital to export into Hungary. Many large American companies are already present in Hungary. Now we have to raise the awareness of SMEs. For whom the opportunity should be even more appealing mainly because they will have access to the top of the Hungarian scientists. More than that, you can do what I did when I, in the name of Ericsson, could strongly influence certain departments or universities.

Further on, the large companies operating in Hungary are saving the local supply chain of SMEs. There are opportunities open for smaller innovative companies to make use of Hungarian workers, American companies can establish a very competitive European presence.

Hungarian membership in the European Union has clearly many opportunities for us and our partners. There are direct factors like jumping boards for companies wishing to enter the European market. In addition, another important advantage is the bridgehead situation for Hungary. A European Union member close to the eastern European market is an ideal location for firms planning to export to the east. This opportunity has been discovered by large multinationals. The influence that they have reached, the slide shown, entire companies are bringing high value added activity into Hungary. It is clear that firms creating corporate R&D centers have come to stay. They are not in Hungary just for cheap labor or our location, but for our knowledge.

In conclusion let me sum up by highlighting the main messages of my presentation. A new Hungarian innovation system has a renewed commitment for boosting corporate innovation. First we are creating a favorable environment for innovation. Second, significant funds are made available. From this basis we are offering our partners investment in R&D in Hungary. We do so because we believe that such an investment brings mutual benefits.

Among many incentives for American investment should be an access to the high quality, low cost labor force. The opportunity is there, not just for the large companies, innovative SMEs can benefit even more. Millions of Hungarian immigrants have contributed to what America is today. We are here to find out how America can contribute to what Hungary will be tomorrow. We now announce a new cooperation in a new initiative specially assigned for CSIS and Mr. Handy who has offered to organize this meeting and I am confident that we will not let this opportunity slip. Thank you.

George Handy

Thank you for a very crisp and focused and inviting, engaging presentation. Now let's turn to the unique strength of the Hungarian science base. In order to do that, it's my pleasure to welcome Dr. Norbert Kroó. As I mentioned at the outset it was Dr. Kroó's suggestion that brought us initially to a discussion of this idea and ultimately to this table. We are simply amazed that we were able to get on his docket. Thank you very much for being here and the floor is yours.

THE UNIQUE STRENGTH OF THE HUNGARIAN SCIENCE BASE
Dr. Norbert Kroó, Secretary General, Hungarian Academy of Sciences

Just a few opening remarks, let me speak just in a telegraphic style in order to give you as much information as possible. It is known for all of us that the United States is still the homeland of high technology, despite all the current efforts of the European Union and in the temporal difficulties you have in this country in connection with security. Therefore, we Hungarians put high emphasis on the cooperation with US institutions in the fields of basic and applied research. We want to learn from you how optimally funding can be covered, how infrastructures can be optimized and maybe even shared, how the real and vivid scientific atmosphere can be created which is varied in this country, how industry-academia relations can be put on that level which exist here. We are interested in cooperation in technology transfer activities and in business activities as well.

I myself feel privileged now, as Dr. Boda mentioned to you, to use the Hungarian research landscape, not with a special emphasis on the Hungarian Academy of Sciences. In the handout I showed you some highlights which you may see and if you have questions then please ask them, I don't have time to stay with them now. But we will pay attention and put emphasis on as a high-level research partner as an appropriate frontier for other cooperative activities, based on the strengths of our basic research and possibilities, opened up our EU membership. And on the creativity which has been proven by Hungarians in this country too.

In May or April when the Hungarian commissioner to the European Union was questioned by European Parliament, he was asked what he thinks will be the special value Hungary is going to bring into the Union. And then he took out of his pocket the Rubik's cube and said we are the creativity, which is behind this cube. And I share his view. Hungary has been centered around Budapest for a long time in history and in the Middle Ages it was a booming town but it was booming in the twentieth century too. You may remember the article of the first issue of Nature in this millennium on the 6th of

January 2001. The cover article is projected now, which is referring to von Neumann and the title of this is Genius Loci: The Spirit of the Site and the subtitle is the twentieth century was made in Budapest.

My mission is that we could have an article in 100 years saying that the 21st century has also been made in Budapest, I am afraid that this is not going to happen but we shall work very strongly to achieve at least a minimum of it. And I am from this building from the Hungarian Academy of Science, which is a 179-year-old institution, and this is its headquarters. We have always had very good relations with a number of country scientists on a personal basis. The big change in 1989 was we could institutionalize our scientific compacts and that's what we intend to do now.

Let me give you just a few numbers. How has the situation in the world changed since that time? Well the data is a bit late but they still reflect the changes. You may see that in every respect, Hungary made a big leap forward in all of these macro parameters.

And it is still relatively cheap to do research in Hungary. On this transparency I am showing the number of published papers in international research journals from 1 million in USD investment. Now you may see that Hungary from the OECD countries is the leader of this list. Our reputation reflected for example in citations is increasing. Now it's about 5% of all the world's citations. And I want to mention that the population of Hungary is less than 0.2% of the world population.

This is our research intensity where citation intensity is projected against wealth intensity. Citation intensity is the citations per GDP and the wealth intensity is the GDP per capita. You may see Hungary with relative low wealth intensity and relatively high research intensity and it has improved between 1997 and 2001.

You may see that Hungarian science is internationalized. More than 50% of our publications contain foreign co-authors. And we are very proud of this figure, I wish it were completely right, Financial Times published in October 2001 a set of data which is reflected here, based on OECD data, which ranked countries on their knowledge-based economy. And you may see on this list that only Switzerland, Sweden, the United States, Ireland and the Netherlands are ahead of us. This is not supported too strongly by our research investment. You may see Hungary is the further point there; we are relatively low in GDP and relatively low in investment in R&D.

This figure has been shown already which is the share of foreign affiliates in manufacturing R&D where we are in the leading position. But what is again an interesting issue is how high tech exports are presented in all manufacturing exports and you may see that Hungary from the OECD countries, in this respect, is in fifth place. And this is even more visible if you look at the change of this list of the high technology exports where Hungary's growth between 1996 and 2001 has been more than 50%.

We are actively participating in European Union programs. We participated already in the force framework program when we were not members yet. We were active in the

fifth framework program with 375 participating teams and with a positive balance between the contracted back money as compared to the money we paid for the program.

Of course, we feel some responsibilities for many things. You may remember that in 1999 the first UNESCO World Science Conference was organized in Budapest. And since not too much happened afterwards we thought there should be follow-up meetings. We had the first World Science Forum last year, which was a success, and we had some outstanding American lecturers from the Academy of Engineering and NIH. And I hope that the American presence at the next one in 2005 will be even stronger. But we want to convince the taxpayers also that money spent on R&D is useful and on that line we organized, what I call the University of Omnisciences, which is a success story. That is one lecture per week and the attendance is large, three TV channels projected, one radio channel, you can see it on the internet and probably that is the reason there was a polling of 19 Hungarian National Institutions and this program is organized by the Academy of Sciences and therefore it turned out that the most popular organization is the Academy of Sciences. I wouldn't have to mention it but I still do, that the last place is taken by the trade unions.

What are the specificities of our research in professional institutions? I am representing that. We have highly educated personnel, with direct access to medium and large facilities for example in Europe. But many times in the United States too, many of my co-workers used to do secretive radiation work at Brookhaven National Laboratory. There is an increasing emphasis on applications, which is governed by demand. A close cooperation with universities in post-graduated education, 40% of the profession research staff is teaching at universities. And the critical size in these professional institutions can much easily be reached.

We have a lot of fields that we need improvement. For example, infrastructure for technology transfer, which is a weak point for us, a public-private partnership is still at an early point. The legal environment is much better than our surrounding countries but there are still many things to be done. We have to boost private interest investment in research and development. Enhance foreign funding of research through new initiatives and smooth out appropriations in government funding; we have a yearly budget in research, which sometimes is very difficult to follow. And of course improve the predictability of strategy for research.

I listed a few points where I see the possibilities for Hungarian-American cooperation. There are already several structures for organizations and joint ventures, which support international protective transfer from Hungary to the US. New opportunities can be opened improving utilization of technology transfer through small businesses. Additional joint efforts are required for the use of intellectual property to create value for businesses and, in my opinion; a closer cooperation in the form of US-Hungarian ownership and management could bridge gaps in the business culture in my country. The support for US investments in Hungarian high technology industry; participation in training of the professional personal, better exploitation of the existing NSF-Hungarian Academy of Sciences cooperation channels, and a stronger involvement of Hungarian experts working in the United States in our issues.

Many times these Hungarian communities in the United States are called the Hungarian Mafia and we would like to exploit this mafia much better than we do at the present time.

My conclusions. My conclusion is that foreign capital filled the largest part of the vacuum in the Hungarian economy after the collapse of our political economy from 1989 to 1995. The multinationals play a significant role in it, 66% of Hungarian industrial export comes from multinationals. The country is capable to develop high technology activity partnerships. The basis is that individual excellence and achievements are highly valued in my country similarly as it is in yours. The professional elite plays a significant role in Hungary that's why I mentioned the popularity of the Hungarian Academy of Science.

My last conclusion is that the cultures of the two countries are similar and my experimental proof is that those Hungarians who came to this country are successful and contributed to the wealth and security of the United States. And I hope that this road becomes a two-way road, it will happen similarly in my country. Thank you very much for your attention.

George Handy

Thank you very much Prof. Kroó for your presentation. Right now let's complete our discussion of parameters. Please your questions and observations on the remarks of Dr. Marburger, Dr. Boda, and Dr. Kroó.

Question

I have a question to Dr. Marburger. First of all thank you very much for this wonderful overview on the structure, how to find science in the US. You have also mentioned that each year there is a priority list among the scientific fields. My question is how do we identify the priorities in the scientific field? You know that scientists and professors are just like prima donnas and everybody thinks that his or her research is the most important one. And the second question is, how do you convince the scientific community if his or her field is not on the priority list?

John Marburger

The key to identifying priorities is to be very abstract. Because there are certain obvious opportunities that everyone seems to be able to agree on that come from science itself. So these are intrinsic force and then there are extrinsic forces that come from society and if you simply pay attention to these forces then its possible to identify priorities.

For example in intrinsic forces, since the end of World War Two the ability to manage large amounts of information rapidly and efficiently and inexpensively has contributed to opening new areas of science. And together with information technology the improvements in instrumentation many of which came along with the computation of Moore's Law, the miniaturization and the integration of electronic components, have created the ability to manipulate matter at the atomic scale and this first is exploited in material science and chemistry but also biotechnology as its basis in molecular level understanding of life phenomena.

So this opens possibilities in science that we never had before, so by the end of the twentieth century we had these many different kinds of microscopes and imaging technologies that could actually see materials; both biological materials and inorganic materials at the atomic scale. And we had information technology that made it possible for us to simulate these phenomena at the atomic scale and also to reduce the very complex, X-ray diffraction for example, and other atomic level information so we could manipulate this information. I describe this capability as the frontier of complexity so we have nanotechnology, biotechnology, and information technology all developing very rapidly as a result of these intrinsic forces. Everyone agrees to this so we put them on the priority list.

Alright then, we, because of population pressures and the increasing development of economies and the need for energy and agricultural resources, its very clear that energy and environmental related issues are going to be important to us. So everyone agrees to this so we put them on the priority list. Then of course for the US particularly now, national security has been an issue, homeland security, and finally everyone agrees that education is important, we must encourage young people to enter into science and technology and we must do a better job of teaching them, even at the lowest grades, so you put that on the priority list. That's our list!

And then it boils down to individual cases and then we get into arguing which one is better to do and which area of science and so forth. But I think as long as we remember that the science is somewhat independent of politics, you have to pay attention to nature and to what is actually happening in society to make your priorities; every country does this. So it's not surprising we converge.

Gail Cassell

I think that one of the beauties of the scientific community and the government as it sets priorities in this country is that the opportunity for scientists to contribute to those priorities. So while Dr. Marburger has explained the long-term investment in major priority areas on a year-to-year basis, what happens is that NIH for example and CDC for example, Centers for Disease Control, will get their advisory bodies. We spoke yesterday about the Scientific Advisory Committee for the director of NIH, Scientific Advisory Committee to CDC to help them prioritize and in fact all year long the agencies are constantly calling on the external community to help prioritize.

There is another example of a way in which some priorities occur and that is a unique program that the United States has with Japan called The Cooperative Medical Sciences Program, we're celebrating its fortieth anniversary this year and in fact past history has it that that group in cooperation have identified high priority areas for research and in particular I think the Japanese government, the emperor's science advisor usually, sits on the steering committee, has taken advantage of this group in terms of helping to set priorities.

Question

Changing the topic slightly and this is really a question for Professor Kroó. As a biologist my experience is that most post-doctoral scholars that I've met that are Hungarians, I usually find them in European labs not in American labs, and you know one of the quickest ways to develop of course valuable scientific interactions is at the level of young scientists spending time in the laboratories of each country. And I wonder are there barriers, historical or are there barriers to Hungarian scholars spending time in American laboratories?

Norbert Kroó

There are more than 3,000 scientists working in the US from Hungary. And yesterday we were at NIH and we were surrounded by a couple dozen working in the field from my country. The European Union has some special programs and these programs are exploited, of course, by us. They are the medical fellowships; they are the programs, which makes open large national facilities for our use on the basis of money from Brussels. And similar programs help for the Hungarian scientists in this field and then of course that is a European organization, the European Molecular Biological Organization and Laboratory, where we are already associate members and very soon we shall be full members. And so we have a European institution where we are members and many of our biologists work there.

Question

My question is a general one; I'm not sure to whom I should address it. But much of the growth of technology in the United States has been due to the willingness of the financial markets and private investors to support not only the efforts being made but also to support success but in the United States, unlike at least my observations of other parts of the world, those markets are also willing to support failure. In the sense that if you've made the attempt, picked yourself up brushed yourself off start over again and you've learned a lesson and so it makes you more attractive not less. Is that the case in Hungary as well?

Norbert Kroó

To a general question I have a general answer. There are three things what I admire in the United States. One is the mobility, the preparedness to take risks, and to make fast decisions. We in Europe are not so strong, and this applies to Hungary, in these fields. And probably that's the reason why venture capital is more conservative in my country than in yours. And this could be the explanation.

Miklós Boda

I agree with what Professor Kroó said but we have to remember Hungary is not really used to running business more than 45 years and to learn that is difficult. Year by year almost every body is connected somehow to the family business; you learn at the kitchen table what this really means. It was not the case in earlier Hungary it takes times before we can adopt policies and learn, which we'd like to do, learn from you.

Question

I'd like to pick up and address an issue from the presentation of Dr. Boda. He said that the American enterprises can find highly motivated and talented departments at the universities in Hungary and can strongly influence their scientific and R&D profile. I have a bit of questions to you. Which is a more advantageous perspective to you, encouraging students and young researchers to come to American institutes, the so-called brain drain, or to go to Hungary and encouraging enterprises to do the opposite way to have a long term contract and base their researcher basis in Hungary?

John Marburger

Well I'm not sure its directed to me, but the fact is that from the US perspective we think that a flow both ways is important, because we offer the ability for young people to grow very quickly in their scientific knowledge and also their visibility. So when they return to Hungary they take with them a network of colleagues and skills. Technology transfer is accomplished most effectively by people and bringing their skills from one place to another. And so I think mobility, which was the top of Dr. Boda's list is very important.

Answer

Well I could easily second what Dr. Marburger said but let me make one additional point. That as was said in all three of the presentations; these technological developments are based on an international community of scientists. It's been that way for many decades, likely to stay that way for many decades to come. So the transfer of mobility is a natural characteristic of science, the transfer of the technology probably needs to be a little more international as we go forward. And encouraging young people to do this is certainly more optimistic than encouraging older people to do it. And so I think the educational systems, as you perhaps identified are critical to this concept with the generation of students being educated in Hungary and the United States probably will be easily convinced that their future lies in a joint effort. I would encourage that point of view.

George Handy

I would like thank all three of the speakers for establishing exactly what we had hoped for, the parameters for a useful exchange. Without offense to the three speakers let me assure you that it will get even better from here forward. In terms of delving from this superb foundation and the direction they cast into some very significant and practical experience both on the US and the Hungarian side. Please join me in thanking our three speakers for the fine start they have given us.

COFFEE BREAK

George Handy

We've laid out the parameters for a useful exchange and we are now about to go into the issue of challenges in the innovation process from the US vantage point and we are very fortunate in that we have the two experts we do drawing on both the university and business experience to offer two sides of this issue of challenges. The basic challenge that has come to the fore in the organization of this program is effective cooperation and particularly the effective exchange of responsibility, leadership, and resources between the government/public and the private sector. We are first going to look at it from the

vantage point of Dr. Gail Cassell who speaks from the private sector, although she brings public sector experience as well. Then we will look at it from the vantage point from Dr. Mark Rohrbaugh who will talk from the public sector viewpoint. By virtue of these two presentations we will put a very specific framework together as to how the US deals with this essential challenge along with other points that the speakers will make.

WHAT IS REQUIRED FOR INNOVATION FROM THE INDUSTRY PERSPECTIVE, SYNERGY OF THE PUBLIC AND PRIVATE INDUSTRY

Dr. Gail Cassell, Vice President of Scientific Affairs, Eli Lilly

I really appreciate the opportunity to be here with you and thoroughly enjoyed my quick discussions with some of you yesterday and have tried to tailor this presentation around some of the discussions we had yesterday afternoon and will try to bring my 30 years or so of academic experience along with my 7 years experience in industry. I want to talk about the challenges as it relates to pharmaceutical innovation today, what is required for innovation, what drives innovation in the pharmaceutical industry and also the importance of the synergies between the public and the private sectors as we talk about pharmaceutical innovation.

What are the most important drivers of innovation in the pharmaceutical industry? First and foremost, this cannot be underemphasized, is market-based pricing. I'm going to give you some very specific examples that I have personal experience with to tell you what can happen with this does not occur. Intellectual property protection I would certainly rank second. Third is sustained public support for basic research and policy environment that protects the current complimentary and synergistic worlds of public and privately funded research. I'll talk a little bit about that. Then lastly, also equally important, is the predictable expeditious, with the key word being expeditious, regulatory climate based upon sound science, absolutely essential, and innovative leadership in the regulatory authorities.

In response to the question asked by Dr. Földesi - what are the factors that influence the decision making of a pharmaceutical company to invest in a country? I would say the answer is based upon the following factors. First, access to a skilled workforce and scientists, which obviously Hungary has. The quality of the science in the country is also extremely important. I would add that the peer review system in place in a country, judging the quality of the science, is also extremely important. That's where the role of your national academies and your funding agencies certainly play a big role. The advantage of having academia universities in biotech clusters that create synergies in the appropriate environments would also be important mechanisms in place to provide and promote industry government partnerships. I'm sure that Dr. Rohrbaugh will talk about the small business grants program of our funding agency and if he doesn't have time to do that I have requested that Chuck Wessner play a role in helping to write the White Paper that will be part of the project. He and I and others at the National Academy of Sciences are currently providing a review of all of the small business grant programs within the US and all of the different funding agencies. So you will benefit, I think, from this review that is already going on for about a year and a half, almost bringing it to a conclusion. The last thing, and again something that may not be so obvious, and in fact I

think a lot of people think that they are completely separate, that is the fiscal and economic climate in a country can certainly influence return on investment and the importance of that. Some examples are delays in access for new products, which in some cases can be up to 300 to 400 days. This results in a year really off your patent life of any given drug and in some cases that can amount to millions upon millions of dollars. Lastly, cost containment, which in fact Europe has largely chose to enforce and it has clearly led to transfer of R&D to the United States. We can certainly talk a lot more about that. There is a lot of data now that bear that out and the very fact now that the EU has decided to start re-investing and upping its investment in basic research I think is a good example of this.

Just to clarify a couple of the comments I will make later on I thought I should say a few words about the realities of drug discovery and that it is, as you know, one of the most high risk industries there are with a 90% failure rate even from the time you're working with a validated target and one that has been well characterized – failure rate is still 90%. This is extraordinary. Today, even though you may have a compound in phase three, which is nearing the approval process there is now a greater than 50% failure rate of that investment. So, that becomes extraordinarily important when you consider the cost and have to account for that 90% failure rate. There's a lot of quibbling in the public press over the exact cost to bring a new product to market in the pharmaceutical industry and now estimates are even over a billion dollars. Most agree that it is somewhere probably around \$900 million. But what there is no arguing about, because there is tons of data to support this over literally decades, is that the average total time for development of a drug is 14.7 years. Three of the five drugs that Lilly has launched over the last 5 years have been in development for over 17 years – and that was starting with a validated target. More importantly only 3 out of every 10 market drugs produce revenues that match or exceed the R&D costs. Very high risk, very long time before you are rewarded for that innovation and therefore all the more reason why market-based pricing and the ability to recoup that investment are extremely important.

I would like to give you some examples of market-based pricing, or lack thereof, and what that can result in. Nowhere are the lessons learned regarding innovation more valuable and in no therapeutical area is the need so compelling for new medicine than in infectious diseases, the area of my own expertise. I can tell you something you may not know, that is from 1980-1992, in the United States, deaths due to infectious diseases increased over 58%. That was not just due to AIDS, but other things that we can talk about later. So you would think certainly the medical need has been identified. However, in a report released by our Institute of Medicine of the National Academies of Science, a group I was a part of, released in March 2003, we declared a crisis in development of vaccines and antimicrobials. Now why is that? There is an innovation gap that relates to the science and the reasons, there are technical challenges, but the regulatory hurdles have been huge in terms of numbers of patients required, therefore costs of performing clinical trials with regards to antibiotics is high. Also, the lack of value of antibiotics in general because they are acute care therapeutics instead of chronic long-term therapeutics. We have two things that are rather unique that are happening in the country right now, and indeed the world. One is the impact of bio-defense funding where there has been an artificial market created in this country around 6 billion dollars in the form of

legislation for purchase by the government of counter-measures for bio-defense. The other is a burgeoning of public-private partnerships for drug developments, specifically with regards to TB, malaria and others.

Now just to kind of explain the lifecycle of research-based pharmaceutical business, to make it absolutely clear, obviously it's based on research and research is an integral component, as I'll come back to, of drug discovery/drug development you have to have commercialization obviously - and if you didn't have the research-based pharmaceutical industry please be aware there would be no generic industry because in fact you have to have the innovation to get the generic. And that's another thing that is often not that appreciated. The protection of intellectual property and why that is so important is obvious, it has to do with exactly that and the ability to recoup your investment by having your intellectual property protected over time.

Let's move onto sustained public support for basic research and policy environment that protects the complimentary and synergistic worlds that I mentioned. You heard this morning a little from Dr. Marburger about the US commitment to bio-medical research. I want to expand that investment from not only the public sector but now also the private sector and let you know that the US government, as well as the pharmaceutical industry in this country have had a sustained and long-term commitment to bio-medical research. It's the sustainability and the constancy that is the important thing, not the fluctuation. We can obviously share a lot of experiences there, and I can give you some histories of federal agencies where that has not been the case and what the result has been in terms of impact on public health. The second, resulting advances in both basic and applied research have lead to the discovery of many new medicines and vaccines. These advances have resulted in greatly extended life. As you know, the data is clear that these advances also save billions of dollars in health care costs. Again, something that people don't often appreciate. At the time they are making the investment in these long-term projects, they don't see immediate benefit in terms of health care savings.

What about the roles of industry, government and academia as it relates to innovation in pharmaceuticals? First, I think it's apparent that advances in the medical research are widely accepted. What is poorly understood by the public and our policy makers in this country is the unique, essential, and complimentary roles that both the public and private sector contribute to development of pharmaceuticals. We partnered with Research America, an organization I hope we'll have time to talk more about later here in the day, and how such a not for profit organization might be very important as it relates to the research in Hungary. But we did a survey with them to establish how much the average American citizen knows about drug discovery. You can see from here, they really don't know where drugs are discovered, with the perception that most are discovered by the government. The one thing they are very clear about, however, is that they felt that the public and the private sector should be cooperating to develop new drugs. There is tremendous support for this cooperation - 91% said that they should absolutely work together. Now I have mentioned this because we are currently in an environment today where there has been a lot of congressional pressure as it relates to conflict of interest between academic government scientists and industry, and we can talk more about that as a policy that can perhaps jeopardize research in the future and the synergistic roles.

Traditionally the publicly funded research has focused primarily on basic research and training, i.e. more of the target identification, target validation, whereas the private has focused not only on the basic research, but also the applied and translational, i.e. the development piece.

Going forward, and already today, the gap between fundamental and applied have narrowed. In fact, a large proportion of what the NIH road map and a lot of universities are going through today and even private funding, like the Boros Welcome Fund, is focusing on translational research and how you can better promote translational research. We have a big shortage of clinical investigators in this country and that's one of the reasons that so much attention is being placed on translational research.

Just a few more fundamental facts. First and foremost, never underestimate again the role of research, because it's absolutely key to innovation. What you may not appreciate is that it is the D part that turns discovery into a product. So when we think about the role of the universities, even in translational research and how important that absolutely is, it's the D, not it's the right limiting step in terms of experience and an area where there still has to be a lot of research done. But again most people don't appreciate the research and formulation that goes into manufacturing, and perhaps in fact enough research has not gone into manufacturing practices. Technology transfer is critical and Mark will say something more about that. I just want to point out that in 1980, of 28,000 patents that the American government owned, less than 5% have been licensed to industry. Thus, the taxpayers were paying for 60% of all academic research. They were getting very little in return in other words. In 1979, universities were granted only 264 patents but in 2001 over 8,000 patents. There are some universities, not many, that are now receiving upwards of 200-400 million dollars in licensing and royalty fees. When you think about it, if there is a 90% failure rate in product development, it's no wonder that you only have about 10% of those universities that are research intensive in terms of pharmaceutical research that you're only getting about a 10% return on that investment because those are the successes.

Just a few words about the D. The average pharmaceutical company spends about 17% or more of their sales on R& D. We are the most research-intensive industry in the US. Surprisingly to most people we invest 3 times that of the telecommunications sector and 4 times that of the space and defense sectors. You heard what Dr. Marburger told you a few minutes ago about this country's investment with regards to defense R&D. In 1999 an analysis by NIH showed that of the 47 top selling drugs 43, or 90%, were discovered and developed primarily by industry. But in fact I cannot over emphasize the synergy that exists in most drug development based on that investment in the very basic research. With regards to drug discovery today, I need not tell this group that it is a lot more complex as we begin to apply the principles of systems biology and screening of pathways as opposed to individual enzyme targets. Therefore, the need for the synergism between the public and the private sectors to be able to unravel the complexities using the data from the human genome and all of our new technologies absolutely requires more synergism than currently.

You know also from the public press there is a lot of pressure on the industry to fix the pipeline. You know you are simply not turning out drugs quickly enough and there are many reasons for that. The biological complexity is one of those. I would also argue that because many of the drugs in the pipeline are biologic, which are not as straightforward from the manufacturing standpoint of small molecules, is also slowing the process down.

There are a number of forces acting on the industry that are influencing our ability to simply focus on the research and development side. I won't take time to go into these, but just to simply say that all of these pressures are coming to bear at a time when biological breakthrough and the potential for these has absolutely never been greater. But in order to capitalize from the biomedical revolution that we've just experienced you absolutely have to have a policy environment that nurtures and rewards the process of innovation, otherwise society will not benefit. We all talk about importance of access to medicine, but the ultimate denial of access is that we have no new medicines at all. So I think we have to bear that in mind when we start looking to the future and what the US and Hungary might do together. We believe that you can extract greater synergy from combining forces with regards to the public and the private sector, not just pharma, but also biotech. You heard yesterday about the NIH road map and I would encourage us, as we begin to work more in detail on the Hungary project, to look at those areas of the NIH road map that right now is funded with about 2 billion dollars. I know that Mark could tell us a lot more about it than I, but a portion of that road map is focused on translation, and high proof screening within the intramural and NIH program, building libraries that will be publicly assessable and also public-private partnerships. So NIH and it's director, through the leadership of Dr. Zerhouni, I think is beginning to think, how can we promote more synergy.

Lastly, with regards to the FDA, the regulatory body that I said was so important with regards to innovation and as a driver of innovation, I am proud to say that on March the 16th Dr. Mark McClellan, then FDA commissioner, announced a new initiative called "Innovation or Stagnation." The way he sees it right now is that we have blockage in the pipe and the opportunity is that we have to in fact improve this critical path to new medical products, and what we will do is basically speed the translation by improving the synergy between the public and the private sector.

Lastly, just to say again looking towards the future we must charter a course for the future that balances the need to control health care costs for the appropriate investments and incentives that will speed the roots of the biomedical revolution. But we have to consider not only the costs, but importantly the value of the innovations. Valued not only in reducing costs of health care, as I alluded to earlier, but most importantly, in reducing patient suffering pain and disability as we all think about the fruits of the labor. The bottom line is, in order to have innovation in pharmaceuticals you have to have a robust private enterprise, but you also have to have a very robust public enterprise working together synergistically. You have to have both to ultimately get translation into economic development outside of the provision of new jobs that we can talk about.

I hope to be able to share some experiences with you from lessons learned from Japan that I am a little bit familiar with. They have moved to try to improve transfer of technology and interactions between the public and private sector. Thank you.

George Handy

It's hard to imagine that a speech on something called Innovation from the Industry Perspective could be as powerful and as engaging as you made it for us Gail, thank you very much. Now we are going to take a step sideways in this same sphere and turn to Mark Rohrbaugh. I hope that in listening to both Dr. Cassell and Dr. Rohrbaugh that you will agree with me that the fundamentals that we are putting on the table in terms of drivers of relationships and so forth apply in all high technology areas in general and in a meaningful way.

MECHANISMS IN PLACE AT NIH TO STIMULATE INNOVATION; TRANSLATION FROM LAB TO PRIVATE SECTOR AND ATTRACTING INDUSTRY INVESTMENT IN PUBLICLY-FUNDED RESEARCH

Dr. Mark L. Rohrbaugh, Director, Office of Technology Transfer, National Institutes of Health

Thank you very much. I want to thank Dr. Cassell for leading into this so well in terms of several of the issues she mentioned. What I'd like to do is cover some ideas and topics that relate to how the federal government, with respect to bio-medical sciences has incentives and systems in place to harness innovation that is coming out of our laboratories – both our own internal laboratories at the NIH and those that we fund at research universities and hospitals, mostly in the US, but around the world as well. Out of our 28 billion dollar budget, about 9% of that goes to support our own internal program; I think you had a little taste of it yesterday with your visit to NIH. We have about 6,000 PhD-MD scientists that work for the NIH and it's my office that's responsible for handling those innovations and inventions and working to transfer those to industry for commercialization.

We also support investigators through grants and contracts. That's just over 80% of our budget. All told, there are over 200,000 scientists that are supported under those programs. Of that extramural research budget about 90% stays in the US and about 10% goes outside the US. So it is an international endeavor but focused on the US. Most of our research is basic research. Although, there are a few products on the market that compare to the total that were developed directly with technologies that were licensed from either the NIH or are grantees recipients of funding.

We also play an important role in building the groundwork, or bedrock, of science and technology that leads companies to invent new drugs and new vaccines. For example, the whole class of statins, that continue to grow in numbers, were developed as a result of basic research that the NIH supported. So while NIH didn't fund the development of the drugs themselves, the statins, it funded the basic research that allowed industry to understand the mechanism and then move forward quickly to exploit that understanding of the biology with new drugs for those purposes.

Our goals in technology transfer are to first and foremost benefit the public health, that's why we do what we do. Whenever we need to consider conflicting goals or conflicting needs we always err on the side of thinking about benefiting the public health. We want to insure the public availability of new technologies ultimately, as Dr. Marburger said, that's what Bayh-Dole Act was about. We don't have public benefit from new technologies if they are not transferred in a manner that allows those technologies to reach the public.

We want to utilize intellectual property rights appropriately as an incentive for commercial development of technologies. Some of our policy guidance relates to how one balances those incentives such that one doesn't inhibit basic research but stimulates the commercial development when that's appropriate. We want to use these mechanisms to attract new research and development resources, mainly by industry, to move these technologies forward. In licensing the technologies, we do get money back – royalties. In doing so, we want to obtain a reasonable return on the public investment in these technologies.

Ultimately, as Bayh-Dole was an act related to improving the economic competitiveness of the US, one of the ultimate goals is also to stimulate economic development, and it's certainly done that through some of the statistics we heard Dr. Cassell give about extramural technology transfer numbers that have been increased significantly since the Bayh-Dole act was passed.

When I think of ingredients for technology success it starts with the science and fortunately we've heard about the good solid science that is occurring in Hungary and in the United States and that really is the core. That's where innovation comes from, supporting researchers who can explore new areas of science and be innovative. We need people who are well trained who cannot only do the science, but handle the technology transfer infrastructure. It takes well-trained people to engage in this activity, it's very different from science, but it involves science. When I think of the people involved in technology transfer, particularly for example, everyone engaging in this has to have at least a solid background in science, but it also takes experience and understanding of business and what business needs. Some of the people in my office, for example, have worked in businesses. I've worked in business before in biotech before I came to the NIH. It also takes an understanding of law and the legal issues with respect to negotiating terms in licenses. I see it as a combination of science, business and law that must come together to make successful technology transfer.

Finally, you need resources. You need resources to move technologies, to develop technologies and to move them forward. The greatest challenge we face is how to take these early stage technologies developed in government or academic labs and move them forward. We often have a patent at an early stage, sometimes before proof of concept has been shown. We need to find new ways to attract new resources to move those to a point that industry is ready and able to take them on and make that investment. So some of our efforts, particularly in the road map are geared towards those efforts.

Finally, I mentioned policies that tell us how to handle this, give guidance to the recipients of funding, but also internal guidance as to when and how we patent inventions and how we license inventions. It's really important to have that framework of knowing where you are going and what the rules and constraints are and what the goals are so that everyone is on board, from the scientists up to the people engaged in tech transfer, about what we are doing and why.

I have provided some samples of our policies. One on sharing research resources, talks about the need for sharing unique materials with all scientists for research purposes. Balancing that with the need to give, sometimes exclusive, licenses to industry to promote technology and move it forward. One can achieve that balance we have and the guidance talks about that.

Dr. Cassell mentioned the statistic about the number of drugs on the market among blockbusters that have been developed with technologies invented with NIH funding and that's in this document called "A Plan to Insure Taxpayers Interests are Protected." We provided this at the request of Congress in 2001 and it's a good discussion of, not only the drugs that are on the market as a result of our tech transfer efforts, but also the process – what is the role of government funding, government laboratories, university researchers and the role of industry. Sometimes people think the government or universities develop a drug and hand it to a company to produce. Obviously we know that's not true. There's a lot of effort money, time and resources that industry invests to move the technology to the market place.

So when we think of policies and procedures; people need to know where to go. We can't have this kind of confusion if somebody has an innovative idea; a scientist, he or she needs to know what to do. Who do they talk to? There has to be a process in place and understanding and education as to what to do when they have an innovative technology and how to move it forward. Then the people handling it must know what to do. An example of this, with respect to our patent policy at the NIH: patents are expensive, it can cost upwards of \$20,000 in the US and hundreds of thousands of dollars if you are patenting internationally. That's a lot of money to spend, and we want to spend it wisely. So we only want to patent when we need to and we need that kind of incentive. So the goal of patenting is to facilitate the availability of technology to the public. We want to patent when there is high public health priorities, when there is practical utility and it's necessary to have that incentive of a patent for investment in R&D.

On the contrary, we generally will not patent if no further R&D is needed. For example a research tool, if we have a mouse model of Parkinson's disease we can disseminate that to researchers, we can even give that to a company to sell it to researchers, but we don't need a large investment of money and attract new researchers to move that forward to commercialization. We don't want to patent when there is low public health or commercial priority or when patenting actually hinders the technology transfer and access of new technologies by the public.

This is just an example of our internal portfolio at the NIH. It has grown to be quite large, but it has taken a long time to grow this technology portfolio. We have about 1,500

active licenses, receive more than 15 million dollars in royalties, and have about 250 active cooperative R&D agreements with industry. Now that's just the tip of the iceberg with respect to how we collaborate with industry. CRADAs are one form of collaboration. We have many other ways that we collaborate with thousands of clinical trials going on and other collaborations. Ultimately, in terms of looking at the benefit, there are about 200 products that have reached the market that contain technologies licensed from the NIH, 17 of these are vaccines and therapeutics, those specific ones are listed on our website and I also have some handouts that I'll leave outside for people to look at.

This is by way of example to look at our royalty income and you can see it's taken a long time to reach a high level of income. Look at 1987, where we were under 5 million dollars and now we are over 50 million dollars. It's a long steady effort. It's a marathon, as some people have said, and not a sprint. So, it takes investment of time and effort and in early stages, you're often not bringing in more money than you're spending. That's true of many universities in the United States. They are not making a lot of money, but they are engaged in this effort for the long-term and primarily to benefit the public health, in the case of bio-medical research, and the economy, by moving technologies forward.

So how do we measure success? We primarily measure it by the public health impact; with lives saved, cases averted, etc. We want to also explain the role of NIH research and corporate research and getting to the market and the value and role of the technology transfer of the patents and licensing. We've done studies with respect to some major drugs as a result. There is also some information on our website with respect to this.

We also want to encourage public-private partnerships between industry and the NIH, between academia and NIH and between all three groups. There are times when two of the three interact and times when all of us interact to move technologies forward. There are a number of resources that we also provide through grants and contracts, repositories of reagents, assistance with screening, pharmacology and toxicology testing, formulation and manufacturing, clinical research labs and clinical trials – everything from our SPIR Program to small business, to take new ideas and move them forward. For example, as of August of last year, more than half of the anti-cancer agents that had received approval from marketing in the U.S. had an IND, a clinical trial sponsorship by the National Cancer Institute. Although it may not have been the primary indication, it sometimes is an important work that NCI does, in this case or other institutes at NIH, to be complimentary to industry, not to do what industry does. Precisely by complimenting areas where they find the risk too high or the market too small, but there is still an important public health benefit. We fill that gap and that is an important niche for us.

The important thing I want to mention is that we want to make sure that our licensing doesn't interrupt the basic research. So we wouldn't want to take that mouse model of Parkinson's and give it exclusively to one company. We want everyone to share in that technology. When we have a new drug or vaccine, where investment is needed, that we can give exclusively to industry, to insure that they bring it forward. There's follow-up as well. You need to make sure that the diligence is there in terms of the company and monitoring the license after the drug or vaccine meets the market.

Ultimately, there are royalties, as I said, which reimburse expenses and reward inventors since they are an incentive for them. They are a return on the public investment and we can use the additional funds to reinvest in further research.

I want to mention briefly our activities in international tech transfer. We often share best practices with other governments and institutions from the EU to Latin America, Asia Africa, where we focus especially on developing economies. We have some special projects with Asia, Latin America, Africa and Central and Eastern Europe. We have had success so far in transferring, for example, DDI to Mexico for treating HIV, meningococcal vaccine, collaborating with WHO and a foundation, to produce it in India for use in Africa. You can't get more international than that. We have licensed some technology to a Hong Kong company and developed an anti-HIV drug in clinical trials in Malaysia and have had some licensing efforts in India, South Africa, China and we think tomorrow, hopefully, with Hungary. I understand there are some negotiations going on. I will leave you with some contacts that will provide you with some more information about this and answer any questions you might have. Thank you.

George Handy

Thank you very much. As Dr. Marburger said, NIH is the largest single government source of non-defense research and development. To have captured it all in 15 minutes is rather remarkable. Thank you.

We are ready now for the questions and observations – first and primarily from the Hungarian side on this look at challenges to innovation.

Tivadar Tulassay

Thank you very much for both presentations, I have learned a lot. First, I learned what I knew, that life science is a vital technology. It is of utmost importance towards innovation. This is, in a way, what we aim to develop. We established a technology transfer organization last month in Budapest at our university. I am also convinced that public basic research and training, and private applied and translation research could go together. But I agree with you that the D, in R&D, issue is the most important, and probably the right limiting step.

Our climate in Hungary in our university is rather optimal for the TTO, namely we have a rather good quality of sciences in our university. We would like to create a university academia biotech cluster, which may create synergy. You will find during the break some paper prepared by myself and my coworkers about how we will develop and what organization we would like to develop. There is a problem regarding the industry and government partnership. This is where president Boda should work and create a better climate for us, for the basic research and innovation.

There is also one aspect you have mentioned, the fiscal and economic climate, which is basically an internal, and or, external regulation, which we should be improving in Hungary. Listening to the figures for the last twenty-five years, a factor of almost thirty has been established regarding the patents of the universities. I do not want to wait for

another twenty-five years when Hungary will reach that kind of level. We certainly will need your skill and your knowledge about how to speed up our TTO activity. It is also important, and this in my question, how many percentage of basic science will develop into innovation and commercialization. This is a basic question. I aim to reach some 20% within 5 years in Budapest. Is it a good aim or is it a bad figure? There is a combination of basic research and applied research, which will turn development into innovation and ideally be commercialized. But there are two sides to the coin. How much percentage of the basic science, basic ideas, basic researches will develop into commercialized product?

Gail Cassell

I think that there is not good data on that. I can give you the ratio of chemists to biologists, as we were talking a little bit about yesterday. In terms of actual numbers I think that, as a former NIH grantee myself and chairman, I always argue that it's not the number of scientists but the quality of the scientists and their resources available for performing the research that ultimately leads to the innovation. Productivity, again, I think depends on the environment in which their research is being done and the nurturing body administration, say for example, of a university. The administration should make it easy for the scientists to do their work and to have time to read and think; results in innovation and creativity. I personally, would not focus so much on the numbers, if that is what you are asking.

I don't know how Mark feels, but I mentioned to you yesterday that NIH hosted a symposium two years ago looking at big team science because so much of this complicated science that I mentioned in terms of the systems biology approach does require big teams of different disciplines, mathematicians, physicists, etc. But one of the biggest concerns that we all expressed at the meeting after thinking together for three days, was that we might be losing a lot of creativity from individuals by working in teams. A lot of people will still argue that it is the individual investigator grants that result in the most advancement. Mark, I don't know if you want to comment on that, but that is really the principle by which the scientific community is arguing for increasing NIH funding. The point we have always tried to make is the value of the individual investigator-initiated grant. You don't want to stifle that creativity.

Mark Rohrbaugh

I certainly agree. I can give you some numbers and statistics but we don't normally think of our research as segregated in that way. We want good science and good research to move forward. While some things you can expect in certain areas more inventions because the technology, the research, is more applied. Sometimes you are very surprised of how important new inventions come from basic research. I would like to give as a prime example, the basic research funding in studying bacteria and how they exchange DNA lead to the discovery of restriction enzymes and recombinant DNA. It can't get much more basic than studying how bacterial exchange DNA, and yet out of that came the surprise invention that led to the bio-technology growth in the US and the new industry.

Just as a way of an anecdotal story, I was giving a talk to scientists at the National Institutes of Allergy and Infectious Diseases and one scientist, whom I knew, came up

afterwards and said, “I’m a basic immunologist, this is very interesting but I will never expect to work with your office and I am glad you are doing this, but thanks.” Within two years she called me and said, “you know a company called me and they heard my talk at a symposium and they are very interested in using some of these concepts that I have, and patenting them and using them to develop some new immuno-diagnostics.” So sometimes you don’t expect it, and the scientist doesn’t even expect it. As Dr. Cassell said, you need to promote an environment that facilitates and encourages scientists to flourish and those scientists to come forward when they have a new technology so you can exploit it.

Gail Cassell

I don’t want to overwhelm you with all of the emphasis on the D part, but really just to make you aware; it is the right-limiting step and often the most expensive. In fact, in many cases the failure of many drugs is in the D part, not the R part. But I wanted to give you some words of encouragement, something you may think about. That is that a number of American universities have started building their own GMP facilities on the campus for the purpose of, not only training students in GMP, but also to begin to work with companies to develop products. For example, Purdue University in Indiana has a good manufacturing facility for small molecules. Washington University in St. Louis, a really premier medical school, opened a GMP facility for biologics in December of last year. As I mentioned, this line between the basic and the applied is becoming very blurred, and really because of the complexity and the cost of drug discovery in the future, I think the only way forward is more synergism, not less, between the public and private sector and government – if we want the new drugs for patients, which should be our ultimate goal.

Norbert Kroó

My conclusion in connection with the question of Professor Tulassay is what I call a one to ten rule. About 10 percent of basic ideas turn into applied, 10 percent into development and 10 percent of it into products. Of course the other way around, applied cost 10 times more, development 10 times more and to bring it to the market, 10 times more.

Erno Duda

I was really glad to see the list that you showed on the criteria that are really needed for pharmaceutical investment. Sort of talking in a combination of the biotech and the pharmaceutical sector in Hungary, I really truly believe that every one of those criteria we fulfill. Hungary is strong on everyone, even on the last step. However, during the past ten years, we’ve seen very extensive developments in R&D centers, by large multinationals, in the field of telecommunications and IT. Erickson and Nokia have built big R&D centers in Hungary, exploiting the talented young workforce. GE has invested close to 2 billion dollars and moved all of its light-end research from around the world to Hungary.

Above all this, the pharmaceutical sector also has a unique advantage with, during long traditions, a lot of very well trained people, got on the market when the industry was privatized. Unfortunately, there were times, even a few decades ago, when two-thirds of the drugs of all of the COMECON countries, including the Soviet Union, were actually

produced in Hungary. So there is a very strong pharmaceutical sector, but when it was privatized, with the exception of Richter, it was mostly privatized by the French, who followed the unique rule of firing all of the scientists, basically, and keeping it as a generic manufacturer and sales and marketing organization. There is still some research going on, but a lot less than before hand. So there are a lot of people out there on the market who would be obvious candidates.

However, despite all of these good factors we haven't really seen any significant investment either by big pharma, or by biotechs in the R&D field. That is partially, I think because the IT and telecom sector has better lobby power and represents themselves better than we do. The problem with biotech is that we don't belong to any of the ministries, but we are a little bit to this ministry, a little bit to that one, and it is difficult to represent our rights. But also I think the pharmaceutical sector was not strong enough in lobby force. What I would be curious about is; how do you think we could sell the country to the big pharmas? What are the ways that we could boost investment in that area? Because I really think that there is an unexploited opportunity there.

Gail Cassell

I think that I would rely on some of my colleagues that are more regionally involved in Hungary to help me answer that question, if I might.

Robert Sienkiewicz

If I can make an attempt on that question, I think, from a regional perspective, we are very aware of the advantages of Hungary in terms of it's lengthy history of pharmaceutical innovation and the manufacturing capacity and base that was built up in the 1980s. We are aware of the potential that exists there, and as things are, we do a disproportional amount of our clinical trials in Hungary and Central and Eastern Europe. Certainly, disproportionate to the work we do there. On the other hand, there are some very clear obstacles towards turning Hungary into a center for pharmaceutical research and development.

I personally would disagree with your statement, that at this point Hungary does fulfill all of the criteria for being an attractive center for pharmaceutical research and development and commercialization. I think there is a debate taking place in Hungary now about what the future of the country is, and what the future of the pharmaceutical industry will be, and whether that is best served by the country adopting stringent intellectual property rules, and perhaps to an extent breaking ranks with some of the other Central and Eastern European Countries that are asking for a 15 year derogation on the imposition of data exclusivity. There are other issues with the pricing of reimbursement environment, where we feel that Hungary still has some distance to go before it will be an attractive market for the commercialization of molecules. At the same time we certainly accept the need for cost control and how to spend health resources most effectively.

With that said, I think there is a lot of unexplored room for cooperation. Certainly as a company, we have made some positive statements to the Hungarian government about the extent to which we would like to part of this process. The possibility of exploring

more with universities and with small Hungarian biotech firms, the possibility for deeper cooperation – we are certainly open to those possibilities.

Hungary, to a certain extent is caught within the trap of overall European pharmaceuticals policy, where Europe has departed very much from the Lisbon Agenda, and we don't see overall very promising signs that Europe will be back on track to close the target of reaching three percent GDP investment across Europe by 2010. So, it is in a difficult situation. I would certainly be very supportive of Hungarian policy measures to continue and to consider differentiating themselves from some of the other Central and Eastern European countries by making themselves more committed to R&D and more committed to intellectual property than their neighbors.

Linda Powers

Just to jump into the discussion on this, I would like to plant the seed for looking at that question maybe from a couple of angles that might not be what come to mind first. There is a major, major, opportunity to capture the moving abroad of the large population of small biotech companies in the US. We have already seen small, 6-12-20-person IT companies, starting to do lots of outsourcing and, in fact, to a large extent venture capitalists on the West coast today write into the term sheets for the investment that the company has to outsource this much, that much, either R&D or production within X period of time. That's much more advanced in the high-tech side. People are just beginning to think about it in small biotech companies, 6 and 12, and 20 person biotech companies. This is a thriving pool of companies and we have never had 12 person biotech companies traipsing off into foreign jurisdictions before. What is driving them to do that is partly what Gail already mentioned; it's the regulatory hurdles. It's easier to get into a phase 1-2 trial in Europe than in the US, sometimes the difference is ridiculously so. The cost differential is getting to be a killer also.

I would encourage you to think about a couple of angles. One, since you are a biotech association, think about the small biotechs in the US, which is a totally different pool of actors and requires a different strategy than big pharma, which is also of course hugely valuable. Secondly, I would encourage you to approach the VC community to get your case across, as well as to approach the companies themselves. Because the VCs control the purse strings and they dictate a lot of these decisions for venture capital. Lastly, I would encourage you to think about it from the angle of, even if ultimately your goal is to increase R&D activity in your country, I would encourage you to come at it starting at the later stages of process first. Clinical trials, and then late stage general studies, and eventually early stage research cooperation. Why? Because that's what the problems are that the US biotech companies are concerned with today and that's what they will be the most responsive to. We are overstocked on R&D. That is not going to be a selling point. You have seen the same evolution in the high-tech industries, where they went abroad first for low cost manufacturing and it evolved earlier and earlier from that to do R&D. So those are some suggestions.

Anne Solomon

I have a related question for both our Hungarian guests and for the Eli Lilly visitors - that has to do with the contentious issues now in the United States regarding stem cell cloning

research. Has Hungary established a policy regarding this kind of research and to what extent? From our Eli Lilly people, is that issue of country policy one of the criteria that you look at for research and development abroad?

George Handy

First can we turn to the Hungarian side, is there a policy with respect to stem cells?

Norbert Kroó

We are in an awkward situation, because we would like to drive a more liberal policy than the European Union. But the regulations break us. In spite of that, there are groups, which try to avoid these difficulties and do so. Our policy is more liberal, nearer to the US policy than the old European one, with the restrictions, which are imposed on us by the European Union. I can tell you examples later.

George Handy

How does that track with the business side and from the US standpoint?

Gail Cassell

I would like to say, and I am very proud of Lilly, not unusual. In the very early stages, during the debate on whether the US should spend federal funds on fetal tissue research, we established a bio-ethics committee to begin to weigh the bio-ethical issues as it pertains to research in general and drug development. We established a policy that, in fact, Lilly would not invest funds or perform research utilizing fetal tissue at that time. This was shortly after, you may remember, in 1994 and 1995 when President Clinton asked the NIH Directors Advisory Committee to give the US guidance in this area.

In addition, I would say that currently we are certainly not performing stem cell research. It is not a contingency upon which we would base our judgment on investing in an individual country. What we do is to continue to follow the debates here in the US and to be involved in those debates. But at this point in time we certainly are not currently conducting, or at least not to my knowledge, in the near term stem cell research. But nevertheless we are very interested in the policies that are being developed in the US and abroad. What I can tell you, what I see as an individual scientist, is that I do believe we are losing scientists from the US to other countries that do have more liberal policies as it relates to funding and actual work using stem cells.

George Handy

We will have two brief comments and then we will break for lunch. We will come back and continue our work over lunch with your permission.

Linda Powers

I am going to go back to your question regarding what's the appropriate way to measure transfer of technology and add a word of caution and amplify what Gail said. As everyone around the table has pointed out, Hungarian scientists are very smart. If you tell them you are measuring something like, the number of patents that are applied for, they will, in droves, apply for patents. I think it is very important, as you develop the policy for your technology transfer office, to use the kind of things that Mark described as the

basis. What's sort of best for developing economic benefit and so on. I'm sure you have thought of these things. But metrics are very difficult and you have to be very cautious as you build those up.

George Handy

This is going entirely too well. It's too interesting and the comments and ideas are too relevant. So, I think we have everything under control for our schedule. I'll turn to Dr. James Lewis and then Dr. István Földesi and we will go ahead a break for lunch.

James Lewis

Thanks George. I was just going to make an observation, which I'll try and do quickly. One of the things that has occurred to me listening to the speakers in both sessions is, I think one of the problems that has come up here is how do you connect science to economic growth. If you don't connect it then it's just ornamental. So your question is how do you connect it to economic growth? In the US we also ask, how do you connect it to international security, and that might be something for you. That issue, connecting science to economic growth in some ways falls outside of science. It's a question of what some people call soft infrastructure, which is the rules, the government policies, the laws, the financial markets. So one of the things we might want to think about as we go forward in the afternoon, and this is really for the last sessions, is how do we make that connection between the things we've heard here today on science and enhancing research and the importance of research. What I hope is the government goal of turning that into economic growth for Hungary.

Gail Cassell

I'm sorry I just feel like I have to say something. I apologize. I think that with regards to economic development, again something that is underappreciated in this country and perhaps elsewhere, is the fact that it is the creation of high-tech jobs that results from a robust pharmaceutical industry, in terms of life sciences, but also the funding of research. One of the things I didn't take time to mention is that now some of the most research-intensive universities are the largest employers in their states. Did you know, for example, that the University of California at San Francisco is now the largest employer of the Bay Area? Imagine that. The University of Alabama at Birmingham continues to be the largest employer in the whole states of Alabama. And that has now been true for over a decade. Now I could go on and on with all of these examples. This is something that you can't necessarily, I don't think, over estimate. It is that investment in research, and all of the good that spills out of that investment in the way of job creation, that is part of this economic development as well.

One caution, as we begin to think about economic development and tie science to that, I would just say, one of the most precious things we have is the university environment for performing science and research and we don't want the pendulum to swing too far and focus strictly on economic development. I think what we've seen in the states, is our state legislators are pressuring the universities to go in that direction. I think it is a huge mistake. We have to keep the balance or else we will loose our most valuable asset.

George Handy

Dr. Földesi you have been very patient, go ahead please.

István Földesi

Mr. Chairman, on account of Hungary's great worthiness, with due respect, I would use my brush with a somewhat lighter touch. Just a couple of very quick comments. There are US corporations in Hungary and they were listed with a good record, they have research facilities there and their work is most admirable. Number two, I think that there are well-proven vehicles to solve these issues that you raise, to clarify them and find the right solutions. I am sure that Mr. Kimball, from the Department of Commerce can subscribe to this view. Thank you Mr. Chairman.

Jonathan Kimball

These issues that András raised are actually key issues that we are engaging on and that we do need to find a solution; because no matter what we say from a government perspective, it's the businesses that are making these decisions. From the US government perspective, what we are trying to do is facilitate that dialogue to get a situation where the Hungarian business climate does develop to a place where Eli Lilly says let's move in there and make some R&D investment. I think these are key points that András raised and I think it's this dialogue that we need to help further.

George Handy

Thank you for your outstanding presentations of ideas and observations in response to the two stimulating presentations made by Dr. Rohrbach and Dr. Cassell. Please join me again for a round of applause for those two presentations and for the discussion.

Now we said at the outset that there were some outstanding reasons that brought us to the table today. One of the most significant is the energy and visionary leadership of Hungary's Ambassador to the US. Ambassador Simonyi has been, in so many different ways, an example of all of the great aspects, both of Hungary and Hungary-US cooperation that we have discussed and displayed around the table today. So it is with great pleasure that I turn the floor to him for some remarks before we adjourn.

H.E. András Simonyi, Ambassador, Embassy of Hungary, Washington DC

Thank you very much. First of all I would like to apologize for not being with you last night. I was in New York attending a dinner where Kofi Annan, and Jon Whitehead and Paul Walker and the speaker of the Hungarian Parliament was present, so I had to be there. But, honestly, I was torn because this meeting is so important that it is so close, not only to my heart, but close to what I am trying to achieve as an Ambassador in the United States – namely, a much closer business and technology cooperation between Hungary and the United States.

Having said that I am so pleased that I have had one on one with almost each and every one of you and it's kind of funny to see you together – but it's great, because it does make a difference. You will be the cluster of people who will help make this relationship

happen. I am so pleased to see Professor Kroó here, President Boda. Mr. Chairman, we have had so many conversations in the past, you never believed that this was going to actually happen, but I told you it would. Mrs. Posteiner, who, with some others, come from Budapest directly for this meeting. Also, on the other side, Gene, thank you for coming to this meeting. You are a great friend and you are one of those who are pioneers of this cooperation. I will not go on.

I am so pleased I was not here for the previous conversation because I have some very strong views about the pharmaceutical dialogue that we have. I have personally been, I think, operational in helping sort things out. But I was very blunt to the US corporations when I thought they did something that was not exactly the way it's suppose to happen. International, multinational companies should understand that the code of conduct, the way that they do business in Hungary, has a huge effect on the Hungarian business community on Hungarians. Therefore it is so important that we are straightforward with each other and if something is not exactly to the standards and some actions are not to the standards that we expect from actors within the business community we will be blunt.

Also we expect the American business community to tell us, the Hungarian government, if they do not feel confident about the environment. I just wanted to add this because I am so thrilled I was not here because I would have then had to interfere, or leave the room, or maybe make some positions that would not have been popular. But, I want to make some popular comments.

First, I just want to make sure that you understand that this relationship between the United States and Hungary is a lasting relationship. It's not tactical; it's strategic. This relationship will be there, if we Hungarians can help it, will be there for the next 100 years, and beyond. I say this because Hungary just entered the European Union and I want to make sure that everyone understands that we will be Europeans. We will be a member of the European Union and will work really hard to make sure that this relationship, the transatlantic relationship, the relationship between Europe and the United States, Hungary and the United States, is not weakened.

On the contrary, we should be inventive. Now Hungary would be among those countries, which will help repair, if there is any repair work to be done. We will be there to make sure that there is a good understanding that we do not see an alternative to the transatlantic relationship. We don't see an alternative to the transatlantic relationship when it comes to security, or war against terrorism, but we also do not see any alternative to strong business ties and very strong technological ties.

Having said that, I want to let you know that, when we look at the United States we are not looking for models. We are looking for examples and solutions, because we are not in the business of copying. We are in the business of working together. And we will ask you, we will even demand from you, to share with us your knowledge, your know-how. The bottom line is that I think Hungarians, Hungarian scientists and the Hungarian technology sector, are pretty good at answering questions. Help us ask the questions. We are good at answering and please help us be equally good at asking.

I have been encouraging the Hungarian technology community to make sure that in Hungary people understand that technology, university research, academic research, cannot act in isolation. It is as good as the world appreciates. It results in science and research, which is only as good as the international markets, and the business communities appreciate. What we are doing here together, basically when we started working with Mr. Handy, this is really what we started talking about. What's the missing link? What's the missing link in Hungary? I think this is really basically about finding the missing link. I am so pleased that you have here such a great composition of people. What we are trying to do is import this amazing triangle of university research, business and venture capital. This triangle is really the way it will have to be in Hungary too.

I had, before I drove up to New York on Sunday, we had a heated breakfast meeting, with Dr. Boda, Professor Kroó, State Secretary Jambrik and Ilona was there, and we had a very, very good debate. I think we Hungarians are getting there. I think there is a growing understanding that unless we get real on our research communities, on our universities, on our academic institutions, on how small and medium size Hungarian businesses have to do business. And we work very closely with multinational corporations that have done such a marvelous job in Hungary, who have held out in difficult times to send a message that they believe in Hungary's future. All this has to come together.

I do think that Hungary is a resource. I still believe, having come from a family of mathematicians myself, (they were the smarter line of the family), we are still math based. But we will have to have the international encouragement to make sure that we remain that way, so that the Minister of Education understands that what he is doing is really not about education, but is about prosperity. He should understand that when he is pushing for a tough curriculum, when he is pushing for tough math education, that's really about building business in the future, about training people who will give the answers to which you will help us ask the questions.

We have tried a couple of things. I think we have ventured into new fields that are exciting. I think the cooperation in Virginia with the University of Virginia, where the technology center is, or maybe also with the embassy to come together to push things in a certain direction. The Speaker of the House, which is a novelty, will not only meet with the leaders of your government, not only with Secretary Armitage, not only with Tom Delay in Congress, not only with Congressman Hyde of the Foreign Affairs Committee, but will travel to Texas and will have meetings with Dell Company and will have meetings with Texas University president to talk about the things that you are discussing here.

And then I have traveled to Rochester to see if we could figure out a new structure because we would like this to be a network of structures. So that when Hungarians come to the United States they're not shocked and not scared by the size of this country that they have a good understanding and the understanding that you do business with sizes that respond to the Hungarian size. And I think that's basically what we'd like to achieve.

I'd like to thank CSIS, I'd like to thank you Ambassador, personally for having held out, you writing the letters, even when it didn't look good and the project was kind of stable. And I'd also like to ask each and every one of you from the business community, from the multinationals, the pharmaceuticals, from technology companies, from the universities and elsewhere for reaching out. And on our side, I'd like to thank the Hungarians, I'd like to thank the professor, Mr. President, Mr. State Secretary, for coming as well. And this will have to have a continuation and a follow-up. Thank you so much for your attention and I want to congratulate you all, thank you."

George Handy

Thank you Mr. Ambassador. You've tied together our morning session very expertly and elegantly and given us our second wind for the afternoon. We're going to go into a session now with the Hungarian side looking at three priority areas. We'll then turn to Dr. Atkinson who should rejoin us momentarily for our final session.

LUNCH BREAK

George Handy

I'd like to invite your attention to the next part of our program. As we noted at the outset the purpose of this activity today is to principally provide a sharing of US experience. But in order for this to be a step towards practically future cooperation, it's necessary that we also have the initial understandings or improvement in our understandings of those areas for technology development for which Hungary has declared a priority.

In order to lead this portion of our roundtable session I'm particularly pleased to introduce State Secretary Jambrik. Mr. Jambrik, has for 22 years of his professional career served with leading telecom companies and most recently has been a deputy general manager responsible for economic affairs at Vivendi Telecom in Hungary.

I'd like to introduce him, welcome his remarks, first to open this part of the program with regards to Hungarian excellence in three crucial areas of technology growth. And then to introduce his colleagues who will expand upon his remarks with specific comments on telecommunications, biotechnology and pharmaceuticals. So, I'm sure you're delighted to welcome the State Secretary and I'm pleased to turn the floor over to you.

INTRODUCTION OF HUNGARIAN PRESENTATIONS AND OVERVIEW OF THE HUNGARIAN INFORMATION TECHNOLOGY SECTOR

Mihály Jambrik, State Secretary, Ministry of Informatics and Communications

Thank you very much George. So in this session we will introduce three sectors in Hungary. First I will talk about the information technology sector with Dr. Szekfu, who is the director of the Hungarian Association of IT and after that we will have two presentations about the biotechnology sector, I will introduce my colleagues at that time and they will make their presentation, and finally one presentation about the pharmaceutical research sector in Hungary.

So first I would like to start about giving a few remarks about the Hungarian IT sector. The first thing that was done in Hungary in 2002 was a new ministry was established, which is the Ministry of Informatics and Communications. Our main task was and is to prepare the legislative framework for this sector, which means the most up to date requirements for this sector and also the EU regulation. Basically, we completed this task by the accession to the European Union. Last year we in the Hungarian Parliament adopted the Electronic Communications Act and we modified the legislation about digital signatures and ecommerce.

Taking into consideration the status of the information society in Hungary, our government's policy aims at the intense development of IT infrastructure and providing more Hungarian content accessible via the internet. You may not know that in those countries where the language is unique and we cannot say that it is similar to the English language, usually the internet penetration is much lower if there is not content available on this language. So we have big task to promote, the Hungarian content development on the internet. And launching programs for minorities, the disabled people and establishing public access points throughout the country. We aim to bridge the digital divide.

In this activity we strive for close cooperation with the players of the IT market. Concerning the infrastructure development, in Hungary the PC penetration is not very developed, so one aim is to enhance the PC and internet penetration in Hungary, developing the ICT infrastructure. Therefore, we launched the Public Network Program and in the frame of this program we established access points with broadband access and providing related content services in many places in Hungary.

At the beginning of this month we issued the tender invitation for UMTS in Hungary, building the UMTS services in Hungary and also this autumn we will issue a tender for establishing a Unified Digital Radio System for Emergency Services.

Let me show you the main directions of our ministry's foreign policy in a few words. You have heard all of this morning that Hungary, due to its advantageous geographical situation, in the center of Europe, is qualified to be a hub in the international relations. In this sense Hungary could offer its EU membership that is access to the single European market, but around it good contacts with all neighboring countries, the Balkans and East Europe, Ukraine, and Russia. As you can see the system in the ICT field is filled with several projects. I will talk about only two main projects later and concerning our relations with Asia, I would like to mention that in only two weeks, in Budapest we are organizing a Hungary IT Forum, where nine Asian countries, including China, Japan, Thailand and South Korea will participate. And the delegations will be lead, for example in the case of China, by the minister of ICT.

So I would like to talk about two main projects. The first is the House of the Future. The mission of this program is to demonstrate the achievements of the information society and the technology innovations, which fundamentally determine the lives of people in the twenty-first century. Because of the future our first recommended initiatives and institutions are undertaking to all play in the establishment of the information society. This program will incorporate a huge permanent interactive exhibition in a former

industrial park in the center of Budapest. We anticipate the time of completion of the project is for 2005. And related to this program the Ministry of Informatics and Communications has had negotiations with MIT Media Lab Europe, in order to start to develop a local research and development center in Budapest, as a national strategic research partner of MIT Media Lab Europe. The details of this cooperation have already been worked out and the last negotiations are being done during these days in Dublin, Ireland. Dr. Magyar is representing the Hungarian side of the negotiating delegation here.

The next project I would like to talk about. This is the Hungarian Technology Center in Virginia; that was mentioned already today. This center was funded in October 2003 by a Hungarian international technology public benefit company by the Ministry of Informatics and Communications. The main task of this center is to help Hungarian medium and small-sized companies to enter the American market and serves as a vehicle to attract capital to Hungary. HTEC is a major initiative to bring Hungarian scientific knowledge, technological expertise, and affordable global sourcing capability to the US market.

While other countries may compete mainly on cost, Hungary can offer comparable value and quality R&D innovation, a strong work force and business acumen beyond programming skills. Innovative start-ups are emerging from the Hungarian IT community. We already made the selection of ten companies including companies specializing in 3-D visualization, smart region initiatives, and graphical regionalization; among others. These companies have to and will show that they have the ingredients of services and products that US companies and markets need.

The expert, HTEC director Dr. Földesi, who is here also and his able staff will be a matchmaker between the Hungarian and American companies. I know that he has the knowledge and experience to meet this challenge and we support him. I would like to ask Dr. Szekfu, the director of the Hungarian IT association to give a presentation about what Hungarian IT companies can offer to the US market.

OVERVIEW OF THE HUNGARIAN INFORMATION TECHNOLOGY SECTOR (FURTHER OBSERVATIONS)

Dr. Balázs Szekfu, Director, Hungarian Association of IT Companies and Founder/Member of the Board, Carnation, Ltd.

Thank you very much and thank you for the opportunity to be here and to address this very special crowd. So let me introduce you to IVSZ, the Hungarian Association for IT Companies. I happened to meet a gentleman yesterday, a great Italian gentleman having his eyes fixed on the White House. He said some 200 years ago that knowledge and light shall be the two prophecies that every nation has to strive for. And I think the words of Jefferson pretty much marks the way Hungary wants to go. We think that knowledge intense economy or knowledge economy in short is basically the only way for Hungary to go forward in the twenty-first century. And if I want to summarize my presentation in just one sentence is that we welcome every help and we welcome more of the US

companies and associations, institutions, governmental, non-governmental to come to Hungary and to help build a Hungarian knowledge intensive economy.

Some words about IVSZ. Just to go through these ten slides. IVSZ is a common voice of multinational, large Hungarian, small Hungarian companies which is a unique position in the sector and also in the region. Usually these companies are in different associations; we try to build a common a ground for these IT companies. We are quite an older organization, founded in 1991, about 270 members, good relations to the ITAA of the United States and also WITSA and EICTA are our mother associations; the European associations for IT companies.

Just a few words about Hungary that you might all know better than I do. It is a stable and transparent political environment, lately, a little bit of unstable but now getting even more stable until these commotions, and customs-free market to about 600 million consumers in Europe; strategic location, etc.

ICT market in Hungary is growing about 10 percent a year, which is about three times the growth of the GDP in Hungary. The estimated number for this year, for 2004, is about 6.4 billion euros and about 6.8 for next year.

One of the drivers of this growth is software products another is carrier services. We do believe that for Hungary the main driver for the economy, for the knowledge-economy, could be Hungarian software production and software export.

Hungarian high-tech niches. Hungary is very strong in very special services in important niches; for instance, we're very strong in data encryption that all of you can see if you turn to our slides printed out here in the States. So we are pretty strong in encryption, CAD/CAM design, the company Revusoft is the second largest on the CAT/CAM market globally, character recognition, our company Recongnita, now owned by Scansoft, an ex-Xerox company has about 65-66 percent of the global character recognition market. Language technology, Morphologic is one of the best companies on this market. Software development, for mobile devices as you've heard before, Nokia, Ericsson, Motorola, all have development centers in Hungary and also a bit of mobile applications. And also there are some gems. We have for instance a company called Colorfront, which basically developed the technology of coloring and shading of digital images and motion pictures, like the Lord of the Rings, has been shaded and colored by this technology during the making of the film.

So basically Hungary can offer either these small companies going out of the country presenting their technology and software exporting and also we invite companies to come to Hungary to get development centers going. There is a long list of reasons that companies can come to Hungary, we offer qualified manpower, as we also heard, for reasonable costs of operations and for ready infrastructure and reduced setup time.

There is quite a few US companies that have already decided to enter Hungary. The American Chamber of Commerce has quite a few members and if would be able to see

anything on the printout you'll be able to go through the list of companies that are present in Hungary coming from the US.

We present what we call an offshore, a near shore possibility. According to a Nasscom study there is about one million IT jobs going offshore between 2004 and 2010 from the US and what we aim for is to get at least some percentage of these jobs going out from the US to Europe and definitely, permanently to Hungary. We think that we can offer possibilities of cost advantages of 30-60 percent compared to the US and regarding software interface development Hungary also has a cultural advantage over India and the far-east when it comes to usability issues in outsourcing any software development

To sum it up the companies that are already present in Hungary from IBM to HP, from Nokia to Ericsson, Siemens, Oracle; these companies have already joined the growing knowledge-intensive economy in Hungary and this is what we aim to invite; US companies, US institutions and development labs too.

Summing it up knowledge intensive economy, or knowledge-economy in Hungary, we do believe that there is no other option for Hungary to do any sort of work on our competitiveness but to work on our knowledge base, to work on how to present Hungarian knowledge to the global economy and how to make exporting, software exporting knowledge our main ways to get the economy rolling. We want to learn from partners like US scientific institutions and companies to shape Hungary's strategy of the knowledge.

Thank you very much and we are very much open to any sort of suggestions, comments, on how to do it better, quicker, and faster. Thank you.

OVERVIEW OF THE HUNGARIAN BIOTECHNOLOGY SECTOR

Dr. Erno Duda, President, Hungarian Biotechnology Association

Ladies and gentleman thank you for the opportunity to be here, it's really an honor. I run the Hungarian Biotech Association, which unfortunately still has fewer members than the IT association but we're working on that. We're only at a few dozen but it grew out of nothing literally two years ago. I also have another hat I'm wearing here I'm the CEO of one the local biotech companies.

I'd like to start off a little bit from a distance, talking about the European biotech scene. Towards the end of the 1990s, Europe as usual started waking up a little bit late, realizing what an incredible disadvantage it has compared to the US. By then the technology force-type professionals were predicting that the biotech industry together with pharmaceuticals, somewhere between 2015 and 2020 can turn into the largest single industry in the world. Also at the end of the 1990s it started becoming evident that those were the years when more than 50 percent of drugs coming out to the market actually originated from biotech companies not from the pharma industry. Europe suddenly realized that we just missed the boat and the US is at least ten years ahead of us and European economies started pouring billions of euros into their industries, which resulted

in a number of very small companies. I have to say that many European countries were very good at selecting the worst possible methods on how to grow an industry. Germany was probably the worst example where they really poured billions of euros into it, started hundreds and hundreds of companies based on which professor had the best position and then they cut the funding so what you have right now is basically half of German companies have already gone bankrupts and about 60 percent of the rest have money for less than six months.

This chart would probably would look very different this data is a little bit old, the number of German companies has been significantly shrinking. The Hungarian government, however, turned out to be incredibly wise because they did not give any support to biotech whatsoever, so they could not end up in this situation. But it also means that if they wake up now and decide to make it a strategic focus then maybe they can learn from all the mistakes that the other European countries have made.

Hungary and generally Central and Eastern Europe is not really on the biotech map yet. However, there are some areas where you can see significant growth and you can see some promising companies. ComGenex, which is a multinational company actually based in Hungary, is the largest chemistry provider in all of Europe. They've been around for about ten years, they're one of the biggest chemical companies in the world. Exbio is one of the best antibody companies in Europe, they're in the Czech Republic. They're a number of good genomics companies in the Baltic countries. And to brag a little bit about my own company Solvo, is a also a small company, started less than five years ago and we can list ten out of the ten top pharmas among our clients and we never received any venture capital, we built from revenues.

To talk a little bit about what we need for the biotech sector and I think some of this was probably already talked about or is obvious. You need the academic background, you need proprietary technologies and you need patented technologies, you need strong intellectual property because without that you can't get very far, and you need the scientific business environment to grow it. I think most of this available in Hungary although I have to say when talk the great Hungarian science we also have to mention that if you talk to Hungarians they will always brag about how Hungary has the biggest number of global partners per capita and we have the highest productivity in basic research and that Hungarians discovered a gazillion things anywhere from helicopters to ball point pens, from vitamin C to I don't know what. Well next time ask them how many of those inventors made any money out of their inventions.

I think that Hungarians also have a unique talent. I think we're obviously number one in the world on how not to make any money out of the great inventions that we come up with. Rubik never got rich on the Rubik's cube or to bring an example from something that we've talked about today, very few people know that Losac, which was for many years was the number on selling drug in the world, there were times it was actually doing sales equivalent to about a quarter of the total Hungarian GDP. Losac was originally discovered in Hungary. I guess you can all figure out how much money Hungary ever got out of the development of that drug. This is I think a trend which we need to change

and it's our role to figure out how not to use this unique talent that Hungarians have developed throughout the centuries, of making other people rich from our own talent.

What is really missing from the Hungarian biotech sector? I really have long debates about this with other players in the industry because everybody cries and complains about the unavailability of capital, which is true. Capital is very scarce on different levels from seed financing to venture capital, it's very difficult to make an exit from a Hungarian company from an investor point of view. However, in my opinion the number one missing link is experience managements. Because if you have good management, I'm talking about biotech management, then those people will find creative ways of getting financing and I think that the United States has a particularly strong role in that, through the four or five thousand life sciences professionals, Hungarians working here. We need to find out a way to take home some of those guys and we don't need to take hundreds, if we could just take home ten really professional guys then we could totally change the face of the industry in Hungary and I think that's something that we have to work on; how to figure out who those ten guys are and how to get them to come home and bring home their projects, their contacts, their money, grants, etc.

So what is the problem? The problem is, this not a unique Hungarian problem – all of Europe suffers with this, Europe does not have the tradition of interdisciplinary education as the United States has. So if you start counting the people who have good management skills, who know what the difference is between a PNL and balance sheet is but can also tell the difference between an amino acid and a nucleic acid, you suddenly end up with very few people. And that's not only true for Hungary it's true for Europe, so education is one part of it that I think we have to concentrate on. This is very different than the United States.

On the capital side, Hungary is a small market, and there's venture capital available among Hungary and they've made tremendous investments in the ICT sector. However, there's not a single VC in Hungary that has a biotech expert, some of them claim to have but they don't. So there's not a single person at any VC who can do evaluation, who can do diligence on a company and that has really locked the door for the sector. I think that with entering the European Union it's obvious that is hopefully going to change in the near future, but we have to convince the western VCs who sometimes have geographical limitations to go to Hungary and set up local funds and invest in local companies and I'm convinced that the first ones to do it will be able to do the cherry picking among the best companies.

The reason I put in this slide is because everybody in Hungary says, and I agree with it, that a very, very, small portion of Hungarian developments ever gets patented. And if you take that into account and see that Hungary still has a very large number of patterns compared to the R&D money spent. If we're able to really setup those tech transfer offices at the universities and force scientists to protect their IPR then Hungary could have a great pool of basic research results, protected basic research results that you can start from.

I don't think I have to convince anybody that its cost effective to do research and development in Hungary although I think that we should concentrate on the quality of our workforce and the competitiveness of our science and not how cheap we are because that's not going to last for long. I usually don't like to take that as an advantage. I think we have to compete in our quality mostly.

So to wrap it up a little bit, what we have is we've got the university and pharmaceutical background, we've got a lot of scientists working in the US – we'd like to return, we've got a very good subsidy system on patenting where the government will actually pay for 90 percent of your patent costs. My company has almost as many patents as full-time employees. We wouldn't have been able to do that if the government would not support a patenting process. Unfortunately very few companies know about that and know how to use it.

And what we're missing is management and I think we have to treat separately, lacking management experience and running a biotech company; that's like the CEO level guy and scientific management skills. We have very well-trained scientists but not scientific leaders who know from experience how to work for an industry and how to work for industry overall. And that sort of ties into the next one; scientists, good core scientists, but these scientists are used to an academic environment and not used to a for-profit environment. And we experience that every day, great scientists who just absolutely cannot comprehend the idea of a deadline. Because they say the word "deadline" is like the ultimate evil for them because cells don't grow on deadlines.

Well there are a couple of 10,000 scientists around the world who figured out somehow, how to do that, so we're going to have to work around that and convince scientists that yes, you can work on specific goals and deadlines, and its doable.

And you talk about results not being protected and then there's the question of how you market yourself. If anybody's interested I can tell you the story of how it turned out when we first called up Pfizer and told them that we've got this great new technology in Segit, Hungary; its much better than what you're using in-house. They said, "Yeah, well. We'll call you back," that was the general results. After you've already sold to five of the big pharma its much easier to tell the sixth one, "Oh you know, Pfizer and Lilly, they already use it." But for most companies getting in the door is an impossible task and we have to find a way to teach these companies how to do the business development because they're totally lacking that.

The structure of the Hungarian biotech companies; its not surprising that because of the lack of capital you see a lot of service companies, a lot of mix model companies because they have to figure out to generate their own revenue because they didn't have access to capitals. The companies that were able to raise capital, they all raised it through their foreign mother companies, so they basically formed a company in the US or England, which was basically empty and just owned a 100 percent of the Hungarian and they raised the money through those. That's basically all the venture capital placements were done like that and its not the most ideal model to do it. By the way this is from a study that was done by a German consulting company together with the biotech association,

there's a 90-page study that was done on the biotech sector, if anybody would like to get it, you can either get it from me, it's a PDF file, its about eight megs, or you can download it from the site of the biotech association but it needs a password because we try to get money for it, but you all get it for free. And its also going to be available on Amazon for next month.

So that was what I wanted to say and I'll hand it over to Ágnes and just what I want to mention is, I think that there is an incredible opportunity in the Hungarian biotech market but without the help of the government its not going to happen. We need commitment from the government there's not a single biotech incubator in Hungary and that totally limits the growth. There are other obstacles, which I think the law on innovation is going to change, that's going to be a tremendous boost. We have to figure out a way to import back scientists, my own company, we've been fairly successful. We just imported somebody back from the NIH and I'm going to the NIH tomorrow to discuss how we're going to get some other intellectual property together with the scientist back to Hungary. But in general that's not a trend and I think that's something that we need to work on. So thank you very much and I look forward to your questions and Ágnes told me yesterday she can speak faster than I can so you're very challenged.

OVERVIEW OF THE HUNGARIAN BIOTECHNOLOGY SECTOR (PUBLIC SECTOR)
Dr. Ágnes Szmolenszky, Project Manager, Agricultural Biotechnology Center, Gödöllo

It's my pleasure to be here and I would just like to add a couple of ideas with respect to biotechnology in Hungary in the public sector. Hungarian biotech research has a strong public dominance. Dominated by well-established public institutions. The main research centers are run by the Ministry of Education, the Ministry of Agriculture, and the Hungarian Academy of Sciences. Research funding is provided by both the state and other competitive grants. There's a very important development to note and that is that the share of state funding in research has been significantly on the decrease. And thereby research groups now have to be able to apply for competitive grants coming from Britain, the EU, and other private sources and this of course also means that these research groups have to meet very high international standards, which they can actually meet very well. Another very important development regarding biotech public sector is going to be brought about by the new Innovation Act, which will be passed this fall in Hungary because that will mean the opening up of the sector for private investment.

What are some of the hot fields in biotechnology in Hungary today? They include molecular biology at institutes of the Hungarian Academy of Sciences, plant biotech, a new national transgenic animal center has just opened in Budapest which was the major investment of several participants listed down there. This center is going to serve as a gene-banking center for the country. Agricultural biotechnology is being carried out by the Agricultural Biotechnology Center in Gödöllo, close to Budapest, the only place where somatic cloning of animals is going on in the country and it hosts also the national GMO test lab for the country. And also biomedical research is a very important area in biotech and its been carried out with several medical faculties.

The last slide actually shows issues we already discussed and mentioned this morning. It's about brain drain and what we would of course much rather have, brain circulation. What I would like to underline is that scientists coming from the US are taking home outstanding skills, competence, experience, brain power, knowledge, and this is of course to a great extent the result of a huge investment into their training education by both Hungary and the US and we believe that it lies in the interest of both countries to actually benefit from that huge investment and to use this potential as a means for market penetration, for networking and for future, collaboration. And we are very much looking forward to a dynamic relationship in the future. Thank you.

OVERVIEW OF THE HUNGARIAN PHARMACEUTICAL RESEARCH SECTOR
Dr. Ádám Vas, President, Science and Engineering Committee, Hungarian Association of Pharmaceutical Companies

Well, originally I wished to start my talk by saying that Mr. Chairman is a gentleman and I 'd like to give you a brief introduction into the Hungarian drug research, but after having so many words on the topic in the morning, this will be probably be a slight turn on the issue and nothing more. Well, let us start with the industry. The Hungarian pharmaceutical industry started in 1901 by the establishment of Gedeon Richter Ltd. the company I work with, in Budapest and it was a rapid growth in number of companies and products until the end of world war II. Richter had a commercial network expanding to the US also at that time. The status has stabilized during so-called communist days and the Hungarian pharmaceutical industry played a leading role in central and eastern Europe providing high quality goods to the communities there. The industry's future of providing high quality branded generic and also original products with reasonable prices, and I put an emphasis on reasonable price because of the reimbursement systems. After the political and economic changes most of the traditional Hungarian pharma companies were taken over by multi-nationals that were privatized with the only exception of Gedeon Richter Ltd. and we would like to build it into the future too.

In figures there is the so-called Hungarian Assoc of Drug manufacturers, and this society has 44 members. Obviously not all of these companies are involved in research and development, but the big ones like Gedeon Richter, EGIS (Servier), Chinoin (Sanofi-Synthelabo), and just now Aventis, and Biogal (Teva). The number of employees is roughly 14,000, this is a figure coming from last year. Net revenues reach 1.6 billion USD. The pharmaceutical industry is obviously heavily export-oriented. Nearly 70 percent of the revenues came from exports. And the R&D spending in 2003 was roughly 100 million USD, which means 6.4 percent of the net revenue. On the last paragraph you'll see that this equals 45 percent of total R&D expenditure of Hungary, but on this issue you must understand industrial R&D expenditure, but still 45 percent of industrial R&D spending comes from the pharmaceutical sector.

We think that we have strengths in that we have highly qualified and motivated personnel. Most of the companies focus on CNS, cardiovascular research and respiratory system. We have, believe it or not, GXP standard activities at all stages of R&D and also

manufacturing. Some of the companies like Chinoin and also Richter, use high-tech, like combichem, HTS, applied molecular biology and so on. I would like to mention that the combichem genetics was originated by Hungarian chemists. Besides the maintenance of some classical research techniques like behavior or pharmacology, I think that we have good academic links both in Hungary and to a certain extent abroad, it could be better obviously, but still the links are mostly good. We have GCP standards in Hungary in the clinical research and I'd like to emphasize that under all these circumstances what we have in Hungary, we have pharmaceutical industry was able to produce and bring to the market 17 new chemical entities (NCE), original drugs, from 1963-1996, and please mark that 1996 was the last year when an original came out from Richter. So this is the situation. We are looking, obviously, for partners in high-quality research labs, bio-formulation is also an important field, where we have some weaknesses in general terms, and also in clinical development because the expenditure in clinical development is exponentially growing.

With regards to the academic research field we have obviously the Research Institutes of the Hungarian Academy of Sciences, and we have the university research labs and these are in cooperation in the field of life sciences, chemical, biological, pharmacological, medical sciences in general. With the pharma industry via contract-based partnership and/or by national granting system, which we have, and also with other academic universities and institutions by European grant system these already mentioned in the morning.

We think that the academic research is strong in traditional fields like chemistry, synthetic chemistry; especially heterocyclic and also natural compound chemistry. Which have increasing importance, probably in the field of cardiovascular and CNS pharmacology. But there are also new fields of drug research and biotechnology: bioinformatics, genomics, combinatorial chemistry and so on. The research is pretty much basic research-oriented and in this area creative and flexible. The teaching system is still strong with highly motivated and qualified personnel for the academic research. But, there is a bottleneck, and the bottleneck is turning creativity into productivity and to make money out of research as we mentioned previously. This is a weakness. So, collaboration with companies and people who understand business is vital for academic research.

One example of US and Hungarian academic cooperation is the story of the American Chemical Society where a Hungarian chapter has been opened just recently and another one not featured in this slide is that there is a US-based company, I-works, active in Budapest, Hungary and they have cooperation with some academic places such as Prof. Mátyus' institute at the Semmelweis University of Medicine.

Thank you for your attention and I hope that I kept the time.

Question

A question about the IT area: how does the quality and the cost of software development compare to your competitors, for example India?

Balázs Szekfu

Basically we think that we are about, as I said in the presentation, about 30-60 percent cheaper in terms of labor force than in the US. In India, I have heard that you can get sometimes as much as 70%-80% price difference, so it means that Hungary wouldn't be able to shoot for to be some sort of a bulk of a software development, like a huge software development power regarding globally, this is why we are aiming to be good in very specific areas. So for instance, when you want to put a product out to the global market you probably don't want to have Indian software development people to work on your interface design then there is a good chance that European - that we'll have problems by using it for instance. So what we think that for instance, Hungary and India can very much go hand in hand in outsourcing in software development - there are certain things you wouldn't want to do anywhere but in India, and there are certain respects of the challenges you would be able to survey in Hungary.

Miklós Boda

Hungary, I mean I would like to answer the question, especially from the quality point of view, which is the most important part of the development. What I can see, Hungary has a really good tradition of software testing and software quality, as remains for that time when still this iron curtain exists, it means Hungary had the luck in that sense being the former eastern European countries' computer base - technology should be developed there. This was the deal between the former eastern European countries. And many times Hungarians developed computers which do the same job as the American ones, but the software, we have to make compatible, and this means the conformance test is really strong in Hungary, the tradition, in university you have even institute which is built with this question, rather unique in Europe; in Europe only in France have conformance test, and that is really important for the inter-operability which is a key issue. We have a really good tradition, which means you do need the science part of it because it is an automatic testing, software testing, is required. So that I should say - the Hungarian software is unique, and when it came to that sense, knowing about software testing which is really important

Jonathan Kimball

Thank you very much for the interesting presentations. I was wondering as the government helps set the market conditions for allowing agricultural bio-technology to be sort of presented onto the market and Hungary in the now larger European Union - I was wondering if the Hungarian government has developed a firm position on their acceptance of agricultural bio-technology, or what is often referred to as genetically modified organisms?

Norbert Kroó

I think the answer was in your question. Yes. Just give to give an example - the research institute of agriculture, the Hungarian Academy of Sciences, has a very fruitful cooperation with Monsanto, maybe Monsanto isn't too popular in this country, but in Europe in general, but many of the developments of this institute were then sold elsewhere by the chain of Monsanto.

Miklós Boda

The government view is we are supporting all these kind of activities and we even, it's not ready yet, but we will have something which we will introduce in the next year, it's an innovation loan, and this innovation loan encloses all the kinds of support we can give to all these kinds of activities. That is what we're lacking up to now, but it is now the formal framework. And I hope the Hungarian parliament is taking that one in October.

Erno Duda

I think I wouldn't be popular with this opinion in many parts of Europe, but if we're talking about acceptance of GMO products and GMO production, if that's part of the question, there is a very strong pressure as we all know from the US side for the acceptance of GMO production in Europe and although they don't speak about it. But this is not really a scientific issue – obviously EU has repeatedly tried to prove that GMO's are extremely dangerous to your health, but really anybody with half a brain knows that these arguments are really not valid scientific arguments; we're talking about economic interests here and about the competitiveness of the European union, which is non-existent yet to the US. Protectionist European Union measures which they are trying to hide behind questionable scientific arguments, and I think as long as the EU is not competitive with the US they are going to try to keep that up, and Hungary has very little room to maneuver out of it – whatever we think about this scientific background.

James Lewis

Thank you. I had a question – I noticed in both Dr. Boda's presentation and Dr. Vas's presentation that Dr. Vas referred to bottlenecks and Dr. Boda referred to a need for more management skills and entrepreneurship and capital management. And that sort of made me wonder, and I hate to say this because I don't like business schools, but these would be the sorts of things you normally would get out of business school – so can someone tell me a little bit about what's the sort of training in these business skills – management, logistics, marketing in Hungary? Because that sounds like part of what you need to turn research into production.

István Takács

I can answer that question. We do have business schools in Hungary, no doubt about it. And unfortunately the attendees don't always have the skills for being managers and this kind of thing – its kind of more if people do not know what to do with their spare time and spend the evenings attending. This is important. The problem is not theoretical knowledge; the problem is the inherited things they do have in Hungary. And then I would just like to quote in Hungarian – a writer who made a false statement, the human being can change what they are doing, even 180 degree changes. It's not why he is doing, but how he is changing what he can change – and the problem in Hungary is the "how" – they have the experience, not management because I don't call it directives, and contra-selection, and these kind of things – and this just takes time. Thank you

Norbert Kroó

A brief remark. There is a university in Budapest, which is called Central European University, and we know the person who keeps the balance sheet in order of that

university is George Soros - and this university has a part, which is a business school, and this is accredited from New York. So there are already some places where it seems to work – although most of the students are not Hungarians they are from the region.

Gábor Magyar

I happen to teach at one of those business schools in Budapest. There are 22 MBA programs or 22 schools offering MBA programs, usually with some kind of international connection with very good schools – I don't think that's the question. I think if you want to get an MBA in Budapest you can get all different kinds of qualities and costs of MBAs. I think that's not the problem – I think the problem is who are the guys to go there. In the MBA program where I teach, you will find employees of multi-national companies who were sent there by their multi-national employers who are generally either engineers or other professional lawyers who are getting their MBA degree. You see very few people from the life sciences area because who is going to pay the bill? And I think it is also a concept in people's minds that has to be changed. I remember what a "Chalkit" was when I first came to bio-tech firm here in the US – and to negotiate I sat down with the five guys who all had PhD's and they all had either an MBA or a law degree. And I felt like it would be really tough to make a deal with these guys, it would be really tough to find five guys all together in Hungary with those skills. So it's the concept that if you become a scientist in Hungary, you are a scientist, and business is something disgusting and you want to keep away from it. If you want to become a businessman, you go to economic school or you get an MBA, but I don't want to know what a carbon atom does, it's not my interest. So to get people to understand that they need to know two different kind of things to be successful, I think that is the mindset that really has to be changed and that what you see very little of.

George Handy

Now, what I would like to do is to move into the area of the "how". The issues that were raised, and for which we said the question is not what or why, but it's how, and in doing that I feel very fortunate in being able to introduce to you Dr. George Atkinson, who as noted is the Science and Technology Advisor to the Secretary of State. He also is the Professor of Chemistry and Optical Sciences at the University of Arizona; he comes with a background that is significant in terms of his work in chemistry and optical science, and his work within the Department of State for the actions he has been undertaking over these past several years.

OVERVIEW: MOVING FROM IDEA TO MARKET PLACE

Dr. George Atkinson, Science and Technology Advisor to the Secretary of State, US Department of State

Thank you very much, George. And thank you very much to CSIS for putting together this meeting today, it is a pleasure for me to be here and I've already learned a great deal. I would like to make one or two departures from what I'm about to say in these few minutes to note two or three things. I'm here to add my voice to the fact that the skill-base and the enthusiasm and the entrepreneurship in Hungary is well recognized. And lastly, I also wandered into the business world – and I agree with what was said before.

About the skill-base between science and business – I think innovation is about people, period. The ability of a person who understands the limitations of science in the business world is unusual, but it shouldn't be so unusual in the future. In fact, I think the key to innovation globally is the ability to find people who are interested in both – you don't need all scientists to be business people, you certainly don't want all business people to be scientists. But the mix is essential to innovation – I think we know that by looking back at history, and you find over and over again those people who were able to blend those skills are often times the ones we point to as being successful.

Science and technology advancements of our time have had an obvious immediate and enormous influence on economics, as we are discussing today, but also on international relations. And I want to dwell on that for a moment, because one of the points I'd like to leave with you today in terms of how to get this done, is the issue of whether public policy is well informed about science issues. This perhaps should not be left out of the conversation. Many of these issues we deal with challenge our societies in almost the most fundamental ways, and if we don't in fact deal with this question it's very difficult to have a public/private partnership that's very effective. This point was made some years ago in the United States, by a number of groups, particularly the national academy of sciences and engineering – did a study in 1999, which basically said that the science component of public policy, especially in the Dept of State and its role for foreign policy, was a critical issue for the US. And this report is well known here in this country; it's actually very concise. It points out that our relationships internationally are overlaid by science and technology essentially at every level. They identified 13 of the 16 primary responsibilities as involving science and technology and engineering, I would suggest today it's 15 out of 16, but perhaps the number is irrelevant relative to the point.

What are in fact, therefore, our challenges and what can we reasonably anticipate for this role of science and technology for foreign policy and how would it relate to this question of innovation? Well the fact is that from my perspective at least, the rate of change in science and technology is accelerating at an enormously rapid rate. It is in fact, it's overtaking the decision-making processes in many governmental institutions worldwide. Secondly, in the absence of accurately understanding the science you are subject to the errors of subordinating it to economic and trade issues. You don't legislate chemistry that I know about, you don't legislate physics and a number of other things. So we are at risk for not understanding the accurate pieces of information. Scientists don't necessarily make the decisions, but they certainly should be responsible for informing policy-makers accurately. And then finally, these questions about S&T are not just questions of economics, although today is the focal point of that conversation. They really are challenging some of the ethical and basic structures which use in our institution, and that does have an economic impact and a social impact.

One of the ways in which we judge whether these things are well recognized is by listening to those in our community has responsibilities at the highest level. These are remarks made by secretary Powell made earlier this year upon an occasion where we brought a significant number of new scientists into the dept of state. You notice the last two sentences that the partnership has to be two ways. That the policy has to invigorate science. In the office that I occupy at the moment as science advisor, we have basically

four responsibilities: the first is to increase the literacy and capacity within the dept of state – are there scientists who are at the bench if you will, in making policy decisions. We have been quite successful in bringing in fellows. National Association for the advancement of science has been very successful at this – it's a thirty-year program, and professional societies have done as well. The Jefferson science fellows program is an example of how we have tried to be innovative in this area. And by innovation, I think this refers to the fact that we would like to integrate the vast number of American scientists and engineers in the academic community into this policy discussion. And that's very difficult, I mean, being a professor for many years I know what a terrible burden that is for most of us, you don't expect them to be particularly productive in policy. But I would argue more seriously that the American university system along with its ability to produce technology would not be what it is in 2004 if it weren't for 50 or 60 years of federal funding. Whatever it is it has been the product of that type of commitment and forethought. And so perhaps it's time to allow people to come back from academics into the policy community and procure their expertise and allow us to understand more clearly how we make these informed decisions.

What Jefferson does is allow faculty to come who are tenured, back to State for one year and remain as consultants for an additional 5 years after they go back to the academic community. This program has been supported by two foundations, and about 60 universities, and by support I mean the universities currently pay the salaries and benefits of all those faculty, and the foundations provide the money for them to live in Washington. Here are the five who were selected this last year, and they are now in the dept of state. In terms of total, in the last 4 years, we have increased the number of fellows in the department, including the Jefferson fellows, by 500%. But I think you can see from the chart that there is a substantial increase in the number of fellows who are participating actively. And they are all over the department. This is an organizational chart of the Dept of state., which you cannot read, but the shaded areas are all the offices, which have fellow, since then in 2004. In 2001, only the three on the right hand side with stars were where we started the program. I'd suppose success would be measure when all those boxes are shaded, but you will notice on the right hand side too the undersecretaries of state have science fellows working on their staff now. So these are successes, these are the ways in which we would measure success.

One of the other things we are responsible for doing, we are responsible for building partnerships with the outside science community – and that means partners abroad as well. And so I'm eager to share with you ideas about perhaps more specifics on another occasion when we might be able to join you in new in new programs. We are also mandated to provide advice to the Secretary and other senior members – and particularly on the issues of science and technology at the horizon.

And finally the question of putting a forward-looking attitude towards science and technology is probably the fundamental issue. Now let mention one of these – this is an example of what we are trying to do around the world. My office will fund with national academies a series of new conferences are focusing outside the country, they are only on topics, which we believe are the next generation. If you look back at the history of the US in the last fifty years, one might make a case that our successes have been built on the

idea of the next technology. We've always had the opportunity to look from our educational point of view of how we could develop into the next opportunities that are available worldwide. These conferences are opportunities for us to join other countries in holding meetings particularly focused not only on the existing generation but the next generation; where the junior faculty and post-docs, where will they define their careers? So this global dialogue on emerging science and technology will take place about two or three conferences per year, and these are the first four of them to give you a sense. And here are the topics, which were identified for the type of emerging science and technology of interest to us. The sensor technology based on nanomaterials and nanostructures will be in early 2005 in Japan; in Europe, quantum computing in general and so forth and so on. We view these as opportunities to repetitively engage the world in what we think are the emerging sciences; these are open meetings.

So let me deal with one more subject, why should the world feel so concerned about these S&T issues. Well, I'd like to take a look at number 3, the long-term commitment to high-quality education – what is it in fact about the American system that distinguishes it from any other system? You might be surprised. First of all, the educational use of the value of S&T in the educational community worldwide has already been demonstrated in recent times. If you look at this column over here, you'll see that sometimes we have people disagreeing with us about American ideas and customs, but in this column you'll see very little disagreement about S&T. S&T represents some of the best things Americans present to the world, but what is in fact the S&T community in the United States? In my spare time I still sit on the editorial board of this journal, I'm sure all of you have copies of it, but look at where these articles are written. 59% of them came from outside the United States. Maybe it's just because we are chemists. Here are some other publications you might point to, and notice biologists are really impressive; 55,000 pages in journals. 55% of those come from foreign contributors. The American community is absolutely international, the scientific community is absolutely international, and you can prove the latter point by looking at the educational system. The current numbers in 2003/2004 are 43% of enrollment in graduate studies in the United States are from foreign nationals. In the 7 fields of engineering, the numbers range from %50-%85. This is the American system, we have benefited enormously by having an open and free exchange system. And it is perhaps the major point I'd like to leave you with. If innovation is anything you can pinpoint, what would you say? I think you could say it fairly quickly, a short thesis – it is the history of investing in people, the ability to provide foresight into creating environments which allow people to come in and think about the opportunities and the vulnerabilities of technology.

Now, nanotechnology has always been sold to us on the benefits but in fact we should be concerned about the vulnerabilities that those two technologies produce, just as any other technology. Biotechnology certainly comes to mind, but the values are enormous. So within the context of a conference on innovation, and for the question addressed to us of how do we get there from here, I think the answer has to always come back to the investment in human resources and for that we stand ready to join you. Thank you.

George Handy

Thank you very much Dr. Atkinson. The intent of this section was to discuss the points of how. In this segment, which is divided into two parts, we will initially look at the national level and the regional level. We'll take a break and then we will examine the university level and we will talk in conclusion about the complex business of attracting business financing. Our second point then on this afternoon journey, is to go to Robert Sienkiewicz. In addition to his current responsibility he has been involved as an international finance manager. But more importantly and more immediately he's been working in the world of advanced technology for some time. He's ideally suited to talk about the national level dimension of the "how to" issue.

SUCCESSFUL INNOVATION; POLICIES AND ACTIONS AT THE NATIONAL LEVEL

Dr. Robert T. Sienkiewicz, Senior Advisor to the Director, Advanced Technology Program, National Institutes of Standards and Technology

Mr. Chairman, it is indeed an honor to be here today. I am going to take a couple of minutes to follow up on what Ambassador Simonyi said- not looking for a model, but looking for an example of best practices, of things that work in the public private innovation partnerships at the national level. So many of themes that I am talking about resonated this morning with a lot of the comments from Dr. Marburger. How do you listen to constituents to determine what your priorities are for an innovation system?

To Dr. Cassell, companies not looking or not seeing the immediate benefits that you are going to get. To Dr. Rohrbaugh, how do you encourage businesses to take on technological development? What is the importance of different metrics?

We are an industry driven partnership. We fund enabling technologies with partnerships with the private sector. By enabling technologies, we mean that the technologies we fund are either infrastructural, path raking or multi-use. We fund the A through X in technologies, anything from aquaculture to xenotransplantation. We do not have a "z" yet, we are looking for one. We have even funded fuel cells and nanotechnologies for the past decade. We are known at the godfather of tools for DNA diagnostics. We have funded such companies as Athametrics in its infancy.

We will fund up to prototype development. Last year our budget was about 200 million dollars. The key feature of my program, which is housed at the National Institute of Standards in Technology, is that it is indeed a civilian sector program. We are driven by good ideas from the civilian sector. It is not defense related, not government related, but rather the civilian drives it. Industry leadership is key. We do not determine the types of topics or the types of technology areas that we fund, rather industry does it because it is all industry driven. Again, enabling technologies with high spillover potential that is reflected in our source evaluation boards and who we have on these source evaluation boards. Not only do we have the best and brightest minds in the federal government from the science perspective, there are also people like me who are afflicted with being an economist. So we are evaluating, not only the technology, but we are also evaluating the broad economic benefits. Both of these play an equal role in this type of innovation with

the public-private partnership that we are trying to advance. A demonstrated need for ATP funding for federal funding is imperative and we do have some set provisions.

Finally, what we try to do in my organization is to coordinate with other funding sources. I would like to focus on the importance of rigorous evaluation. Again, we are part of NIST. I would like to focus on six lessons that we have learned that may be beneficial for anyone. Especially, for you who are trying to set up an innovation system. These six lessons that we have learned in our decade and a half history, include addressing a national problem or need, avoiding duplication of effort, keeping it at an appropriate level, the importance of strong well-publicized criteria, the ability to leverage other resources from both the public as well as private, and evaluation early and often.

With regard to addressing a nation need, the real issue in programs like the advanced technology program, where there is significant underinvestment by the private market, is that issue clearly of underinvestment. If there is insufficient private sector, then according to mainstream economics, the federal government does have a valid role to play here. In the United States, what we have seen is that there is substantial underinvestment is what has been commonly referred to as the “valley of death.”-that area between basic research and prototype. There is underinvestment. I need not tell any of the industry executives in the room here about the short-term focus on investment. You are not worried about the next decade, but instead, the next quarter. So that adds to the complexity of the issue here.

When we are looking at the types of technologies that we fund, while we are industry driven, keeping it at the appropriate level also means keeping it at the appropriate level of managing it. While we are industry driven, our technologies can be grouped and managed to address national priorities. For example, our investment in the last decade in manufacturing has been about a quarter billion dollars, tissue engineering about 100 million, nanotechnology about 142 million and homeland security about 300 million dollars.

One of the second lessons that we have learned at the advanced technology program, is the avoiding of the duplication of effort. As an economist and a steward of the tax-payer funds, of federal funding, it is critical to look for the efficiencies. It is critical to avoid having the duplication of effort. If another federal agency, or the private sector, will be funding the types of technologies that we are funding, then clearly we have no business funding those types of technologies. There are only so many resources that go around. There is simply a quote up here that says, look, the ATP and the SBIR, a program that we have been compared to often, are very different and important ways. It is important to understand how we differ from the other federal programs to know the appropriate people to talk to know the appropriate technologies. Who is going to fund what?

What is also critical from our perspective is the level of communication that goes on among the different federal agencies. Even if we are bound by secrecy, by a non-disclosure agreement, it is important to talk to other people to get a good handle on what they would fund versus what you would fund. We are just doing our job that way.

Thirdly, keeping it at the most appropriate level. Having recently gone through the business school experience, we hate the word synergy. But by keeping a program at a national level, you are able to take full advantage of the regional differences that occur and who has the various expertise. Many of our projects in the advanced technology program are not only filled with sub-contractors and joint venture participants, but we have participants in any single project. We had one project where we had one person from Washington, someone from Oregon and someone from Virginia trying to do the coordination. The reason being, because that is where the expertise lied. So keeping it at the appropriate level in terms of a national program is critical. Thank you very much.

Gail Cassell

Yes, the Council on US Competitiveness has done quite a lot of work on clusters and their impact over the last three years and have now a number of reports based on the different geographic regions. So for anybody that would be interested in these I think they are very good references with a lot of data and they're currently following up on some of those now for this year in 2004 in terms of how this is effecting our competitiveness."

Linda Powers

Just a little view from the trenches. I don't know about theory but I can tell you that when you're trying to finance a real world company a cluster is a very powerful thing. It makes every aspect of doing the deal easier. It means that if you recruit management you don't have to move them across country, you don't have to persuade them, you don't have to give them a pay package like a big pharma company would pay to be in a twelve-person biotech company. It means there are other VCs who will join a syndicate with you and who will come to more than a quarterly board meeting. I mean, just every aspect of the expertise, the resources, the processes that you go through to build a company, I can tell you, clusters just facilitate everything.

Comment

What we see basically in Hungary is that there is a lack of communication between the governmental sector, the academia, the companies, and the civil sector. What we do believe on the other hand that if they would join hands, if there would be a communication going on between those sectors that would create some sort of an impetus of innovation. So that's basically why I'm listening with very open ears to this part of the discussion because I do think that these models of Fairfax and the theory of clusters and the practice of clusters would be of very much use in Hungary. And hopefully we try to turn it into some sort of a practice of how to get these forces together because I think one of the lessons for myself in this very valuable day is that without these people talking to each other you wouldn't be able to do innovation.

George Handy

Thank you. It was quite a remarkable experience for me in inviting people to this session that for the Americans it was not only very natural for the federal, state, and local government to come here today but the universities, the business community, and the venture capitalists and then the other amazing thing was that they all knew each other.

Dr. Gail Cassell

Well, I'll take a risk in answering your question. I think as you many know, now with all the issues surrounding the potential for bio-terrorism there are some strict technologies, equipment, etc. that are monitored very closely in terms of traffic between certain countries and the US that I would say don't necessarily impact companies like our own but I'm sure perhaps for some it might. There are certain other restrictions right now in terms of exchanging biological strains of microorganisms, particularly those of highly dangerous pathogens that are somewhat restricted and are impeding, we think, research collaborations mainly among academic laboratories. But I'm sure that George Atkinson and others can answer that more thoroughly than I and certainly Department of Commerce could have before they departed.

Dr. George Atkinson

As you well know the typical American science and technology agreement has very clear language about intellectual property and the export control issues. This is one of the things the Department of State has done for many years in terms of looking after that responsibility. And today, you're exactly right, there are more concerns over certain types of technologies, which people have expressed the type of issues that you've mentioned. I think at this stage of the conversation about the future I wouldn't be too concerned about that as an issue.

It certainly affects Raytheon, I'm sure, and many other companies would disagree with me immediately because its an immediate issue. But as you go forward if you concentrate on the evolution of the next set of developments and, JSF is a joint-strike fighter, I've presume you're referring to, not the Jefferson Science Fellows program. But in the case of immediate military application and clearly that's going to be front and center an issue, which countries do collaborate with which you share technology with and so forth. But there is a danger of looking at that technology as the end all, it isn't, it's the next technology, it's the one after that you're probably more concerned about in the long term. And I think the governments in general should be very cautious not to loose sight of that issue. Protect the existing technology which can be associated with a product of commercial vulnerability but not loose sight of the fact that the next type of development may supersede the capabilities that you are now concerned with.

So the technical alert list, these types of lists that are made up to be concerned with certain types of technology are difficult to interpret. As you know the name appears on a piece of paper but the interpretation occurs by a human being, in terms of evaluating how important it is. So in a way it's a reflection of perhaps the last decade or two, probably the next decade but I'm not sure beyond that this list will be as clearly cut as it is today. And with regard to biotechnology, genomics say that you can change that list as soon as you do centric and new genesis on a protein, that there should be something else on that list. So its very complicated and I think will challenge us to figure out how legislatively and from a policy interpretation point of view to meet the needs of the country's security issues while simultaneously not being left behind on the technology issue.

Dr. Mark Rohrbaugh

I just want to comment a bit on the protections in place under the Bayh-Dole act and the equivalent legislation for the federal labs with respect to the US versus other countries. Since those laws were to spur economic development in the US there are a couple protections to encourage development in the US. Any invention that's made with government funding can be licensed to a foreign entity but there is a preference for US entities. So for example in our portfolio 85% of the licenses are with US entities. That still leaves quite a lot other technologies available for foreign entities. Also there's a requirement that for manufacturing that anything sold in the US market using that technology must be substantially manufactured in the US. But there is a process when there is a need to grant a waiver to give a waiver to a foreign institution to one that's justified as in the best interest of the public health of the US to manufacture it elsewhere. So we find that we can still comply with those regulations and laws and still have a robust portfolio overseas and sometimes also carve up the market so that we might give a US company the US and we can give a European company Europe and an Asian company Asia in terms of the market and sometimes that works in terms of licensing strategy.

Dr. István Földesi

Mr. Chairman I am very grateful to Mr. Sharman that he raised this question. I'm director of the Hungarian Technology Center, which is tasked to help Hungarian IT companies get access to the US market. And I guess that these companies will encounter the problems that you described. This is a challenge and I don't think that it can be solved on a commercial basis; I think all diplomats and policy makers should get together and find a way to solve this problem. I think that the Hungarian IT companies have some products and services to offer to contribute to our mutual defense.

The fields that I would immediately mention are cyber-security and cryptology. And I think that the Hungarian companies again can be very valuable partners to any US company here.

George Handy

Two points before we break. First, I appreciate Mr. Sharman pointing out that there aren't a lot of corporations here today, in fact there aren't a lot of any individual type of participants. The idea was to get as broad a variety as possible of our US sector to begin this partnership with you and the Hungarian delegation. And to keep the table small enough so it would be comfortable talking back and forth to each other. But let me assure you that there is a big network within our activity and a lot of interest on the corporate side to what comes out and how they can participate in the practical events that will follow.

The second point is that, may I say again, it still gets better yet. After we come back from the break we're going to take a look at what is one of the cornerstones both for Hungary and the United States and that's the university picture. And then we will go to where, as the saying goes, 'the rubber meets the road'. And that is the issue of venture capital and some other approaches for the financing of high tech ventures that I think you

will find incredibly valuable, whether you are Hungarian or American. So don't go away yet.

COFFEE BREAK

George Handy

Ladies and gentleman may I have your attention please. We are now ready to begin the last in our segments of activity today, still on the subject of moving from idea to marketplace. We are at the point where we can look at the last segment, which involves two important elements. The issue of the fit of the university is very central in our process, certainly very central in the process in Hungary and the issue of financing innovation. In order to begin this concluding segment it's my great pleasure to introduce Dr. Gene Block who's the Thomas Jefferson professor of biology at the University of Virginia and serves also as the vice president and provost. He has been in the business of education in serious terms since 1978. He's the founding director of an activity called the Science and Technology Center on Biological Timing and that was supported by the National Science Foundation. His work within the state of Virginia and from the vantage point of the great University of Maryland is well-known in this state and I'm sure within the circles of education and within the community that focuses on US-Hungarian partnership. So it's a pleasure for me, Gene, to introduce you and to ask you if you'd talk a little bit about the university role in shaping innovation and as a participant in the innovation process.

THE UNIVERSITY ROLE IN SHAPING INNOVATION AND AS A PARTICIPANT IN THE INNOVATION PROCESS

Dr. Gene Block, Vice President and Provost, University of Virginia

Thank you. I want to make three brief comments that are peripherally related to my presentation. The first is as you mentioned I studied biological timing and I have to warn all of you that at about 3 o'clock you're still in an area called 'post-lunch dip,' where even if you don't have lunch, and that's the remarkable thing, you're going to dip in performance from about one to three. So many of you will have your eyes closed, I will not be insulted, but if I'm not coherent it may be because I'm in this particular phase too. So kind of fascinating the change in performance at just the time when Latin cultures have figured out that, you know, siestas are so important they really have biological importance. But we're resisting that for some reason, that perfectly good idea to rest in the afternoon.

Second admission is when I was invited to speak and I saw that I was speaking late about universities, I thought it is hopeless to put together a PowerPoint because every point will be mentioned because I was betting that nearly everybody would mention a university in their presentations. Everybody mentioned universities, every point has been mentioned. So I'm going to try and work my way around the very good points that have been made so far and perhaps be a little bit combative about the role of universities because we're thinking about them, I think in a fairly narrow sense when we talk about the activities we're talking about today.

Finally, truth in advertising, I'm giving you a provost-centric view of the university. I was vice president for research before I was the provost and I had a very different view, much more in line with some of the discussion today and now I'm responsible for making sure there's enough Spanish classes and enough calculus classes. You do get a different view about the university, I'm going to share that with you but it's a little different perspective perhaps than many of the people in the room have.

So the first point I'd like to make is, you know, the university has three traditional roles. As you know, teaching, research, and service those have been the traditional roles for a very long time and I'd like to say the major technology transfer product we have occurs in May when we graduate with 1200 or 1400 students who go out and most of them never to return to the university. I mean we're talking about a very small group when we talk about university researchers; that's the five percent that come back for advance training. So I would argue the effect we have on our economies is largely shaped by the job we do at undergraduate education. And we learn remarkable things when we talk to companies about undergraduate education. I had a chance a few years ago to sit down with some folks from allied signal, big company in Virginia, and they said technical training, baseline. Give us minimum technical training, that's not a problem, we can train the engineers. What we need are exceptional skills at speaking, exceptional skills at writing, and then we will have first-rate employees.

The emphasis on undergraduate education is obvious, I think to all of us, and hearing it more and more that companies expect, global experience, they expect ethical training, they expect language training, a great deal of facility. So undergraduate education, I don't want to overplay this but in fact most of the individuals at universities leave the university and our first obligation is to make certain they play an important role in technology transfer through moving to companies and playing a role in companies. Research, the traditional role is obviously basic research with some applied research, and a traditional role of service as relevant to today's discussions is really consulting.

And I want to put a word in for consulting because we talk about technology transfer at the universities and we tend to think of a technology transfer in terms of invention, licensing, or revenues to the university. We don't talk much about consulting because frankly, consulting is difficult for us. We're always worried that consulting leads to our intellectual property leaking out the door, without any revenues coming into the university; faculty member gets paid handsomely for consulting. So from the university's point of view consulting is a problem and actually we have policemen, we warn people they can only consult one day a week, we want to know who they are consulting for, we warn them that they can't be giving all their laboratory results out, they can just be using their expertise. In reality we all know that consulting is a huge flow of information out of universities with consulting. A lot of intellectual property leaves the university and from the university's point of view we say that's terrible but in reality that's wonderful. If you look at it from society as a whole, consulting plays a very critical role in intellectual property transfer.

We spent a lot of time talking about the two or three million dollars we make in licensing, but really what our faculty are doing, and especially true in institutions with large engineering programs, most of the engineers are consulting and that's in fact had the universities playing a role in technology transfer. So we spent a lot of time talking about licensing, it's a new activity, commercialization to some extent but in fact consulting is one of the major areas where universities play a role. So I would say traditionally, teaching, basic research, service through consulting are actually critical roles and for any university that wants to serve its community and help grow the economic strength of the area, you have to be thinking about those as well.

So then obviously there are new activities that have occurred over, for example, the last twenty years. So one's an increased interest in translational research. So now, you know, our medical school is talking about creating a center for translational research, there's small centers at our university, many universities have made huge investments in translational research, that's obviously new activity. Technology transfer and commercialization, we've all now grown, we have a foundation that handles technology transfer, we're all making huge investments with only small returns, I might add, in a lot of these activities. But this is happening. Also universities sponsored and supported research parks. We have two research parks. You know we're busy now trying to fill our research parks up with companies. So universities are playing new roles, I think the jury's out on how valuable in the long run these activities are vis-à-vis our other activities. So in fact, you know, it's interesting we're all doing these things and we've all talked about them but we'll have to actually see, you know, research parks, universities what percentage of sort of activity, you know intellectual research activity they actually generate.

So along with all these activities have come a whole new set of problems. We've always had conflicts of interest but now conflicts of interests come in all kinds of forms that we have to deal with. And I don't want to bore you with conflicts of interest but you know we have objectivity and research issues. If a faculty member has stock in a company can they really be objective in their research if their research may impact the value of their stock. Objectivity and research problems with institutions, an institution invents a drug and wants to do clinical trials at our hospital. We as an institution have a conflict of interest because we have an interest in the outcome of that experiment. Now we will say that will not affect the outcome but in fact from the outside world, the outside view, it might be quite questionable.

We have the faculty, and this is something we're dealing with now more and more, faculty and the conflict of faculty as mentor and faculty as employer. We have faculty members who own companies, we have graduate students working for faculty members through their company contract that's left back to the university and all of a sudden you have the difficulty of a person acting both as a mentor and as an employer with a financial interest and, you know, why did the student take seven years to get her PhD? Was it because the faculty member wasn't very eager to have the student leave? Was it because the faculty member, you know you can't determine sometimes in those cases what the situation is and therefore we have to build new mechanisms, and all this means

more rules, essentially, to protect ourselves and to make sure that we can do these activities at the same time that we continue to be equitable in the way we treat students.

There's also conflicts of commitment and I'm going to stop with the negative aspects very quickly but these are just things that I deal with on a regular basis; faculty excessive and intrusive consulting takes faculty away from the classroom, faculty owned businesses raise all types of new issues about how faculty are spending their time, and obviously extensive amounts of faculty participation on scientific advisory boards and on companies also creates a problem. So it's challenging and I think we as a moderate sized university, I think, are struggling with these issues much like all of you associated with universities.

So how do we promote innovation at universities and how do we promote innovation above the baseline of how we promoted innovation, let's say, ten years ago? And I point to a couple of aspects of innovation. So the first is that private philanthropy in American universities plays actually a pivotal role in innovation that often its not given credit for. Most of what we do that's innovative, the state of Virginia, and the federal government really doesn't pay for it to get-go, they may pay for it eventually but not initially. Almost all of our innovative inter-disciplinary programs seed research monies, fellowships, graduate student fellowships, especially for students, international students that can't get US supported fellowships all come about through philanthropy. Our university raised about 1.6 billion dollars in its last capital campaign, its announced a campaign of 3 billion which we hope to collect over the next seven years. These are huge campaigns that involves everybody's time at the university and it's a distinguishing characteristic of American university now both public and private that philanthropy is the pivotally force for innovation. And most universities, our university now has 8.5 percent of its total support comes from the state of Virginia, if you take our entire operating budget, whereas the research budget from the federal government and philanthropy are your two largest factors along with tuition in supporting the university.

So I'd say key, and this is not a tradition among European universities or its just starting, is philanthropy is going to be critical to be innovative because somebody has to pay for it before proof of principle. Seed funding through philanthropy pays for all these innovative things you can do at universities that you cannot get NIH support for, until you've really proved you're a little further along, and pays for a lot of core activities. Many of our endowments pay for our core facilities, actually at our medical school, things that are hard to recover if you can't charge an investigator enough for histology lab or a cell culture lab, those are all paid for through private endowments set-up at the university. So when I think about innovation, I first think about dollars, actually private dollars, and that's a critical part of it and then I think about the second part, I think about trying to break down the traditional barriers of disciplinary research but providing interdisciplinary opportunities. I'm not telling you anything you don't know here. Everybody's experimenting with how to generate more interdisciplinary opportunities and the requires space that's not owned by individual schools, its owned by the university where schools come together. So you have a business school and biologists together in the same building. I mean the surfaces where people interact have to be pretty close, you know, if you're even downstairs from someone it can make a difference in the way you

interact. So creating multidisciplinary buildings is a big part of multidisciplinary activities. So I think that we as many universities are again, catalyzing innovative research and I think we're doing that again by adequate financial support for international students, by providing new space for interdisciplinary activities, for providing seed funds for high risk research that gets you really some of those interesting data, and core infrastructure, like quantitative infrastructure, paying for the bio-mathematicians who probably can't support themselves off of grants because of the service nature of their work. So there's lots that can be done it all takes dollars and my bottom line on that is that its private dollars that's driving a lot of that.

Finally, just an impression, I had a chance to visit Budapest Technical and Economic University about four months ago and that was a remarkable experience. I'll just share some observations. I spoke to probably about twelve faculty who have active research programs, probably more but twelve that I really focused on. And the thing that struck me which is so intriguing was, because we're sort of on the opposite side of the divide and stage of development, Budapest Technical University has incredibly innovative faculty and their doing innovative things. Most of them do have relationships with companies. Many of them have started their own companies. They have relationships, they're entrepreneurial, they're positive, they're incredibly optimistic, but they're pretty unregulated. I mean its like the Wild West, you know, I think they're not being overseen by a lot of rules and certainly that's a negative and a positive. I mean I think what you see is a tremendous amount of innovation because its pretty wide open but I was impressed by how many faculty had things going on, you know with Nokia, with Ericsson, they are all kinds of relationships that have been established. So the faculty have figured it out. So I don't think that's the lesion if you're worried about technology transfer. What was missing, I'd say, it probably needs a bit more oversight for regularity and was missing was real central assistance at the level of the university administration. I mean technology transfer offices, people who are knowledgeable about reading contracts. So a lot of folks were signing contracts with companies without a whole bunch of oversight because there wasn't any central university resources being dedicated to that. So I was thoroughly intrigued because I think great things are going to come out from this sort of early phase where there's a lot of sprit and a lot of thoughtfulness but not a lot of oversight. So I was very impressed, I left with, I think, a feeling that things are going to move very quickly when the mechanisms are in place.

What I leave you with is we have to remember that universities play a much larger role than their technology transfer offices, they're transferring technology in a whole set of ways from the students that leave the university to consulting as well as our technology transfer and that innovation is best funded through philanthropy. And that getting universities in Hungary into the tradition, graduates into the tradition, of supporting the universities, the state-universities, is going to be a challenge but its well worth it. If you can develop a loyalty when students leave the university that they feel it is their responsibility for when they leave, to help support it, however little, it's very valuable. And if you would like help with development and visit I'd be more than happy to have our development folks spend time. Development at universities is really a well-developed effort now and there's quite a bit of methodology associated with it and it takes a long time but we'd be happy to share our expertise we're certainly competing for

different donors so I'm not nervous at all about offering that. And I'll stop here, thank you.

George Handy

It's a logical step from where the last four speakers have taken us to the point we go to next. And that's the issue of venture capital. In order to present a picture of the venture capital function and the challenges of financing innovation and high technology growth. We went immediately and we're very happy to find acceptance from Linda Powers. Ms. Powers has worked with CSIS on a number of occasions and we're proud of that association. She has seed and early stage venture capital experience she has been involved in corporate finance and restructuring, merges and acquisitions, joint ventures, and she has been appointed to three governor's commissions. She is on various boards and councils, particularly including the National Academy of Sciences and NIST, and it's a real pleasure to invite you to take the floor and talk to us about this very mysterious function.

EARLY STAGE PROJECT FUNDING AND CONDITIONS THAT ATTRACT VENTURE CAPITAL

Dr. Linda Powers, Co-Founder/Managing Director Toucan Capital Corporation

Thank you and it's good to be back at CSIS after a gap of 10 years or more, I think, since I last talked here. And I think we have to take the advice of Mr. Duda from this morning to hurry up and get over to Hungary before all the universities get highly regulated like Gene is going to help them do. What I'd like to do in my 15 minutes here is try to walk through the landscape a bit of early stage venture capital. Give a little bit of the sense of why it's so hard to attract early stage venture capital to commercializing technologies, what are the kinds of things that will succeed in attracting it, and what are some of the kinds of initiatives that a variety of American states are trying in this regard, cause you've got a giant experiment going on.

So let me start just by setting the scene about this giant experiment with the US states. California and Massachusetts, I think, most people know are totally in a class by themselves in terms of both on the innovation side, the research side and on a commercialization side. And what's interesting is when you look at how the pie is divided up, California and Massachusetts are getting more than proportionate share of the pie in the case of capital availability than they are of research dollars. So that should right away tell you that there's a different set of factors at work determining success in the research arena versus the commercialization arena. Apart from California and Massachusetts the other 48 states, 41 of them have all undertaken big programs to be in the top five or top ten states within the next five or ten years and they're all going to be there, they're sure of it. So it's going to be very interesting to watch. Our investment fund is working closely with five of the states and with four foreign countries, three of them in Asia and one in Europe that are all trying to do the same thing. And the first thing I would say to everybody is there's a lot of data out there, there's a lot of accumulated experience about what works and what doesn't and some people have

mentioned not reinventing the wheel especially not reinventing the wheel on mistakes and I think there's really a lot to be learned and the opportunity for Hungary to leapfrog over a lot of experience of US states.

The key message I would lay the scene with is that strength in research does not necessarily correlate with strength in commercialization. Just to give you a sense of it, here in the mid-Atlantic this is the third largest region of the country, the state of Maryland is a good example. I didn't put this in writing on my slides but it's something that the state of Maryland is very concerned about. They are extremely strong in research and they are extremely weak in commercialization.

I just want to give you a sense of my perspective and where I'm coming from because it will give you some sense of how I'm looking at things when I'm describing them to you. Our fund is actually a very unusual fund, we're a venture capital fund, we're located here, we focus mainly on life science but we do high tech, nano-tech, advanced materials, and so forth also. We're one of the four largest life sciences funds in this mid-Atlantic region, third largest in the country. We're the largest fund specializing in seed stage companies meaning creation of companies from scratch and building them to either an IPO or acquisition exit. We do this in a very hands-on way and part of the reason we're able to do that is because of our in house team of PhDs, engineers and MDs. I think it's also important for policy makers to understand how much just one or two or three funds that we do what we do can contribute. This is our third fund; we've seventeen companies in the portfolio right now eleven of the seventeen we started from scratch. Sixteen of the seventeen are fundamentally novel technologies. These are stem cells, these are gene therapies, these are fundamentally novel technologies and they were all at the very early stage, just coming out of the laboratory, many of them hadn't even reached proof of principle when we entered with our first investment financing. That's very early.

Another key point, when you're going to build companies you have to amass intellectual property, typically from a good half dozen or more universities, labs and so forth. It is very rare today that one single university has invented all of the intellectual property of an entire enabling platform that's sufficient to build a company on. So in just these seventeen companies we're working with close to two dozen universities in ten different states as well as NIH and the federal labs. That's how much technology we had to piece together to create these companies.

I also always think that people underestimate the economic development effects of just having just a few venture capital funds like us. We've created over 200 new jobs in these small companies and these are great jobs. They're everything from technician to senior scientist jobs. We've created over 200 jobs in three years and the growth is accelerating cause these are young companies. I love to use Lilly and its colleagues as my benchmark for this sort of thing. I always say it only takes three of us to equal one Lilly plant. But most economic efforts are oriented towards the one big Lilly plant, as they should be of course. But people don't realize the scale of economic creation that can happen in a rapid period of time with relatively small amounts of venture capital mobilized.

This is just a little sense of the novel that we're focused on, novel technologies; I'm just going to pass right over this.

All of the 41 states, the reason they all got these initiatives underway is because everybody is concerned that nobody has enough capital availability in the 'value of death,' the seed stage. I would suggest this is a market imperfection. Look at those financial rates of return. As it should be the earlier high-risk investments of seed stage VC has consistently returned higher financial returns than later stage venture capital. Now just for those who aren't in the financial industry, the one and three-year returns are always negative because you're putting the money into the company but haven't yet harvested and taken it out. So you look at all those columns, five, ten, and twenty-year returns and the returns are always higher financially.

One other thing is, its not only the early stage venture capital returns that are higher, later on when companies have exited by IPO, if you look at their performance as they grow up as a company, the stronger performers have tended to have the novel products not the need-to products. And this is just a sampling of some of the recent IPOs in this current IPO window in this country.

The perplexing thing is, despite the financial returns and the sustained financial performance of companies after IPO, seed and early stage gets the smallest sliver of total venture capital funding. As you see, and these numbers hold true over years and years, these are recent numbers, 2003 and 2004, its one percent of total venture capital that's going into seed stage. So all this tech transfer that we're talking about is all competing for that one percent of capital availability. Read as a pie chart it's that tiny blue sliver.

So why is this the case? Why are VCs sort of holding back despite strong historical returns and what do they look for? I think the comment about it being a mystery is a very common comment. People tend to view venture capital decision making as sort of this weird black box and its hard to understand why venture capitalists choose some things to invest in and not other things. The sorry truth is a big part of it is just plain old herd mentality and we all run in the same direction as each other. But when we're being sensible, I'm going to go through a couple of slides that tell you kind of what VCs look for.

In really simplified terms this right here is exactly what VCs look for. They look for large profit potential, they look for an exit time frame, that means how long until they can cash out and take home their profits, and they look for an acceptable risk profile. And I've given you just a sense of it. Different VCs will give you different requirements of how much profit they're look for. But whether its 10x or 7x or 12x or whatever its not 2x if you're an early stage venture capitalist. So that means if I put three million dollars into a seed-stage company, that technology has to have so much market potential that after subsequent rounds of financing and my small percentage of the company, it can be worth ten times that amount, thirty million dollars.

Not all this comes to pass. Lots of them fail, not unlike drug product development and the winners in the portfolio have to overcome all of the losers in the portfolio. And those

are the scale of returns that venture capitalists look for. So one of the most important things in technology transfer is that first fork in the road decision of whether the technology in question is really suitable to build a company around or whether it should be licensed to a big existing company. Sometimes the technology is really great but it's just a particular product, a new kind of imaging or a particular drug molecule or whatever; as opposed to a broad enabling platform. And in those cases where it's just a particular product, that's not suitable for building a company around.

The exit time frame needs to be three to five years or shorter. People often forget venture capitalists themselves are in a food chain too and we have investors that we answer to; the investors who put the money into our funds that we turn around and invest in the companies. It's like that cartoon with the small fish and the bigger one behind it, swallowing it, and the bigger one behind it. So our investors won't wait forever for their return either. A typical venture fund is set up for a ten-year life, the first five years are investing the money, the second five years is making follow-on investments and harvesting and exiting. And typically it doesn't take the whole five years to invest and it doesn't take the whole second five years to exit but that's the scale. So that each individual investment needs to be not more than three to five years, you can start thinking about some of these technologies you want to commercialize and asking yourself, especially with biotech products if I'm three to five years away from an exit, where do I need to be before a venture capitalist will come in. And the risk profile, that's its own subject we'll come to that in a second.

So when VCs evaluate whether there is 10x or 5x or whatever X profitability potential, they look at factors like this and I won't go into them, I think you're all going to get these slides on hard copy and can look at them. It's the size of the target market and so forth. I think what's more interesting is if we talk about time frames and risk profiles cause those are more the black box aspect of venture capital decision making.

Here's the famous valley of death, in biotech, say this is a biologic, new bio pharmaceutical product. Start with the most important piece of this picture to a venture capitalist, it's the red arrow on the right, potential exits, that's my cash out. So the first eligibility of a company to be acquired or to go IPO is usually not before the end of a successful phase two, human clinical trial, at least. So late stage human clinical trials. Remember I said that venture capitalists are in a food chain and they have to be out of an investment within three to four years. So just do the arithmetic, subtract back from there, and you see the first red arrow and you immediately, and suddenly it all becomes blindingly clear, why are venture capitalists so uncooperative and they won't typically put money into a company until it's at the threshold of clinical trials. Well right there that's why and that leaves that whole valley death period that most venture capitalists, unlike our crazy fund, won't touch that. That valley of death is where we specialize. But that is the timeframe aspect of the black box.

Risk is really important to understand. One of the important things I was taught early in my career is that risk is not something to be avoided it's something to be chosen selectively and compensated handsomely for and in the meantime manage the hell out of. So when venture capitalists look at different kinds of technologies, and I've just given a

few examples in the left hand column, and they evaluate the risk profile. First of all they look at the time frame for a product getting to commercialization, to being on the market, to generating revenues, you've got short, medium, long timeframes for different kinds of products in the chart. Then there's also, how big is the pay off. You know, investments in tools companies were really big for a while and now it's really hard to get a venture capitalist to put a nickel into a tools technology because the pay off was way too small. Medical devices, it varies, the payoff can be small or it can be quite large. Payoff is big in the other categories.

Now here let's look into risk. Technology risk, well everything has technology risk. Technology risk just means does the technology work or it doesn't. Okay, fine, everybody's on the same footing there. Regulatory risk just means do you have to regulatory approval before you can sell the product and how tough are the hurdles. Then you get into the really nitty-gritty, pioneering risk and what I call spillover risk. Pioneering risk is, if you're the first party; say taking a stem-cell technology through the FDA process. Everything is being figured out for the first time. How many animal studies do you have to do? Is one on small animals alone enough or do you have to do primates? If its primates, is it six months, or is it twelve months or is it eighteen months. All of those impact hugely directly to the bottom line in terms of the timeframe until exit and the amount of money it takes to get to exit. So being a pioneer, you know there's all this conventional wisdom and maybe its more true in IT and so forth, first to market, being first to market in some industries is a real cost and risk factor. Lastly, spillover risk is something people often don't think about, but here's a very simple illustration. When you're in a pioneering technology and something goes badly wrong and you're in a clinical trial and you kill a patient. For example what happened at Penn with the gene therapy trial, then everybody says that gene therapy, that whole category is bad. If somebody's developing a small molecule drug, and something goes badly wrong and they kill a patient in a trial, people say that molecule is bad, not that that whole category is bad. And what does that means for an investor is that if you're in one of these pioneering areas and somebody else completely unrelated to you screws up big time, your whole field can get shut down for years and you can't go anywhere and you can't exit and you can't do anything; even if you had the best technology, the best management team and you did everything right. Does that scare the daylights out of investors? You bet.

Having talked about the venture capital landscape and that small blue sliver that tech transfer has to all compete for and having talked about how this mindset, the black box of venture capital decision making works, my last segment is going back to the beginning; a few points on initiatives that these 41 states are trying to attract a disproportionate share of that blue sliver, the venture capital. And one of the first and most important things before any state or country embarks on this is they really have to focus on technology commercialization not invention. I can't tell you how many governor's commission sessions I've sat through where we're trying to figure out how to build an industry and people say well the first thing we need to do is get some world class faculty added to our universities. Well that's a great thing to do on its own but it has nothing to do with building an industry, zero. The focus has to be on commercialization. The second point I cannot emphasize enough, universities and states and others always underestimate how

mobile technology is. Technology can go anywhere. I'm commercializing technology here locally because I'm writing the checks so I tell them where they're going to be located. From universities in ten different states around the country as I said, I'm taking technology from Louisiana universities, California, Washington state and I'm putting it in companies that are here in Maryland. And the reason I'm doing that is because I'm writing the checks so I get to say where it is and that technology can go anywhere.

So you can have a huge value and not get the commercial value captured is where the research value is. And that remains true until a company reaches a fairly good stage of development; it remains true certainly all across the valley of death and into early clinical trials for a biotech company. The biggest determinant and the biggest problem that biotech companies and other startups, non-biotech companies also, face, and this is why it determines where they get located, is getting the funding that they need. And lastly, I've already touched on the point about the allocation of state resources, how many does it take to equal one Lilly.

So if one has the right perspective, first there is a taking stock of what kind of mix of anchors and small biotechs and this would be true of any industry, high tech, whatever, capital availability, concentrations, clusters, I already spoke about fully, competition from other states, particularly key as to geographical proximity and or particular sectors where the state really wants to develop a leading position, because its going to be hard for states to develop a leading position in everything. The state budget situation usually dictates that whatever incentives are done need to have minimal cash involved and again remembering the factor in deciding the state game plan is the most effective tool is money.

These are the sources of early stage money in the US; I'm particularly focusing on venture capital funds. I would not overlook corporate partners, a recent trend in just the last two years in the US, is that corporate partners, the pharma companies of the world, have been more gutsy than our fellow venture capitalists have been in doing early stage deal. So there are several kinds of incentives that states have tried and as I said there's lots of accumulated experience. Incentives tied to making the investment, incentives tied to mitigating losses and incentives tied to successful investment result. I don't really have to go into all of those and these are the four that I have here, and number four I think Tim's going to talk about a little bit cause he's got a good example of that in his program are the ones that have worked the best in actual practice in US states. But let me close, this is my last slide and just let me spend my last 35 seconds on this. There is a really great opportunity and I think that Hungary is really well situated to do this. One of the most powerful things that a state can do is use their credit capacity, not cash, their credit capacity, to guarantee pension funds and other large investors against losses. If they invest in a venture capital fund and that venture capital fund, there's always eligibility requirements, a number of state programs in the US are good examples, now a venture capital program has to put its money, at least X amount of money into early stage biotech in Hungary, you have free mobility of capital, for the most part, in Europe now. You have major institutional pension funds, if you only make experienced venture capital funds eligible and if you only say to the say pension funds, we're only to make you whole on losses on the overall performance of that venture capital fund, not any one investment

cause they're all going to balance out with each other, the risk is very low that you'll end up having to ever make a payment on that. If you do ever have to make a payment on that its five to ten years in the future when the venture capital fund is all done with its ten year life, depending on whether you put the guarantees at the beginning or not, and pension funds are the largest, hugest pools of money you can mobilize and it works.

George Handy

Amazing, a great layout of possibilities, and some invaluable constructs of understanding. Its also amazing that Fairfax County and the University of Virginia are not the only great things in the state of Virginia. There happens to be something called the Virginia Center for Innovative Technology and Tom Weithman has been talking with me over the past several weeks about the center and about the kind of functions the center enters into, in terms of wrestling this problem of obtaining and investing revenue from a different standpoint. As Ms. Powers said, from the standpoint of state seed funds and from the relationship of a center to a government organization. Dr. Weithman, we're glad to have you here, you're experience with the Center for Innovative Technology extends back over some time frame. I should point out to the audience that you also were business development manager for Hughes Electronics and that your work within the state of Virginia has involved you with a wide range of activities familiar to the audience here today. So we're looking forward to hearing from you. The floor is yours.

INCENTIVES AND CONDITIONS THAT DRAW PRIVATE INVESTMENT INTO RESEARCH AND DEVELOPMENT PROJECTS

Mr. Thomas Weithman, Vice President Entrepreneurship and Investment Services, Virginia's Center for Innovative Technology

Thank you. I'm not a doctor although I will never turn down a promotion so I thank you for that. As Linda indicated there have been a number of experiments tried throughout the United States at the state level to solve some of the problems that we've heard about today; economic development issues, several that have been oriented around technology. I'd like to start out with just a little bit of background on CIT perhaps a very little bit of background.

What is CIT? CIT is a state level economic development organization, a science and technology organization that goes back to the early 1980s. Several such state initiatives were put together about the same time, probably the earliest was in Pennsylvania, the Ben Franklin Partnership, was followed by similar efforts in Virginia, Massachusetts, many took on somewhat different configurations, different missions and many of them have changed over the years to adapt to different political climates, different economic needs, different budgetary realities in a state. Virginia is no exception to that. As I recall the history and I've only been there for about six of the twenty years of the organization's history, it started out as a centralized tech transfer office, if you will, for state universities. As universities developed that confidence and expertise, CIT backed out of that business and became more oriented toward solving the kind of, rubber meets the road needs of small technology businesses. We're structured as a non-profit corporation, so we're not a part of the state government apparatus. We have a professional staff, and as

the gentleman from McGuire Woods pointed out earlier, there is a secretary of technology in the state of Virginia and we report to him.

Well, CIT's mission is very simply put to accelerate the next generation of technology and technology companies. We have a very well thought out operating plan that brings that mission to reality. Its organized around three major goal areas and I'm going to spend most of my time today talking about the third goal, this is the one with which I am most heavily involved. We have a couple of efforts to stimulate R&D in the nanotechnology/life sciences areas and have also launched the institute for defense and homeland security. But I want to spend most of my time as I mentioned, around goal three. I'm vice president of entrepreneurship and investment services. I have responsibility for the first three of the four bullets under goal three. My group helps early stage technology companies to attract early stage funding to help develop technologies. Funding from the federal government, we heard about the SPIR program, the STTR, ATP program today. There are other sources of federal government funding of a non-diluted sort that helps early stage technology companies bring their technology to market.

We also work with companies at facilitating private placement. So we act as intermediaries with the venture community with various angel investors and as of January we're also doing some investments on our own. We'll spend a little bit of time talking about that, our GAP fund, our GAP Seed fund, which I believe is a fairly innovative approach among those tried by different states. We have also for the last several years provided an element of consultative support, one on one guidance and direction to companies throughout the commonwealth through our seven regional offices. So we have pretty good visibility into the many technology companies, not just in northern Virginia, but also in all areas of Virginia, through south-side, Charlottesville, the Roanoke Valley, Hampton Roads, Richmond.

George asked me to talk a little bit about how we bring funds together to execute against our mission and the primary source of funding is the state of Virginia, we're still getting about eighty percent of our top line revenue from state level appropriation. And the challenge with non-profits is always to measure its efficacy, measure its return in the absence of a true profit motive. We've tried to do this over a period of several years and we think we've done a pretty good job of it in putting together a system of measurements such as we have laid out here. I'll just walk you through what those are.

It is these measurements and our return against stated goals for each of those metric categories that provide our justification for the Virginia General Assembly to fund us each year. Our three measures our cash, leveraged cash and economic value. By cash we mean money into CIT to underwrite its basic operations in different projects that we take on. An example of cash into CIT would be federal government contract revenues that we bring in, in exchange for obligations that we have bid and won and have taken on. For instance, we won a contract from Defense Logistics Agency to start a procurement and technical assistance center, in Charlottesville, to help small companies in central Virginia to access federal and state government contract opportunities.

Leverage cash is money that we bring to bear, that we facilitate and bring to bear for Virginia entities. If this were an example this would be money into a company, private sector money into a company or perhaps SPIR funding into a company that we are able to help them gain. Finally, economic values, the sum of wages and sales gains that results from our work with a company over the course of the year. As is Bob's priority to keep programs very critical to measure the outcome of your activity to be able to present this to potential government funding sources and we feel we've done a pretty good job doing that. Our total return last year was about \$119 million and that's against state funding of 7.6 so you can do the math and figure that's a pretty healthy return, somewhere between 15x and 16x on Virginia's investment.

In terms of what we do to help Virginia's start-up technology companies, there's a laundry list of things, I won't go into all of them. Point to the access of capital, again what we do in helping companies gain access to private funds, such as Toucan as represented by Linda here today. Federal funding assistance, we offer a variety of educational programs as well as one on one assistance to help companies apply for things like the ATP program, SPIR, STTR program and I would point out that while we are perhaps somewhere behind California and Massachusetts by some measures we're running against them fairly well, given the amount of R&D investment we've had in terms of SPIR, STTR, we are third in the nation behind those two states for aggregate SPIR, STTR dollars brought in. We at CIT like to think we're a pretty important part of that.

We offer various educational forums, I mentioned government procurement assistance, we do some other things in that area, as Gerry Gordon mentioned earlier. When you've got the biggest potential customer sitting in your own backyard, shame on you if you can't take full advantage of that. So we believe the technology companies should always look toward the federal government, perhaps not act on it but at least consider the federal government's prospective funding sources for R&D development and for government contract opportunities. Its up to them to determine whether is a right fit for their business growth and we offer various sundry forms of business development assistance as well.

Next, I want to talk a little bit about our GAP fund, our GAP program. We developed this program having surveyed what many of these 48 states were doing to solve early stage capital issues around the country. Certainly anecdotally, we needed in Virginia much of the Angel money in the very early stage venture capital funding that was available through the bubble period through 2000 had moved out to the right was no longer available to early stage technology companies. We confirmed that by gathering empiricals, such as they exist, for this very early stage investment on the state level, we work with Jeffery Sol up at the university of New Hampshire to document the amount of Angel investment deployed around the country, in the mid-Atlantic region, and across the state of Virginia. And lo and behold we did confirm the information that we had gathered anecdotally and we saw a need for the availability of funding at the very early stages at the pre-seed to seed level. And so having looked at what other states were doing to try to meet a similar need, we looked at Pennsylvania, we looked at Maryland, we looked at Rhode Island, we looked at California, several others.

We launched a GAP program, a growth acceleration program in January of this past year and the mission of the GAP program as the slide indicates is to provide the earliest stage funding to high potential, and this is a key word for us, high potential Virginia technology companies, to move technology from bench level research out to the marketplace. And what we consider a high potential company is a company that is likely to go on and get downstream private equity funding en route to a high multiple exit. Now absent from this definition is any focus on typical economic development metrics like job creation or like new company revenues and we focused rather on the ROI potential of investments because we believe if we invest as professionals would, with an eye toward building a company that these traditional measures will follow. A high potential company will bring jobs with it, good paying jobs as Linda mentioned, and help form clusters of like companies, as was discussed earlier and the rising tide will lift all boats.

Now here we're going to take a deeper dive into and talk about exactly where we invest and how we go about doing this and you can see, if you can imagine in terms of the SPIR program where we are, we're probably pre-phase one SPIR just to post phase 2 and we're looking at putting in very modest amounts of funding; about \$100,000 worth and always in the form of convertible debt so we don't have to haggle the terms of valuation with these very early stage companies where it's, perhaps impossible to determine the investment. We're also looking for a place where we can add substantial value with some of CIT's legacy services, where we can do market research, where we can help coach the management team, or where we can help develop the business plan, or we can help them on their investor presentation. In route to getting that qualified financing from Angels or series 'A' investors. Now often times a 100k, that's a very small amount of money, a 100k is just that a 100k. So we're looking for a clearly definable business or technology developmental milestone that that 100k can contribute toward. That 100k may not get to the prototype it may not get the patent position that you want but it might contribute to it with some matching outside financing. So in the subject of leveraging outside capital we think we are right on here and it is typical that we will write a note that is dependent on a company gaining an additional 150k or 200k of additional outside capital at this early stage.

Our investment criteria, we are chartered by the Virginia General Assembly and so we invest in Virginia companies. We are looking in the technology sector given, the size of our fund, the amount of money we have to invest we're somewhat limited in the life sciences. We probably can't be a player in terms of bringing therapeutics to market and we would look at other forms of technology in the life sciences that perhaps have a lesser capital requirement. We mentioned what we're looking for in terms of high potential companies. We're looking for something that resembles a completed business plan, recognizing that at these very early stages the business plan, the business model, can change drastically within the course of a fifteen minute discussion. And by way of that we're looking for evidence of the entrepreneur's commitment, whether it is in equity or additional cash into the venture.

Our seven step process of how we go about doing this, nothing too out of the ordinary in terms of an investment cycle. I would call attention to two boxes, its step 3 in the upper right, step 5 in the lower left, company presentations to outside panels and

recommendation to our investment advisory committee. We've got a staff in-house that does the initial cut of due diligence but apart from that we've been able to leverage substantial resources from the early stage investment community through the good graces of Linda and her partners, we have Toucan represented on our investment advisory board. The investment advisory board is the agent that actually makes the decision on whether to invest or not, only one CIT person sits on that committee, that is our president, its composed of seven people so we always have potential tiebreaker. But our investments are made by professionals so the question at the table is never "is this a good business decision for your fund to invest in?"; the question rather is, "can it get to a point where it would be a good situation in which your fund might take interest.?" So we are looking to add value along the way as a company is put in our portfolio and ready companies for downstream investment. So we're the little tiny fish in that food chain.

In terms of our value proposition we believe that we are providing critical seed stage and pre-seed stage funding. We have a relatively short turnaround on what are cookie cutter investments. We're doing these as convertible debt. The terms are nonnegotiable. We think we can get an investment turnaround in roughly sixty to ninety days, which is good for the entrepreneur. We bring access to federal funding, again funding which is non-dilutive in nature. We think that adds value to the company along the way to the eventually funding event. We have other value add services and we offer access to the broader GAP team, folks that are on our investment advisory board, that might otherwise be difficult for companies to access and entrée to Virginia's Entrepreneurial Community.

In terms of leverage of private sector investment, I guess this was one of the original subjects that I was trying to discuss here. I guess I'd say that leverage in the private sector is built into CIT's overall success objectives and metrics; that we have as a requirement or our success is measured against as an organization and as individuals within the organization on our ability to bring private sector and federal funding to bear on the activities that we undertake. We have significant private sector contribution to investment and in the risk mitigation processes of our investment both before and after. We have in kind contribution by the entrepreneurial and often times third party match by investors.

So this is looking at a microcosm of our activity and how we bring private sector investment to bear. That's on projects more and companies, that's our contact information, I hope I made my time limit.

George Handy

Would either Mr. Lewis or Dr. Cassell want to briefly revisit the point that we highlighted this morning on the fact that you do have to not only invest in what pays off and produces but you have to invest in activity and structure that doesn't pay off and produce, in order to make sure that we leave this picture in complete honesty.

Dr. Gail Cassell

I think a couple made the point during the discussion in the afternoon and I remember most vividly Linda's presentation that you need to think about its more than innovation. I remember Dr. Block's presentation; I think it came up in it as well. Spending on science

does not guarantee economic growth, its necessary but its not sufficient. What I think you've heard in the afternoon from the last two presentations in particular are some of the other things you would need to turn that invest in science into actual economic return. And so its interesting to think about science but that's just part its necessary but not sufficient.

I think here is where Japan is a very good case study. And that is that about three years ago Japan looked at their investment in research, realizing that they had been funding basic science research and research in general, in relationship to their GDP, higher than any other country in the world. And yet the problem was that it was not been translated into productivity in terms of their national productivity.

We said of course we cannot afford to continue to do this, we have to figure out what we've done wrong. And I have to hand it to them; they did, I think, a very systematic analysis, trying to get at the bottom of this. Concluded they were right in the valley of death and had nothing really to ensure that you could get out of the valley of death. So they began number one to change legislation, which we've already referred to but in addition to, set aside monies to try to promote interactions between public and private sector. You may know that they have dramatically changed their universities, privatizing many of them, reorganizing many of them and even shifting them and I would suggest that this might be something that you would want to do. And that is to pay a visit to Japan and I think the other thing they've done is to set up a science and technology council so that there's constant interaction between the scientists and the government.

I can just say that last summer I was lucky enough to witness what they've done in Kobe. They've built a research city, which includes a man-made island, a hospital for regenerative medicine, to do the clinical trials on new cell based therapies that they're developing in the building right next door, which is the Center for Developmental Biology. The Center for Developmental Biology is interesting in itself, in that they looked around at all the prestigious universities and pointed to the individual scientists, you, you and you, we want you in Kobe. They moved them, they're all under the same roof and by the way they have a building for bioinformatics in the same center and in addition a building for offices for venture capitalists and as only Japan might do it, they are building an airport so that venture capitalists and others can fly in and out even though the Osaka airport is only an hour away. I'm not saying that that's necessarily the wisest thing to do but it might be very interesting to see why they went for this period of time where they were making this large increase in investing in research and yet it not being translated into productivity. Thank you.

George Handy

Thank you. Ms. Powers, Mr. Weithman would you be kind enough to remain after we adjourn so that those people who have some questions in this area would have a chance to offer them. We have reached the end of our planned journey today. We will provide fairly quickly copies of the slides that have been presented today. You'll get them electronically and if there are any slides that any of the presenters are concerned about and would prefer not to have them distributed or distributed only on a limited basis, just let me know. Second, we will prepare a work plan for practical cooperation that will be

out in about a week and a half to two weeks. Number three we will prepare a detailed report of everything that has transpired today as a reference point for this process.

Dr. Boda and I talked about step two as being particularly important that is the work plan for further practical cooperation and Prof. Kroó has indicated guidelines for it as well. What Dr. Boda and I agreed on was that we would put together, within the American community, an initial straw men or set of working issues, along with a group of people who are prepared to cooperate on those issues. We would send that to Dr. Boda, Dr. Kroó, and Minister Jambrik would then field that with the Hungarian side, ensure that we have added to and gotten a good mix of common interest and also Hungarian participants. Once we get that back we'll then put together this plan of cooperation. We'll send that to everybody and then we'll set in motion some instructions for first exchange, so that it gets off the ground and people are actually connected. This is our approach and in following this approach we will reflect the kind of emphases that have been described today on the how aspect, on the people dimension of innovation, on the issues of SMEs as well as large, on the market opportunities that are reflected through the EU, on issues that are theoretical and practical, such as cluster theory, on the issue of two-way research and study, on the nature of the investment process as its changing both in the US and in Hungary, and on the financing aspects as they have been so expertly covered.

The last point I'd like to raise then is to express the sincere thanks of not just my program here at CSIS, but CSIS in general, for the superlative presentations and the extraordinary discussion that we have all witnessed today. I don't think we could have asked for better and we would not have gotten it had it not been, as I mentioned this morning, for the inspired leadership and direction that's come particularly from Eli-Lilly Company, very generously laying out a situation from which all corporations will benefit. And that particular goes for Mr. Briggs, Dr. Cassell, Mr. Fehervary, and we would not have succeed without the skillful management of Dr. Takács. And you have noticed a rather extraordinary crew that has moved around here, all guided by Laura Jones, who is the assistant director for my program, and Zdravko Zdravkov, who is a staff member of the program. And I'd like to ask you to give them a well-deserved round of applause.

It's been thrilling for me to be part of this and even more thrilling to look forward to the steps that lie ahead. I do that particularly because I know that the partnership is one of extraordinary quality; thank you all again for coming and sharing your valuable thoughts and perspectives