

UNITED STATES DEPARTMENT OF COMMERCE

TECHNOLOGY ADMINISTRATION

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BIOCENTERS OF EXCELLENCE ROUNDTABLE

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WEDNESDAY, JULY 24, 2002

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The Conference commenced at 1:00 p.m., in the Department of Commerce Headquarters, 14th Street and Constitution Avenue, N.W., Conference Room 4830, Washington, D.C. 20230, Samuel W. Bodman, Deputy Secretary of Commerce, presiding.

PRESENT:

SAMUEL W. BODMAN	Deputy Secretary of Commerce
LESLIE ALEXANDER	North Carolina Biotech Institute
ARDEN BEMENT	National Institute of Standards and Technology
RICHARD A. BENDIS	Innovation Philadelphia, Inc.
W. STEVEN BURKE	North Carolina Biotechnology Center
SAMUEL I. DOCTORS	Advancing California's Emerging Technologies
WILLIAM P. DUNCAN	Kansas City Area Life Sciences Institute
JAMES S. GREEN	Cumberland Emerging Technologies Fund
JEFFREY GROGAN	Monitor Group
MITCHELL HOROWITZ	Battelle Technology Partnership Practice
JENNIE HUNTER-CEVERA	U-MD Biotechnology Institute
BRUCE P. MEHLMAN	Assistant Secretary for Technology Policy
ANTHONY R. MOREIRA	UM-BC, Council of Biotech Centers of BIO
ROBERT OLSON	Fitzsimmons Redevelopment Authority
THOMAS ROGERS	Technology 2020; Tennessee Technology Development Corp.

PRESENT: (Cont'd)

MARK ROHRBAUGH	Acting Director, Office of Technology Transfer, NIH
ROBERT H. RUBIN	Harvard University, MIT
MORRIE RUFFIN	Bio Technology Industry Organization
DAVID SAMPSON	Assistant Secretary for Economic Development
RICHARD SELINE	New Economy Strategies
JAMES D. SKINNER	NC Biosciences Industry Organization
ROBERT E. WITT	University of Texas, Arlington
BENJAMIN H. WU	Deputy Under Secretary for Technology
GILLIAN WOOLLETT	Pharmaceutical Research and Manufacturers of America

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(1:09 p.m.)

DR. BODMAN: If I could have your attention, please.

First, to introduce myself. I'm Sam Bodman. I'm the Deputy Secretary of Commerce. For those who are not involved with government service, there are all kinds of secretaries in the government. There are deputies, and under secretaries and assistant secretaries, and the "- as I have "- and then there's the secretary, the boss of this place.

The boss of this place is a man named Don Evans, who is Secretary of Commerce, and who came from the private sector, from the business world, as I did. And as I've explained to him, as far as I can tell in visiting with those who are in the private sector, there is no difference between or among an assistant secretary, under secretary, and/or deputy secretary.

To give you a sense of what I do, and why I am here, however, the deputy secretary is the chief operating officer of the department, and my job is to try to see to it that we run things properly here. The Department of Commerce is an eclectic place, with responsibilities for everything from the patent office, to the fisheries. And the "- one of the most fun parts of

the job is the Technology Administration, which is what is represented here.

I am a, in contrast to all the learned people here in the Biotechnology area, I am a retreaded chemical engineer that used to know something about that field, and so I take particular pleasure in working with this series of roundtables which we have assembled here over the past few months to assess the state of technology, if you will, in America.

We started out with a series of three roundtables, one with dealing with universities where we had academic leaders from around the country in a gathering quite similar to this. We had representatives from Federal Laboratories, assessing their state of affairs, and then from industry. And we had research directors from many of Americas leading corporations.

This one is of particular import because of the enormous commitment our nation has been and is making to biotechnology, and so we are all looking forward to this gathering to welcoming the group that is here.

As in past roundtables, I am joined up here on my far left. Dr. Arden Bement, who is the Director of the National Institute of Standards and Technology, one of the premier federal laboratories, and that we always

brag about it here in the Commerce Department. He has, in his bailiwick has "- one of his colleagues was awarded the Nobel Prize in physics last fall, which followed, I guess, three years after one of his colleagues was awarded three years, so this was '01, so it would have been in '98, I believe, there was a similar Nobel Prize in physics. So this is big league science, and they do a wonderful job, and Arden is known to, I think everybody one way or another. Every time I run into somebody, they all know Arden, maybe they taught with him, or worked with him, or were taught by him.

On my immediate left is David Sampson. David has not been a participant in these before, but we're very pleased to have him. He is responsible for the Economic Development Administration, which within the Commerce Department takes responsibility for working particularly with parts of our nation that are in difficulty economically, and he is an expert in the analysis of, and delivery of financial support and managerial support to regions that are seeking to develop economically, and so we're very pleased, David, to have you. He's one of the very fine managers that we have in the department.

On my right, Bruce Mehlman, on his right, Ben Wu, who are among the Leadership Group in the Technology Administration. I'm sure I'm missing some. I know Chris Israel is here, and so we have others of our group scattered about.

We would "- we have a series of questions that we will put to you, and the idea is to try to generate thoughts, reactions on these questions that I know you all are well equipped to deal with. Before I do that, Bruce, did you have some comments that you wanted to make at the beginning?

MR. MEHLMAN: Yes. Thank you. Being brief, I'd like to thank all of our guests for joining us here, especially those who have come in from out of town. Thanks to Dr. Sampson for Co-Hosting, and for Dr. Bodman for chairing this, and the previous roundtables. It's been of immense value.

Certainly, no emerging technology holds more promise or generates greater expectations than biotech, from mapping the human genome, to environmentally framing biofuels, from proteomics to golden rice. Rapid advances in life sciences R & D, suggest the 21st Century will, indeed, be the biotech century.

This period, we are told, and we've been learning is likely to be marked by radical improvements in medical care, environmental protection, industrial processes, accelerating increasingly disruptive economic and social changes, and increasing convergence of technologies and disciplines.

Just as many of today's biggest companies 25 years ago were small IT ventures, it's reasonable to assume that many of tomorrow's global leaders are today's small biotech companies, or at least companies that are moving into the biotech arena. It's worth noting that Blue Gene replaced Deep Blue as IBM's fastest super computer.

Biotech is often also looked to as the economic salvation for regions that are seeking rapid technology in economic development. One expert here with us today has identified over 200 efforts around the world to develop biotech clusters, and promote regional biocenters of excellence. In a recent Bookings report, which fundamentally looked at drug development side of biotech, identified almost 300,000 employees and \$105 billion of revenue as of 1997 in that piece of the biotech space.

The purpose of the discussion today is to bring together national leaders in biotech and techno economic development from industry, universities and government labs to explore the diversity of the life sciences economy, how much broader than drug development it is, to help develop realistic economic expectations for companies, universities, and regions that are investing in biotech, to get some recommendations for economic planners in communities trying to set their strategies, or offer policies that will promote biotech, and to get some recommendations for ways the federal government, and we here even at the Commerce Department, can best support emerging technologies in developing biotech clusters so we can maintain U.S. leadership.

I'll note we'll post a transcript from this discussion on our website, and we'll give everybody a chance, as they say in Washington, to revise and extend their remarks, make sure they were accurately quoted. And we hope that our colleagues at Commerce and throughout the federal government can find further ways to meaningfully follow-up on the recommendations and ideas that emerge here. Dr. Sampson may have something to say too, but thank you, Sam.

DR. BODMAN: David, you want to say something?

DR. SAMPSON: Well, thank you. I feel, as Dr. Bodman says, this is my first time participating in one of these roundtables. I feel a little out of place. I did come from also a ranching background and for me, you know, biotechnology was getting a new set of dehornerers that worked better, so I'm really anxious to participate in this.

The Economic Development Administration, our mission is to help regions around the nation create wealth and minimize poverty by promoting a variable business environment, to attract private capital investment, and create higher skill/higher wage jobs.

Two of our funding priorities, and we have a budget of about \$350 million this year, and a fairly extensive grant program, and two of our funding priorities are, first of all, to enhance regional competitiveness and support long-term development of the regional economy by trying to identify and invest in drivers of economic growth. And then secondly, to support technology-led economic development, and try to do "- promote the linkage of university and industry in technology transfer.

In other words, we are trying to identify out there opportunities to move from mind to market, and

that's kind our theme as I approach this. There are some great ideas. There's some great research that's being done. Where it's possible, we're trying to link that mind work to the market place, and believe that by doing that, we really can play a helpful role in generating long-term economic growth for regions, so I'm honored to be here and participate. Thank you, Bruce, Dr. Bodman, for the invitation.

DR. BODMAN: Thank you, sir. We will start forthwith. We have found the best way to try to do this is to ask for one of the panelists to make a "- some introductory remarks, and kind of open up the topic, and give his or her particular views on the subject, and then to elicit comments and thoughts from the rest of you, so that we can pull together some kind of integrated set of views.

There are three parts to the agenda. The first that was given to me is what does it take, as I understand it, and looked through it. It really "- the subject here are Biocenters of Excellence, or Centers of Excellence for Biotechnology. The first top, therefore, will be what is one? How do we get "- how did we "- we created them in the past. What policies in the past have been useful? What are they likely to look like in the

future, and so we will get some comments on that in the beginning.

Secondly, we'll move on to what lessons have been learned from past efforts. And then, thirdly, what are the future challenges in this area, and what might the federal role be in this regard, so those are the three comments.

We've asked Richard Seline, who is president of New Economy Strategies, to make introductory remarks on the first subject, which is stipulated in the program, "What does it take", but I guess I might rephrase it, you know, what is one? How did we get where we are? And Richard, we'll ask you to take it from there. And would you like us to move aside so that we don't get "-

MR. SELINE: First off, Mr. Secretary, thank you for your invitation, and much appreciation to Bruce and his team for putting this together.

Two very quick observations based on the seating arrangements. (A) Thank you for putting me next to one of the better minds in the scientific side of it, but also putting me next to the two largest grant makers of the Commerce Department, of which I'm sure there'll be a lot of conversations about the future funding of some of the strategies about that. And the second of all,

thank you for "- I am apologetic that I am not wearing my burnt orange tie across from my colleague from University of Texas, but Dr. Witt, good to see you.

DR. WITT: Good to see you.

MR. SELINE: Given the short amount of time, I thought I'd just address some of the items that were on the agenda, but I may veer from that a little bit.

As an opening observation, Mr. Secretary, just flying back yesterday, I reached into my briefcase and just pulled out three pieces of things that tell you that we're onto a topic that is obviously broader than just the issues of drug development and pharmaceutical. One, "The Politician Biotech Created". This is Mike Nat running for Montgomery County Council on a bioscience platform, for which I'm sure Tony and Jennie can talk a little bit about.

Second of all is nature technology. The article, "Bush Domestic Security Proposal Affects Range of Biotech Programs." And then third, front cover of Newsweek, "Fixing Your Brain, The Next Frontiers." So it's not like one of these real simple topics that we're trying to put our arms around.

DR. BODMAN: We want you to take that third one in particular.

MR. SELINE: What I'd thought I'd do is go rapidly through, and just try to kind of set the stage for what I think Steve and Jeff will talk about in a lot more depth.

When I saw this quote, it really struck that this is "- that we literally are in a transformation. And based on a number of conversations with the Wall Street Journal and Federal Reserve in New York and Dallas, we said there's something going on here that looks a little bit different than the economy we've been used. I mean, it's probably easy to say, given that the stock market went down even yesterday, and probably is down this morning, but that there really is a fundamental change in the economy. And I thought this economist's quote from April last year really hit it on the head.

Now one of the things I want to put in context is that words matter, and the words that we're going to use today all have significant roles and relationships to policies and decisions that we're going to try to forecast here, or that we'll talk about and suggest to the Department of Commerce. You can read faster than I can, and so I'm not going to go through every one of these, but I just want to point out a couple of things.

What we're talking about is the issue, at least from our perspective, of competitiveness at a regional level dealing with biotechnology and the life sciences. And our belief is that competitiveness equals innovation, and therefore, we're looking at the cyclical process of innovation. This is not just about brick and mortar. And it's not just about open land space to be converted, and it's not just about a whole set of other things. It's a lot of pieces that have to come together.

The other part is, is that when we talk about innovation, it's not just about technology. It really is about these new kinds of partnerships. And David knows through his work back in Texas, and now at EDA, that you're really having to look at whole sets of ways of getting people to partner and collaborate, that typically have not been collaborators in the past. And so, what I want to do is kind of give you a sense of, you know, where things are going, and where things are headed.

The last example is, we were down in Mexico, Mr. Secretary, about a month ago, and at that point, Mexico is in a very unique position now to try to figure out where it fits into the global economy. And the first thing that President Fox wants to look at is the biotech

life sciences area, and what is their scenario for how it fits in.

The second quick item is, it's just an implicit assumption, and that is, that we've gone through about 18 years of building up to where innovation entrepreneurship are really driving our economy, and how that impacts productivity and competitiveness, and ultimately rising standards of living.

When we looked at the ingredients that you have to have in any type of cluster, you've got to have these types of intellectual capital, human capital, the social networks, which I'm sure Jeff will talk a little bit more about, the financial capital, and proximity does matter.

Frankly, I was in a state north of here, quite north of here, and was driven to a new incubator, biotech incubator. There is off of the highway, then on a one-lane road, and then up a dirt road is a 45,000 square foot wet lab. Great facility, great setup, incredible, but there is no research university, no clinical trials, no nothing to be blunt, within a 500 mile range of this facility. Proximity does matter, and one of the things I'm sure we'll talk about is how that proximity comes into play.

Now in a series of roundtables that we've helped put together, and again you can read faster than I can probably talk. I just want to emphasize two points on this. These two national roundtables that we helped drive, one of which was driven by Bio and the U.S. Department of Commerce. Something began to step out for us. One is, is that there's a race going on. There's hundreds of millions, if not billions of dollars amassing, and I'll talk about that in a second, but frankly, the race is breaking two ways. First, towards reducing the cycle times of getting products and drugs to market. And the second towards, obviously, reducing the health care cost.

The other part that's beginning to step out is that researchers and principal investigators are becoming sports stars. It's amazing how often the French and the Germans come to the United States with bags of money, and I don't mean that jokingly, and seek to buy incredible amount of research teams and move them overseas. And then, more importantly, how one region in the United States is literally buying research teams. So in this case, the fact is that we basically believe there's a war for talent. And talent is more important than building the baseball field on which they're going to play.

Some of you have seen this, and I'll race through this pretty quickly. In understanding what the industry is about, we first have to understand what is the model that we're talking about. First off, very quickly, this is the typical cluster model. Jeff, correct me if I'm wrong. I'm close, I think, but basically we're looking at that typically most people look at a cluster, Mr. Secretary, as that set of red boxes up there, the big centers, the labs, the bio firms.

But in reality, there are a whole set of other types of players and participants. And the more a cluster is inclusive of those, the more the stakeholders in a region figure out where they get to fit and play in the economy. And so, it's amazing sometimes where we'll go into a community, and they'll stop at that red line, David, and they'll never think about how these others actually play a role in building the cluster.

The second item is, is that biotechnology is a risky business, and this is based off of 2000 data. And again, I'll make this pretty quick. Twenty-five thousand NIH funded research projects in a year, and you go through this process, folks, and it looks like Dr. Witt drilling a hole in Texas. You ultimately end up getting the top 10 of the biotech-related, drugs account for

nearly all the cells. Meaning, that what's happening in the industry is that there is a plethora of funding going into research, and out the other end is only a few handfuls of opportunities that get created. There's a lot of failure along the way.

There's a lot of, you know, miscues, and off-to-the-side opportunities. What the industry is very focused on in the broader sector of the industry, is ultimately trying to figure out how you go from 25,000 very quickly down to the next big opportunity. It is like drilling a dry hole. Ultimately, what's happening now is a lot of technology is being put in place to reduce the number of dry holes that are drilled.

The second thing that we found is, is that there's a whole decoupling of the value chain, that the first line up there was the fully integrated pharmaceutical model. That's what it looked like. We believe that this is what the model looks like now, and that is, is that about 80 percent of the industry is out-sourced. My numbers may be off a little bit, but that out-sourcing creates a pretty unique set of opportunities, when Merck makes an announcement that they will not expand on their corporate campus any more, and that their next three major expansions will be adjacent

to university research institutes, that tells you that the model is changing. And so, David, the opportunity in those four yellow bubbles have a big impact on regions that may not have all of the total ingredients to be a San Diego, or a Boston, but they have an opportunity to play there.

So what we said is, is that here is the fully integrate company model, and now it looks like it's a distributed model, and let me just jump to what I mean, is that for a long time it was believed that you had to have all of these elements in your locality, in your proximity.

And the reality is, is that in San Diego, for instance, Region A up there, San Diego basically out-sources its clinical trials to Houston, which does some research and further work over in research triangle, and manufacturing. Regulatory in Region G is done up here in Washington, D.C., you know, so you see that now the industry is much more of a network industry, and therefore, the regions are much more "- have a lot more interdependency than they had in the past.

Quick item that we looked at, and I promise, Bruce, I'll try to stay on time. I'll go through this pretty quickly. What we've been looking at is the issue

of how do you go from taking an idea, forming a company, growing it, and ultimately maturing and sustaining it. And one of the difficulties is, is a lot of regions will look at this chart, and they'll look at all of those ingredients around that circle and go, I've got one of those, five of those, you know, two of those. Boy, I'm really doing great. And reality is, is that what's happening in somewhere along the idea of the technology transfer to commercialization, something breaks down in their community. As they begin to form their company, and grow their company, something breaks down even further.

What's interesting is we found in Boston, Seattle, San Diego, and the Bay Area, about every 18 to 22 months, they actually complete this life cycle, because they have enough companies, and enough talent in each of those quadrants that people begin to drop-off out of the growth stage and start forming their own companies. It's the reason why Seattle is what Seattle is, because Immunex created so many companies, it's the reason why Hybertech in San Diego created so many companies. So you do need a sense of the gadding process that more companies start creating themselves.

Let me skip this. The Brookings report has gotten a lot of folks' attention of late and, Bruce, you mentioned it, so I want to address something right up front. One is, the conclusion from the Brookings report, Signs of Life, said that place still matters, even in a quintessential knowledge industry. It's not just research, but the ability to turn the ideas into businesses. And ultimately, the power of clustering provides decisive business advantages. So of the 50 regions that Brookings analyzed, only nine have the above characteristics, and a total of 13 are competitive or are in reach of being competitive. All right? There's 50 some odd that they looked at.

Now that made the other 30 some odd regions, some of which represent this rim, pretty ticked off. I heard at Bio 2002 up in Toronto from every one of those regions, for some reason, telling me why they were ticked off. But what we began to look at deeper in that report, as Bruce mentioned is, is that that report is really an aggregation around the first wave of drug development. It's somewhat noted in the Brookings report, as that there are a handful of regions that have almost made the rest of the regional effort somewhat non-competitive.

But we really believe that there's a second wave of opportunities that, you know, are abundant for more regions than the so-called, and we'll hear about medical devices. We'll hear about bio infomatics, and we'll hear about a number of other technologies. This is not just drug development, and so we define this second wave as emerging bio economy, and again, I'll fly through these pretty quickly.

When we looked at how you're applying bio technology, again, there are a whole wide range of opportunities here, and it's not just the pharmaceutical industry. For instance, if you go deep into, Mr. Secretary, the HP-Compaq merger documents, one of the lines in that merger document basically describes that for the merger to actually have an economic impact, one of which is, is to bring the two companies together so they can be competitive in the life sciences. The iPag hand-held computer, its fastest growth sector is in the health care arena, which kind of surprised Compaq when they came out with it, so there's a lot of opportunities to consider here. And we're not just, again, talking drug development.

When we define the bio economy, we started listing out a whole set of areas that had impact, and

again, federal government has a significant role here, obviously, through its research, and funding and other sources. But there's a lot of other folks that have an impact on this industry. As I keep on saying, this is not an industry that you can go downstairs in your underwear with a credit card and start a company tomorrow. The barriers to entry are significant enough, and this is one of the reasons why they are so significant.

So what do we say about the bio economy? In our tracking of about 40 some odd regions around the U.S. has led to a couple of things, one of which is, the prediction that by 2007, 2010, 18 to 20 percent of the U.S. GDP will be in the health care/life sciences. And we understand the health care part, because it's an aging population. But what we're really saying is, is that this is as much driven by the response to that care and the future, and the future prevention of other types of diseases and issues. So this now, by 2007, 2010, will comprise the largest chunk of the GDP.

In our survey and work around the country for these 30 some odd regions in the U.S., we've identified \$18 million of "- this is regional money. This is not, David, your money, or Dr. Bendis' money. This is

regional money, some of which is tobacco, some of which is personal wealth. This is \$18 billion over the next 10 years. Coupled with that is 22 million square feet of new space that's either under construction, or about ready to be.

The NSF made a prediction three years ago that the United States was 28 million square feet short of wet lab and research space. I think this is catching up pretty quick.

And then finally, one of the other items is when you take a look at the bio economy, is that the average superstar researcher is attracting about \$250,000 U.S., to get a team, to buy a team and move them to your community, just like the Doris Duke Foundation has gone into two places in my home state of Texas and bought two Diabetes research teams. The average price tag for buying a team now is about \$1.4 million dollars, that's before you get into the facilities.

You can't read this, but let me emphasize what I'd like to at least raise, is Rand, through the NSF, has a contract to look at where federal funding falls out. The NSF data, by the way, is about six to twelve months behind, and therefore, it's not the most current data that we can look at, so working with Rand, we've been

looking at how to take, for instance, the 2001 data and bring it up to 2002, first quarter.

And what we're finding is, is that by doing this, working with Rand, and I'd like to suggest that the Department of Commerce continue the relationship further, is we are able to actually look at Arlington, Texas and find out exactly where all the federal funding is coming from, how it is aggregating, where it's breaking out into some potential growth for commercialization. And the issue that "- the reason why I put this up is, a lot of regions don't have the complete data that they need to make the right amount of decisions. And you folks on the federal side have access to that data, as well.

And then I took the liberty, Bruce, to just put at least four challenges I want to walk away from today, and I think the Secretary mentioned them, is I think the challenge for today is, how do you advise and council regions interested in growing their life science capacity, or frankly, their lack thereof? Because now biotech is the next new thing, and there isn't a region, David, I'm sure that you've gotten everybody in the world asking you for federal funding to build a biotech cluster, when in reality, the ingredients do not exist.

The second is, is how do you articulate a role for the federal government for this administration and the Department of Commerce? And then more importantly, how do you engage a wider framework, and hopefully Steve will cover some of this, is how do you engage a wider framework of the federal family, in having a positive global competitiveness view of an industry that's in flux? Labor, Department of Agriculture, the whole set of other federal agencies beyond NIH and NSF that impact this industry. Somewhere, sometime, hopefully, we will be able to bring all those folks in the room.

And then lastly, my point that I would just raise, and that is, how do we obtain, David, the best information and knowledge on what is happening, and what hinders or facilitates U.S. competitiveness in the bio economy? There is a lot of federal data that exists here in Washington, and somehow we've got to break the code and be able to help people at the regional and state level make some policy decisions that acknowledge for them they've either got it, or they don't got it. Thank you for your attention.

DR. BODMAN: Comments and/or thoughts from any of the rest of you? Yes, sir. If you'd be good enough, forgive me, to introduce yourself? I got around to meet

everybody, but not everybody, and that way we can at least get it on the record who's speaking. Thank you, sir.

MR. HOROWITZ: Mitch Horowitz with Battelle Technology Partnership Practice. I think the point that I think Richard brings home, that I think is another way to summarize it is you need a real market-driven process. And so, if we're going to get in over the course of this session into a lot of discussion of particulars, but I think the one breakdown that you see is everyone thinks that building a bio science cluster, you know, is all about just research.

And clearly, without research, it's very difficult to do it, but I think the key element is how do you build that market-driven process for that community that captures all the kinds of benefits. And then I think what becomes real important is that that market place and, you know, I think Richard was very kind to the authors of the Brookings report, because they seem to be extraordinarily narrow-viewed. And I'm not sure they saw that second wave. I think that was a very nice way of broadening their view, is that that market place is actually quite extraordinary, and very robust. And, in fact, biotechnology really is a technology that's

applied, and that to enablers, gets even further applied. But the big things for communities, and we face just in Maryland, where I sort of cut my teeth with Tony and others in putting together that strategy and moving that forward, is if you don't figure out how, in your community, to build that model, that market model, then you're in trouble.

So, the question becomes how do you look at it? How do you think about it? And you've got to start with what you've got. You can't worry about what everybody else, and what Silicon Valley has today, or what, you know, 128 in Boston has because the reality is, is they're so far advanced that you can't even begin to understand what the dynamics are completely.

What you really need to look at is how communities, like Maryland, which really started out in the early 90s sort of nowhere, other than fantastic research, how it thought about, and how it went about figuring out where its gaps were, and addressing that market process. And I think that's really what helps communities go forward. Others may have other kinds of approaches to it.

DR. BODMAN: Yes, sir. Dr. Rubin.

DR. RUBIN: I congratulate Richard on a brilliant exposition, and a most efficient panel. I wonder if I might add three things?

One is, in my experience sitting in academia, a key element, if one wanted to look at where facilitation in biotechnology or blockage of biotechnology, the key person is the person who runs the Technology Transfer Office in the academic institution. If it's done well, and my experience is just in Boston, the head of the Tech Transfer Office at MIT, Leonard Nossun (phonetic), does it brilliantly.

I've had less fortunate experiences with other tech transfer on both coasts, and it's a disaster. And that single-handedly can stop the develop of biotechnology, because the source of many of this is the academic laboratory, that then gets commercialized.

The second is, I wonder if you might object, is I'd like to see some bi-directional arrows, rather than arrows in one direction. I think my view of this kind of thing is that there's a partnership that's going on. It's not a one-way process going from the academic laboratory to the private company, and never the two should meet again.

Rather, it's a shared experience with different disciplines coming together to affect progress. And I think we need to think more about it, because I would suggest that even if we need to increase that more, so that there's partnership between government, the private sector, and the academic.

The third issue which I think comes up there, and I'm not sure if everyone will agree, is we can't think about biotech in the abstract. Biotech and Big Pharmas are inextricably linked for the majority of this kind of thing, and so when one hiccoughs, the other feels poorly. And I think we're going to have to think very clearly about how each of these two big efforts that are very important in the U.S. economy are influencing one another. And one's battle is the other's battle, as well. And I think this is an issue that will be very important as biotech develops and contributes more to the development of new compounds or new devices. Thank you, sir.

DR. BODMAN: Yes, sir.

MR. BURKE: Steven Burke, from the North Carolina Biotechnology Center. Our topic today is Biotechnology and Bioscience. This is the world in which we live, increasingly, and it's the world of our

intention. And like any world, it seems important both to chart the future, and to take note of where we are. And where we are is in the midst of a phenomenon that we often forget, but it informs our thinking today, and our thinking into the future. And the phenomenon underlies a lot of what Richard said.

The phenomenon is this. There has never been an economic or technological sector in history that has been so much the child of targeted intervention, as is the case with biotechnology. I am the putative expert that Mr. Mehlman referred to earlier. I have totted up about 200 targeted initiatives in biotechnology worldwide, representing the imperative of states, regions, or places to do better and to gain from this technology.

Now all would be successfully, and this underlies our topic today. In fact, some will not be successful, and we hope to see how all can benefit as much as possible. But this is something without precedence in our technological, as well as in our civic history, and it yields a great deal of experience that should be drawn upon as to what does and what does not work. It also yields recognitions. The reason why we have so many targeted recognitions, targeted initiatives

is that biotechnology is potentially the most important endeavor we have going.

The challenge as Mr. Mehlman and Dr. Bodman have reminded us is to see how we can best drawn on the experience of these targeted interventions and do better. Thank you.

DR. BODMAN: We have several comments. Yes, we'll work our way around here.

MR. ROHRBAUGH: Mark Rohrbaugh, Office of Tech Transfer at the NIH. I'd just like to make a few comments about how NIH is approaching some of these issues, and on two ends of the spectrum, one on the "what someone called the ingredient level. We have a series of grants, as I believe NSF does, targeting areas, states that are low in ranking of NIH funding. There are 25 states plus Puerto Rico that qualify for a program in which we provide research grants or infrastructure grants to help build their infrastructure, to help build their science, so that they might be more competitive in pursuing these kinds of efforts if, in fact, academic excellence is one factor, as we've seen, with respect to building and spinning off biotech companies and technology transfer. So, for example, in 2001 NIH awarded grants in the academic research program to these

lower successful states to the tune of about \$24 million, and to the infrastructure program about \$60 million last year.

On the other end, when we talk to our SBIR grantees and contractors, we find that two things that "- two roadblocks to their success are business acumen and money, so we're thinking about ways in which we might provide them further funds beyond the traditional phase two award, and we're also helping them in a couple of programs, pilot programs.

One, our National Cancer Institute has the Commercialization Assistance Program, whereby under a pilot program through a contractor, they're providing assistance to 50 SBIR grantees that have had success through Phase II and are entering their Phase III. And this contractor will provide them advice in building their business plan, and positioning themselves to go before a venture capitalist. And 35 of them will be selected to be "- to present their case, and their business plan to venture capitalists, and hopefully, we will see some success with those efforts.

The National Institute of Allergy and Infectious Diseases is doing something not quite as large, but working with some SBIR grantees, in helping

them present their case towards the Bio Venture Forum in San Francisco, so we're working in those areas to try to increase the success, and some of these companies are not from areas where you expect high tech industry to develop, like the Bay Area, or San Diego, or the 270 Corridor in Maryland. Some of them are from states like Montana, which are not known for their high tech, so we hope that this will "- these projects will be successful, and also by monitoring them will learn what works and what doesn't work so that we can expand them appropriately.

DR. BODMAN: Thank you, sir. Mr. Sloane, is it?

MR. SLOANE: Hi. John Sloane with the Biotechnology Industry Organization, and I'll be joined later by Morrie Ruffin, who is Vice President of Development. I'm in the government relations shop, and so wearing the political hat really quickly, Richard, I think you did an excellent presentation of what it does take.

I wanted to point out, one thing I thought was missing, what it does not take in the public policy and legislative arena. We talked about what it does take, grant funding, so on and so forth, but what it does not

take both at the federal and state levels is some legislative initiatives. For example, right now the U.S. Senate is debating what's called McCain - Shumer, which could stifle patent innovations, reimbursements if it's going to be a government-run control, if there's price controls. These are efforts that really could stifle innovation because it could hurt the investor confidence in the companies to bring forth these products, so I thought it was important to bring that up. That's one section I thought was missing.

DR. BODMAN: Thank you. Gentleman in the back row. Maybe you could get up and "-

MR. BILKER: Vince Bilker, I'm Division Chief of Biotechnology at NIST. I noticed two words that seem to run together in the presentation, and I'd just like to caution that they be understood in separate contexts. One is biotechnology, which literally has been made synonymous with the pharmaceutical industry, and the other is the bio economy.

Now with respect to bio economy, if you look at ag bio, marine bio, there's many areas where the commercial impact of biotechnology is yet to be fully realized, and the clustering aspect is going to be a dynamic process that all of the role models that have

applied to the pharmaceutical clustering will not apply to a clustering of ag bio, for example.

One of the nine clusters that you did not mention is what's happened in St. Louis. We're rallying around Washington University, St. Louis University in Monsanto, and the long-term impact of that is yet to be understood or felt.

And the other part of the presentation in ag bio is the lack of mention of the nutritional values of the new things that are going to be added to plants using biotechnology, so there's a big market out there that's yet to formulate. And I think some of the aspects of clustering and economic development need to be incorporated.

MR. SELINE: Let me respond "-

DR. BODMAN: Sure.

MR. SELINE: "- to a couple of things. One is, we're definitely in favor of the idea. Whenever I "- we use bio, my preference is always to say life sciences, and this is inclusive of a whole range of scientific opportunities, not just farming. I think you're right, St. Louis is a very interesting model of a community that woke up and realized that Monsanto was in their backyard, and that they also had 300 research Ph.D. scientists

sitting at a horticultural center that happened to be the Ladies Rose Tea on Tuesday afternoon, and didn't realize how much research was going over there, second only to Harvard. But I think what you're saying is there are broader opportunities.

One quick thing, Bruce, that we ought to consider somewhere down in our discussions is the SBIR piece that you mentioned. There's inherently two things, and I'll be "- Steven Burke is much more diplomatic and polite about his being provocative. I just kind of jump into it.

MR. BURKE: I'm a southerner, Richard. I have to.

MR. SELINE: I haven't lost my roots yet, but the SBIR, there's a very interesting issue here about SBIR funding. For instance, California ranks the highest in SBIR funding, but the majority of their SBIRs never go to three. And there's an issue that we really need to talk about, is that there's a lot of SBIR utilization that end of being churned at one and two, never seeking companies to ever go to three. They play a role in the industry, but there is a whole significant set of opportunities around SBIRs that I think you raised, that's on one sense very positive. And I think we ought

to consider how SBIRs can spur more commercialization than they usually are.

The downside to it is, are we creating false hope. And I think somewhere along the lines, not to say Montana doesn't have a chance to play, but is the sense that Montana now has a company in biotech that's now reached a certain stage of growth, where does that now put Montana, meaning state and regional policymakers in charge of? Are we now basically saying yahoo, you're now in the biotech/bio economy as we would refer to it, and does that now put them in a position of saying we've got to get five or six more? Probably right, but do they have the capacity to grow critical mass?

And if not, then, David, you've got to be prepared with your federal grant money to start building them the critical mass infrastructure, or somewhere along the line today we, hopefully, will be able to help you figure out, saying this tongue in cheek, how do we respond to places that don't have critical mass capability, and how do we help those who have certain critical mass?

DR. BODMAN: Thank you. Mr. Green.

MR. BENDIS: Rich Bendis.

DR. BODMAN: Oh, Mr. Bendis. Excuse me.

MR. BENDIS: Yes, with Innovation Philadelphia. And I think that while we have raised opportunities that we have with life sciences in the United States, it's also one of the greatest challenges. What we've done is got some false expectations and false hopes created around the United States right now because we have probably 45 states who all have "- want to take part of their tobacco sales money and apply it towards life sciences and biotechnology. And within some of those states, we have two, three, and four regions. They're all going to compete with each within the state, and potentially not partner with each other, and that's a challenge.

So the question is "- I like the question "- it says, "What does it take"? And it's defining what does it take within what Richard set the stage for with his presentation, that I think needs to be focused on right now. And what it takes first is you've got to go back and analyze what you've got, and how can you differentiate yourself and focus on something that can make a contribution within the life science community, where you might not be a leader, but you might be a critical component to it. And that's where some of the

secondary and tertiary markets can all have a role in this, but everybody cannot be a leader.

And I think that's one of the biggest challenges that we have within the United States right now. Even with all the money that the federal government, state government, tobacco money, venture capitalists, which is inadequate at this point, is going to invest in this market today, where woefully underfunded in order to support the kind and the number of initiatives we have in the United States going on in this industry today, so I'll just take one stab at what it takes, very briefly.

First of all, you need to do your analyze within your computing. What capacity do you have within your state or your region that can differentiate you from everybody else in the country? If you can't build around a world-class or a global technology that you can't establish some pre-eminence in, I don't know if you belong in the big game. You can do some small things, but you might not be able to be in the big game, so that's differentiation in world-class research that you can build around in your local community.

Second of all, if you do not have long-term stable funding, you shouldn't be in the life science

game. You can be in the medical device game, you can be in bioinformatics as a component of it, but if you want to get into biotechnology or pharmaceutical research, if you don't have long-term funding and stable funding, you can enter, but you can exit very quickly, and you better have private and public partnerships who are willing to work together. Sit at the table day one, make the commitment at the beginning, and don't walk away in the middle of the process.

Second of all, or third of all, you've got to look at convergence of technology. If you look at technology today, it's not just the life sciences or biotechnology. Let's take a look at bioinformatics and nanotechnology proteomics. How do you look at the convergence of these technologies and how they interact, and interface with one another today?

I think sometimes we just get too narrow and look at our silos, but we need to look at the leveraging of the resources between the scientist and the resources within the academic institutions and industry so we can convert those together. And I've got a few more on the list. I don't want to go too far with this, Mr. Secretary, but industry presence? If you are an academic island without industry that you can actually leverage

within that area, it's going to be much more difficult to commercialize, because technology transfer is not commercialization. And I don't know "- you didn't introduce yourself, so "-

MR. RUBIN: Bob Rubin from Boston. I'm sorry.

MR. BENDIS: Okay, Bob. So I "- everybody else knows you. I'm sorry, but you're correct there. Tech transfer is not commercialization, but there are very few academic institutions in the country that do commercialization well. There's a lot of them that do tech transfer, and the initiatives for doing tech transfer and the motivation for doing tech transfer is you can generate royalties and license fees.

Commercialization and creating spin-offs is a longer term payoff, and you have to have more patience for that. And there's a lot of administrations that aren't willing to be as patient as it takes to create a company, and wait five, ten, fifteen years for the economic benefit you'll get from that, versus the short-term gains you'll get with royalties and licenses.

What happens is, it's unfortunate, and it happens in Pennsylvania and Philadelphia in Penn which is the number two NIH funded academic institution in the country, they do great tech transfer. But we get six

spin-offs in the last reported autumn data, and we have 55, I think, up in Boston. And with that, you have three times as much federal funding, but I guess the question is, does that mean that you should get ten times as many spin-offs from a commercialization standpoint in Boston, versus having world-class research in Penn, where you're basically transferring it. Those assets are going outside the community, so the question is how do you do this in a way that you keep the assets in the community and build upon the future? And I'm just going to stop right there, because I have a few more things to say.

DR. BODMAN: Thank you, sir. Yes, Leslie.

MS. ALEXANDER: Leslie Alexander, soon to be at North Carolina Biotechnology Center, and I just want to pick up on that.

When I read the Brookings Institute report, one of the things that really stood out to me, and it was some weeks ago, is one of the final conclusions; which is, you can make these investments over a long period of time, and you can get some what we would consider very successful biotechnology companies. Anyone that actually gets a product out on the medical side, which is where that report focused, gets it through the FDA and gets it in front of patients, I think we would all say, that's an

incredible home run. But if you're doing this for economic development because you expect to have a great number of jobs in your area, you might want to think again, because the vast number of these small companies, their business model is to license out what they develop.

And it goes right back into the world, as was pointed out by Bob, an inextricable link between the pharmaceutical industry and the biotech side is these biotechs are the pipeline for many of the Big Pharmas. And the jobs do not necessarily end up in your community, so in my mind it starts with expectations.

What are your expectations? If it's really economic development, and you think you're going to make this investment, get all these companies, and have thousands, or tens of thousands of jobs in a community, that may not be matching up with the reality of this sort of quirky industry, which tends not to do the manufacturing, and tends not to do the sales and distribution. So I think, from my mind, I'd like to hear some sense of reality about what our expectations are in terms of economic development.

MR. SELINE: Leslie, I got asked a couple of months ago what I thought the industry looked like, because everybody always try to find like a kind of

benchmark, and I thought about this for a long time. This industry looks a lot more like the independent film industry, than it does some similar manufacturer, because you've got a bunch of major studios who basically turn to somebody who writes a script, and somebody else who funds a script, and somebody else who "- and Hollywood's great cluster is that they're able to churn off that critical mass of all those right kinds of player.

I don't think there's any other industry that I can find that's similar, that you can sit there and say we've seen this business model before. And I think you're right, that how do you help people understand what the business model looks like, so that they then can really understand where they may fit in? And there's some conjecture that we may be saying to a lot of people this is a big employer, when it may end up being like independent industries that are all networked.

DR. BODMAN: Mr. Skinner.

MR. SKINNER: Yes. I'm Jim Skinner from North Carolina. This is a meeting at the federal level as opposed to locally on redevelopment. I'd like to "-

DR. BODMAN: We seem to, however, have disproportional North Carolina representation.

(Laughter.)

MR. SKINNER: In order to have a biotechnology community, whether it's Boston, California, North Carolina, it takes three ingredients, money, management and technology. And not all locations have that, although I believe that there are many locations across the country that have excellent technology that could provide significant medic and biotechnology benefit to the country, and from a federal level. It may not be necessary to create or try to create local regional programs to replicate what is already in Boston, for example, or at other locations around this country. Frankly, it probably won't be possible. A lot of money goes down the drain in that respect, and the key issue in my mind is that benefits of the technology that resides in those various rotations gets lost.

Venture capitalists will fund a new development in some particular areas of the country because they will try to put together more meetings, and may get the technology, but that's also unlikely. Certainly, to try and create a biotechnology community in Arizona, New Mexico, South Dakota is not going to happen. You're not going to get all of the people to go there, even if there is a wonderful technology. And perhaps, a new model needs to be looked at.

But just like every biotech company that started ten, fifteen, twenty years ago are known to be FIPCo, Fully Integrated Pharmaceutical Company. It just isn't that way any more. There is a specialization, and I think that in terms of technology, universities, states, they may not be the equivalent of a biotechnology FIPCo area. But I think it's important at the regional level, and at the federal level, is that the technologies that exist there don't get lost in the shuffle of either not being in the right place, and therefore, not being funded.

Look at the technology and see. Some should be replaced, but they're in the wrong place, and they're getting lost. And I think this is the challenge that you folks have, is to make sure the technology doesn't get lost.

DR. BODMAN: Thank you.

Dr. Rubin, do you have a comment?

DR. RUBIN: Just to follow-up on something Leslie said. I think one has to take a broader view as one design the biotechnology effort. And I'm speaking from knowing Boston, and it really is the only place I know slightly what's going on.

If you look at biotechnology just by itself, you're absolutely right. It's not creating a lot of jobs, but what's happening is we've got AmGen, we've got Merck, we have Pfizer. We have a lot of Big Pharma. Novartis is relocating their whole thing. And one has to ask a question as you develop biotechnology why? And in part, it's due because of the biotechnology, but I would submit that it's more likely to be due to what's going on in the universities.

And so, as I look at this from the point of view of helping the general economy, and nurturing biotech, the biggest piece is how well we sustain the effort in the university, because that becomes the critical element in nucleating not just the biotech advantage, but bringing in the jobs in the bigger picture. So the planning has to encompass that, and just not be narrow focused to just biotech.

DR. BODMAN: I wonder if, at this point, needless to say, with a panel with the wide ranging intellects here, trying to control the agenda is, as they say, a bit like trying to herd cats, I think. So more or less arbitrarily, I thought I might interrupt and ask our next speaker to maybe help us pull some of this together.

Jeff Grogan is a principal with the Monitor Group, who as an organization, has been a leader in developing strategies, developing the ideas behind clusters. And perhaps, Jeff, you could give us some thoughts that might fit in with some of these comments we've already heard, and talk a bit about where the concept came from, what lessons have been learned by efforts that have gone on in the past.

MR. GROGAN: Thank you, Mr. Secretary. It's my pleasure to be here, as well. And I think a number of these conversations will inevitably overlap, and there are a number of individuals around the room that I've interacted with. Rich Bendis is one who I would certainly look to for color commentary, and expertise as it relates to, be it Pennsylvania, or Kansas, what have you.

I'm privileged to be here. I represent Monitor Group, which is first and foremost a consulting firm. We have a small part of our practice where we've concentrated on regional and economic competitiveness. One of our co-founders is Professor Michael Porter of Harvard University, and he's been long interested in regional competitiveness, and has spoken at length about, after having studied hundreds of industries, countries

around the world, this whole notion of competitiveness through clusters of industries.

Richard was "- you know, your point about innovation and productivity equalling competitiveness, I couldn't understate it more. That's one of the sort of key underpinnings of the work we've been doing. And this work has stemmed from our work most recently with the Council on Competitiveness Project, where we looked simultaneously at five regions around the country, and 17 different industry clusters. But we've looked at, you know, what it takes for a region to become competitive and sustain it's competitive position, and what are the appropriate roles of government in the private sector. And I think one of the fundamental definitions would differ for any region, and I'm speaking broadly beyond biotechnology, biosciences.

It's the fundamental definition of victory to create a high rise in standard of living through innovation, through competitiveness, by creating competitive clusters of industry, and there are distinct roles that government and the private sector can play in doing that. And in our view, we would underline the private sector led initiatives, that it's government's

role to create an environment in which all industries can flourish.

We're fascinated with the, as Richard discussed, the \$18 billion worth of monies that are being allocated in this area. I think 41 or more states are actively working, and regions around the world are working at it, as well. And if you take Dr. Rubin's comments about a war for talent, you know, at what point are we going to dissipate our energies and the funds that are available?

But nevertheless, that having been said, we've looked at regions around the country and tried to define, you know, what has made them successful. In North Carolina, it transformed itself from a region highly dependent on textiles and tobacco, to one with positions in fast growing industries like information technology and biotechnology, pharmaceuticals. This was a decade's long process though, and it came about through investments and education, and strong collaboration between business and government, and academia. And I'd emphasize the role of state government in that.

Massachusetts weathered a down-turn in the early 90s where it lost over 360,000 manufacturing jobs, and it became a knowledge-based economy with world-class

positions in life sciences, financial services, information technology, and what we would call knowledge creation. That came about through an explicit strategy, an economic strategy, a shared economic vision, and the concerted efforts of public and private sector of leaders.

San Diego was a sleepy tourist destination, and it became a national center of innovation with strong positions in aerospace, and later biotech and comms. And, you know, it didn't just come about. It came about through concerted action creating a port for the Navy to come in, creating the wherewithal for defense and aerospace firms to locate, and for research institutes to locate, and that spawned other industries.

In at least one of the regions we looked at, it has dedicated all its economic development resources to focusing on communications and bio pharma. Well, if over a five year period you double employment in each of those areas, you wouldn't move the meter in terms of the overall impact on the economy. So, you know, we're back to the point of, you know, are we running the risk of dissipating effort by everybody trying to focus in on the biotechnology, notwithstanding its importance.

Some of the common success factors as we've looked across regions all across the country and other regions around the world, is three major influences. One is a shared economic vision between business and government leaders. Something people could get their arms around, understand their regional economies, what their strengths are, what their weaknesses are, and what the core elements to an economic strategy ought to be.

A second major ingredient is leadership, not only business leaders, but government leaders working together in a collaborative fashion. I'd add academic leaders to that, as well. And supporting that leadership cadre with an economic vision is an infrastructure of economic development, dedicated professionals that work towards implementing a number of the initiatives, and they, themselves, form a network of what we would call institutions for collaboration, and some of those most important institutions around the country are represented here today. But it's not easy. There are, indeed, challenges, and there are more pitfalls than we could hopefully, you know, talk about today.

There typically are misunderstandings about the business environment and what drives prosperity. Often times, strategies aren't informed by rigorous

analysis, and sound data. And I'd say, coming from England a few weeks ago, one of the worst defined terms is cluster. Everybody wants to define cluster in their own way. Strategies need to be focused on, on the collection and dissemination of data in a way that enables people to act on it.

And a third area is, you know, key individuals aren't asked to sit at the table, aren't asked to participate. And, you know, all the best strategies, you could create a glossy brochure, a nice report, but if it's not actionable, if it hasn't pre-engineered, if you will, or designed the inactionability, then it's going to sit on a book shelf and nothing will happen.

There are other more specific pitfalls that regions experience. Sometime companies engage in cluster killing strategies, particularly in the area of the war for talent. There's neglect for investment in a particular area, or neglect in investment in the physical infrastructure, regulations are over-burdensome.

We just recently went about in the Boston area and interviewed a number of biotechnology executives to find out what's on their mind, and we're about to launch a massive survey to help understand what's going on at life sciences, and how Massachusetts which is one of the

leaders in life science, can sustain and enhance its competitive position. And we are interested to find that executives really were interested in the financing, interested in the technology aspects, the interaction to your point, the interaction with universities.

But when it came to manufacturing products, then you started engaging with them on the difficulties of approval processes, not just in the products, but approval processes in having a plant that's qualified, and so there are issues there, not only in terms of employment, but what activities within the field of lab technology you're engaged in.

We found regions have fallen often into a pitfall of what we would call big game hunting, where instead of trying to look at the cluster in a rigorous way, one of the cluster components, and sub-components, and how can the region fill those particular elements out, that just bringing in a big company here or there is going to help. Well, anchor firms are helpful, but more often than not, I think working on the breadth of a cluster, as well as the depth of particular parts of the cluster are important.

I think for a region, to Rich Bendis' point about you need to differentiate your capabilities and

have world-class research, I think you can think of it in three ways. One is, is building and transforming the region by looking at the regional environment, the environment for business to operate. You can look at it in terms of transforming, or reactivating your industry clusters. And then you can think of it in terms of creating the capacity to act, and there's a role for government, and the role for private sector in each of those areas.

DR. BODMAN: Thank you, sir. Mr. Mehlman.

MR. MEHLMAN: Yeah. Jeff, if I could follow with a question to you, and then to others. It seems we've already heard a bit of this question played out, but the question is, can you grow it? Can you only grow it, or can you buy it? And one thing some regions that have existing strength in university, and people, and access to money, it may simply be a question of whether they've got the right strategy set, having learned from Dr. Bodman here, as a serial entrepreneur and venture capitalist in Massachusetts, he suggests sometimes that success in life science and VC efforts were notwithstanding the efforts of government. And one thing I wonder is, for a lot of regions that don't start world-class university life science programs, or don't start

with history of venture capital investment or world-class talent, is it realistic to think they can buy it, they can bring it in, or they can otherwise through applied strategy turn themselves into a successfully competitive biotech cluster?

MR. GROGAN: I think my bias would be that it would be very difficult to buy it, that unless you are pursuing a related diversification strategy, you're engaged in a risky strategy. I'd actually love to hear Rich Bendis' comments as it relates to Kansas and billion dollar investment, because that might be an interesting case study for us to talk about. But I "- you know, again I think if you're - without mentioning an individual state, I think if the important ingredients are leading academic institutions, and leading thinkers, and sources of capital, then those regions which have those ingredients are going to succeed, and others will have less opportunity, unless they find innovative ways of connecting with the leading centers. I would love to hear other opinions too.

DR. BODMAN: Yes, sir.

MR. WITT: I think there's a theme in both Jeff and Richard's comments that needs to be underscored. I think two behaviors are going to change, or have to

change, if we're to be as successful as we would like to be in hoarding clusters around the country.

When you look at economic developments in many communities, if not most communities, its viewed as a zero sum gain. You try to get development for your community, even if it means taking it from another community.

When you look at workforce development, it's very much the same case. When you turn to the university arena, again you see the same level of competitiveness. And it may well be in a geographic area that you look at the university resources that are in place, and in no single institution can you identify a critical mass that would allow you to say there is the level of excellence necessary to sustain the developments of a cluster. But if you look at the aggregate assets of all of the universities within the geographic area, if they are working together in a collaborative way, you may well have that critical mass.

And I guess jumping ahead to one of the final questions, materials that Bruce distributed, what kinds of things can the government do to facilitate this process? The more the flow of resources from the federal government encourages the formation of collaborations,

the greater the likelihood, I believe, that you will achieve the critical mass of intellectual capacity in universities.

And you can begin to modify the behavior of economic areas, communities that are still very much fixated on getting, and taking, and keeping, rather than trying to look across community boundaries and say what is it that we need to do together to strengthen ourselves as an economic corporation.

DR. SAMPSON: Well, since before I came up here, Dr. Witt was on my board of directors. He, obviously, taught me well, because we've tried to embed that in the way that we manage and make decisions on where our grants go. We believe that you have to think regionally in order to compete globally, and economies are not hermetically sealed in these artificial political boundaries. And the real challenge in dealing with economic development organizations around the country is precisely this problem.

In our scoring mechanism of economic development grants, the first question that we look at is, is this a proposal that drives a regional economy, that provides an opportunity to build a platform for growth for the regional economy, as opposed to a very

one-off type approach. And I think we've got to get away from this one-off type approach to economic development strategies, and so for what little we can, we're trying to embed that changed model among economic development professionals out there, by saying the money will not flow to those who approach it in the old style.

MR. SELINE: The Kansas City story is a great story to answer Bruce's question. Let me just throw it in. You can buy it. But we're not sure, Bruce, if it's successful yet. If the Van de Wald family can step forward with \$100 million in Grand Rapids, Michigan, which basically had two hospitals, one for the wealth of the community, and one for everybody else, and go out and buy eight emerging leading oncologists, build an institute, hook up with the University of Michigan to create the first rotation of post docs, on, and on, and on, you know, \$150 million can buy into the game. We're just, I think all of us would say we're just not sure if they're out of the first inning or the second inning, but it is pretty powerful, that if you've got the resources you can amass the scientists, the building, the collaboration across a number of universities, but it's still too early in the game.

I don't mean to set Kansas City up for "-
against Grand Rapids, but you all I think have put
together probably the best strategy.

DR. BODMAN: Mr. Duncan, by popular request.

MR. DUNCAN: I feel I'm being called on. For
those of you who aren't aware, in Kansas City, I guess we
are engaged in considerable experiment in a sense, in
that, I guess it was about three or four years ago, the
community started looking at the assets in the region.
And about that time, Jim and Virginia Stowers, and those
of you who don't know them, they are the owners of the
American Century Mutual Funds Company, and they decided
that they would do something in the community in
biomedical research. And in fact, were advised from
virtually everyone throughout the country not to do it in
Kansas City, but decided to engage in that activity
anyway.

Getting out the question that Rich brought up,
can you buy it? Well, let me give you some numbers here.
The first thing that Stowers then did was buy a hospital
and renovate it to the tune of about \$300 million. And
they're at 600,000 square feet of probably, I call it the
Taj Mahal of all laboratories, and I've seen a few, but
it really is quite a unique biomedical research facility.

DR. BODMAN: It also treats patients, I take it. I mean, there is research, or it's just "-

MR. DUNCAN: Strictly base "-

DR. BODMAN: Strictly research.

MR. DUNCAN: Basic research.

DR. BODMAN: Okay.

MR. DUNCAN: He then recruited, and thanks to the folks from Texas, but he recruited Bill Mees from Southwestern down in Dallas to head that up, which brought in some significant leadership. And I think leadership is an important point.

One of the fortunate things that Jim then did was endow the Stars Institute with the initial endowment of \$1.6 billion. And he's now, to finish the story, they're well underway. They're using a huge model to build that institute. They have 16 principals there now. Head count at 160, headed for 600 in the existing facility, and talking about a Phase II to add another million square feet and additional endowment. So, in a sense, Jim Stowers decided to buy it, if you will.

Now the Stowers Institute is, in fact, able to attract world-class individuals, and have up to this point. As I've said earlier, they have 16 principals on the board now, and looking at others. But what that did

to the community, I think is rather remarkable. It, first of all, forced the community, the civic leaders to take a look at the assets. And Rich was around during that time period when some well over 100 people in the community sat down and took a look at what are the assets there, and how could they leverage this investment that the Stowers were going to make. And that has led them to a life sciences initiative in Kansas City, and the formation of an independent organization called The Life Sciences Institute, which I represent, which is all about facilitating collaboration, all about facilitating commercialization, and all about facilitating capital formation.

So in a very brief statement, that's what's going on in Kansas City. It's pretty remarkable. The landscape has changed considerably. There's been nine strategic alliances formed between various organizations. And by the way, there's eight key stakeholder institutions doing basic research there, all within "- with the exception of one institution, all within ten minutes drive time of each other, so proximity is important, and I heard that. I think we're certainly demonstrating that, so it's an interesting situation. A lot of joint appointments now between the universities

and private sector, lots of collaborative proposals being written. And in fact, not only involve the institutions, but involve private sector companies and subcontractors, and so on. So it's a remarkable change in landscape, at least in our community.

People are out of their silos and, Bob, to your point, I think in that area there's really not an institution that one would call a world-class research institution. But collectively, the eight institutions, you start getting there. I'm not saying you're there, but you can make some real arguments about collectively how well they back up versus other organizations. And then we're further assisted by the state activities, and I'm going to mention here, the St. Louis activity in ag bio, that's also a significant activity, helps us with state support.

DR. BODMAN: Thank you, sir.

MR. BURKE: I have a somewhat different take, or at least an alternative way of thinking. We are Americans, and we have a kind of touchy faith that money is the only currency. And I submit that there are other currencies that are equally as strong as tools for biotechnology development, and shamelessly, I can only use our experience in North Carolina as a model.

As was pointed out earlier, North Carolina has changed its underpinning substantially. In 1981, our state, as a matter of policy, began to turn its attention to what was then a nascent and untested technology, biotechnology, and to commit the state to a long-term endeavor to gain from this technology, through establishment of the North Carolina Biotechnology Center, which I represent, and which Ms. Alexander will soon become president of.

We began this initiative 20 years ago, two decades ago as actually the first of these 200 targeted initiatives that now dot the planet. Over the course of 20 years, we have spent a touchingly small sum of money; \$140 million over 20 years is not an enormous sum with which to take a large stake to some national and international prominence in biotechnology, but that has been done.

When we started 20 years ago, North Carolina was on no one's short list as a potential leading place for biotechnology. And by conventional gradings, we were mostly B- in everything that was going to be brought to the table. North Carolina has been taken to be by all quantifiable standards one of the leading places in the top five, six, or seven by all measures for

biotechnology. But what was the currency that brought that about?

As I said, it was not an enormous sum of money. A hundred and forty million dollars divided by 20 is not very much, particularly for something as expensive and complicated as biotechnology. What then were the other tools that we spent, that should possibly be spent other places? Chronology, sustained commitment, to play it out over time, patience, agreed upon by policymakers, by funders, and by all involved participants. Targeted programs, appropriate spending of not large sums. Yes, of course, you would think, but also we've currency from leadership, from imagination, from partnership, from fate, from chance, from goodwill, but above all, from a targeted commitment to sustain something important, granting that in this biotechnology community, which because it encompasses will and humans is a larger term in cluster, that in this biotechnology community there was much that needed to be brought to the table over time.

Can you buy it? Perhaps. Can you buy it without all of these other forms of currency? No. Anywhere, not just here, anywhere.

DR. BODMAN: Dr. Rubin.

DR. RUBIN: I would submit the hypothesis that the sustaining engine for success here is what the academic centers create and sustain. The currency being graduate students and faculty that are contributing the intellectual capital that goes on in this area. And as I say that then, I would ask Dr. Witt what he's doing with his university to encourage this, and I mean in two or three different areas.

One, traditionally, at least in the northeast, the university has not had a good mechanism for multi-disciplinary efforts which increasingly are necessary for biotechnology success. How do we encourage faculty to think in multi-disciplinary? How do we reward them for this kind of thing, for being the engine that is responsible for success here?

Our structures, again at least in the northeast, which I know, are not very good. We have to invent new ways of both rewarding faculty, reconstituting virtual departments or units, or centers, or that kind of thing. And that's where we haven't had that initiative, and I think what we're hearing here today is it's time for us to look at creating that kind of initiative. And I'd be interested in how he's approaching that subject in Texas.

MR. WITT: I can respond with a couple of examples. Probably a disclaimer is in order. It's far too soon to say whether or not it is completely successful. Without meaning to be flippant, I think one part of our strategy is tied to a phrase we've all heard, follow the money.

In terms of the internal allocation of research support, we're leaning heavily in the direction of inter-disciplinary research, and in fact, targeting the dollars to that. That has led an increased number of our faculty who want to access the internal dollars to know that the only way they can do it is by crossing disciplinary lines.

Another problem that I can remember from my days as a dean is when you ask people to engage in research outside of the mainstream of their discipline, you are asking them to assume a level of risk, because very frequently the product of those research programs do not appear in the traditional journals of a discipline.

Hopefully, colleagues are broad-minded enough to step back and say this is not in our traditional journals, but it is still good scholarship that will be recognized and rewarded. I think you need to keep your key administrators focused on the fact that when

academics step out of the main stream and start crossing boundaries, to the extent their work does not appear in the appropriate journals, they must be recognized and protected, even if the system is not.

A third approach we're taking, and Richard is familiar with some of this, we're part of a relatively large system. There are 15 components, 6 medical, 9 academic. We're fortunate to have in our immediate area UT Southwestern. One of the things we've tried very hard not to do is to recreate on our campus at Arlington, or to a degree at UT Dallas, the kinds of resources that are present at UT Southwestern.

Richard is intimately familiar with some of the jockeying that's going on now, because part of what we're dealing with, and I think it's fair to say about each of our institutions. And, Richard, you may want to comment. We all want one of our own. If we need this discipline represented, and we want our's, and Dallas wants their's, and Southwestern wants their's, we're trying to break that, because if we can begin to share intellectual resources, as well as physical resources, laboratories, then the collective impact of those three institutions would be very significant. Richard, you may have something to add from your experience.

MR. SELINE: I just think one of the issues, you hit it on the head. One of the issues that we find in a lot of academic campuses is the funding formulas actually work against some of what we're talking about. And it's not just the University of Texas system, I think it's almost every one of the systems that we had a chance to spend some time with, where they actually "- this is going to be those Texas terms, Mr. Secretary, and I apologize, but they fund better "-

DR. BODMAN: We're used to Texan around here.

(Laughter.)

MR. SELINE: So this dog won't hunt. The idea that there are funding mechanisms that encourage and flavor more towards rear ends in chairs, than they do the creation of knowledge, and moving knowledge from the basic research commercialization. So a lot of universities across the country are forced into coming up with programs to get funding, ultimately that really wants to be over in the research and, you know "- and so I think Dr. Rubin's point is, I think it's been raised here a couple of times, the role of the university is truly under a lot of pressure to advance and step into a leadership role that typically they have not played in an economic development way in the past.

DR. BODMAN: Dr. Bement.

DR. BEMENT: I've been waiting for someone to bring up market models, or market inputs. We've had examples this afternoon of several types of industries, so there's a vertical dimension, as well as a market dimension. It occurs to me that there certainly are examples of existing markets requiring new technology. Health care and pharmaceutical would be an example where the markets are well established, and for the most part, they're clearly examples of industries that are in transition. These are markets in transition that can use new and existing technologies.

We heard of ag bio, marine bio, chem bio, et cetera, but there are also other industries that have been mentioned that are pretty opportunity driven, sort of new markets and new technologies for new markets which have high risk. And each of these would probably require different regional models, different kind of business models, different types of investment models, and probably different types of national policies. They are federal policies so trying to target a little bit more on what types of federal policies, or what type of federal investments might be appropriate would require, I think, bringing that market dimension into the discussion.

DR. BODMAN: Yes, sir.

MR. ROHRBAUGH: Mark Rohrbaugh, NIH. This reminds me of a statement that "- a story that Dr. Zerhuni, our new Director of NIH made, about his work at Johns-Hopkins in which he used to "- in emphasizing the need for cross-disciplinary research, and how fertile it is for grounds of new technologies. He said he used to play a game with visitors who were visiting Johns-Hopkins by taking them into a laboratory and having the laboratory explain what their research endeavors were, and then asking the visitor was department do you think this is, this laboratory?

And he said usually they were wrong. They could not guess what department within the medical school the research was occurring based on hearing what they were doing. And so I don't know he did it, and I can't speak for him, but clearly that model works well for Hopkins, and others will see that, and I'm sure try to model that expertise. But I would also say that he has said, and it has been a priority for NIH to fund more cross-disciplinary research, whether it be in the bio medical engineering area with our new institute, or even prior to that with collaborations with NSF, or enforcing collaborations.

As someone said, people go where the money is, so by funding and supporting special initiatives in bioinformatics, in bio engineering, where physical sciences and biological sciences come together, we hope to facilitate and encourage people to cross those barriers and find ways to work together to find and develop new really innovative technologies.

DR. BODMAN: Mr. Horowitz had a comment. Then we will come back.

MR. HOROWITZ: Well, I mean, in many ways our work is sort of we've had the opportunity to work in the St. Louises and the Atlantas of the world, as well as the small Peoria's, Roanoke. And I think there's no doubt, going back to Bruce's question, can you buy it? Well, universities buy it every day, and that's the world that they've existed today, is very much a very competitive role to buy it, and I think it makes a whole lot of sense why they're trying to do that, because no university wants to be a quality research university, even if it's not going to be to the standards of Johns-Hopkins or Wash U. It still needs to have quality biosciences, and it's just that kind of disruptive field.

But I think what it comes back to when you're dealing in the more economic realm, which is I think more

of our concern, which is the science is high quality. We want to keep it going. Communities are going to try to share in it. It gets back to, I think, what Richard was saying, which is that you really have to think very hard about what's the initiatives, and that's really the key to the strategic approaches that these communities are taking.

And then the question becomes how do you best make that work? Well, you better "- you know, you don't just go through to recruit. You better think hard about what you're recruiting, and why you're recruiting it. So in a place like Indianapolis, which is right next to Wausau where they have "- which is the world's leader in medical devices, you better be recruiting quality cell biology, or you're going to lose that industry to the Bostons and to the San Franciscos, and so forth.

So there's a lot of focus that needs to be about those core competencies, and I think that's the most difficult thing in the field today, is that people who do bio tech strategies have to now actually begin to figure out the sectors and relate it back to the industry drivers. And what you find in the universities is that professor scientists are very good at knowing their field and going very deep. What's being demanded of the

professionals now is they're the ones who have to be able to see through and make those connections.

But then it comes back to, and I know we're going to get to it in a second, the federal role, is it really can be "- the federal government can help that, you know, sort of what might be called disruptive things, because I think what Jeff was pointing out is, if you just let the markets go, you know, they'll go to certain places. But if you can have disruptive things happening, like what's happening in Kansas City today, well then the question is, is what's the role of the federal government? And I just put out there that it's not just to throw lots of money, but it's to throw it "- it's to leverage it together with a community that really has their act together.

And figuring out whether a community has their act together is the most difficult thing sitting in Washington to figure out. And I think that's really the challenge but, you know, I think if a community doesn't go back through, and people have said the right things. It's leadership, it's aged universities, it's networking, it's all those critical things. Not everybody is going to have the capital the way it is, but when you begin to think about it, and when you go to the inter-

disciplinary, the last thing I'd point out is, that's where you begin to really see the different market places. And my only concern is, is that we're talking about bio centers. We're not talking about biotech research centers. We're talking about bio centers that can accomplish what St. Louis may be able to do, or what Preoria may be able to do, or what Roanoke has been able to do.

It's different. The opportunity sets are very different, and could have very big impacts on those communities, and I would not write those things off.

DR. BODMAN: Ms. Hunter-Cevera.

MS. HUNTER-CEVERA: From Maryland, previously from California, so having spent 20 years in Bio Tech in California, and moving back east, I think I have two things I'd like to share with all of you.

Maryland is an interesting state. It's a small state, and because it's so close to D.C., because everything in Maryland is focused on counties. And as you know, Maryland holds either, I think, the number three or number four seat in biotechnology companies.

Most of the companies in Maryland are focused in Montgomery County because the federal agencies are there. If you're going to start a biotechnology company,

I honestly think you start it where you like to live. Most CEOs will form the company where they want to raise their children and their families, so quality of life, transportation, good schools, businesses, culture also has a role in which you call clusters. So now that I'm getting old in the area of biotech, I don't like the state clusters. I like to think region.

IN fact, one of the initiatives in Maryland is to help stimulate a mid-Atlantic regional focus bringing it downward, Pennsylvania, West Virginia, Virginia to work together, not only on biotech, but interfacing the industries that you mentioned, Richard, with respect to nano. In fact, I can tell you that the next link in biotech will be the integration of physics to move it forward.

One of the things in Maryland, because we have 13 separate institutions in the university system in Maryland, and Johns-Hopkins, we have formed a bioscience working group for the state. We now have, I think, a very successful program at UMBC Medical School, college part on bio informatics, and bio engineering.

We were told by the state dollars are tight. Get smart. Start partnering or else, and so you have the leadership within our own government wanting this

clustering, this partnering to happen to make us more competitive nationally. Now I don't know how many of you know about UMBI, but it's a unique university created by the state legislators to actually be an economic engine.

Having most of my career in biotechnology and the industry, I remember the days when we went to the universities maybe for some strains or some small piece of work that we specialized in. We never thought of actually having that technology developed already to be handed off through commercialization. IN fact, at UMBI we don't do tech transfer. We do technology management. There's a big difference.

We co-manage other universities property, we link and watch the property in the portfolios. We are cross-licensing with other universities to mainly gain and make it more attractive for venture capitalists and major investors to come in and say oh, I can deal with this rather than several universities.

When you partner universities, I don't know how it is in Texas, but we've got to work very hard at getting all the barriers out of the way in the front so the faculty are so happy and comfortable that they can work with a member of Johns-Hopkins or UMBC, and not worry that oh my gosh, I'm going to get beat up for doing

this. And we've learned a lot from MIT, in all honesty, in how successful their tech transfer model is, as well as Stanford and Wisconsin. In my mind, those three universities do it right.

One of the things we've done in terms of Maryland is it is regional within the state. Western Maryland wants to be a player in biotech, and you're saying well, what's in Western Maryland? There are mountains. There are plants, there are fish, and there is a lot of, believe it or not, a tremendous amount of indigenous knowledge in the mountains of Central Appalachia, so we joined forces with the State of West Virginia, UMBI, and UMB to create the Central Appalachian Center.

Now we're not going to build a huge biotech facility there yet, but we have knowledge creeping in because we're working on teaching people sustainable technology by using some tool in molecular biology, linked with class knowledge in plant physiology and farming.

What we're seeing happening is we're going to have a biotech industry, or we're going to have a cottage industry, we're going to have bioinformatics, we're going to have all these other industries that go along supporting one thing. That, to me, is the regional

focus. Montgomery County formed a partnership with five other counties, and now we have the Potomac Tech Region in Maryland.

Baltimore suddenly woke up and said wait a minute. We have funding institutions within our city limits. We don't have a biotech base here. There's something wrong. They were focusing on the telecommunications. So again, a group came together of business, academia and government, and now we have Johns-Hopkins initiating it's biotech park, and we have another biotech park on the other side, and the big debate is how much biotech can one city support?

Well, they looking in the sense now to see what the real strengths are, and it can be developed partnering with Montgomery County, partnering with Delaware, partnering with other areas. We have a big initiative on the eastern shore because it's all the ag waste, and yet they're not using biotech. Delaware is having serious dialogue with UMBI on how we can work together regionally to do something in ag biotech.

So my point is, is that the buy it, but if you partner creatively "- in fact, we have a huge partner with the State of Mississippi and Florida on marine biotech in the sense of recirculating aqua culture of crustations -

okay - and shellfish, and there are several patents that are being shared, and companies are going to be started in Baltimore, as well as Mississippi and Florida, all linked from the group working together, meeting a need within those regions that serve a common ground, so I think there are ways to do this.

And lot of this dialogue happened through the Southern Governors Association of 18 states, where we actually came out with one report. And it was interesting from that meeting how some institutions began to have more dialogue in the sense of working together to benefit more than one community. So I think that I agree that the future is what now has to be discussed because biotech has changed from when I entered it in 1980 as a researcher at Cedar's Corporation, and lived through PCR, which is one revolution. And now I the next in the sense of the National Labs with all their knowledge in physics and nuclear physics now playing a big role in biology, and understanding it, to take it to the next level. So I think that we're going to see a change in the type of company, a change in the type of infrastructure, certainly a change in the way we do business.

Universities work in what are isolated ivory towers. We're now putting pressure on being the economic

engine, but no one is training the staff how to do that. And so UMBI has determined workshops on what it takes to be an entrepreneur, and we have the entrepreneur professorship. What it takes to work with industry.

We have an industrial professorship that industry pays for to work on their problems, and we have these other workshops on let me tell you what you own and you don't own, because many faculties are totally unaware. And so anything that the Department of Commerce can do to stimulate I'd say more funding for translational research, because in my mind, like at UMBI we have 30 percent applied scientists, 70 percent research, and there's much research to be done in development so it can be easier to hand it off. And yet, very few funding agencies will put money into that.

DR. BODMAN: This is called the Translational Research?

MS. HUNTER-CEVERA: Translational Research, where you're really translating it from a basic idea to an application, but it has to be scaled up. Now the State of Maryland has UM, which has some of this money, but in all honesty, it's not enough. In fact, we are very excited about creating public/private partnerships and state/federal partnerships where there's an equal

amount being put in, and everybody benefits. And also, we work very closely with federal agencies because they are in our backyard, in the sense of how we combine technology. Like we're working with NIH on one current technology that one company wants NIH pieces, and our piece, so there's a nice dialogue.

But there are ways, I think, in thinking to go forward because I will also tell you that many companies from Asia and Europe visit us all the time to want to license our technology. They see the potential, and what we're trying to say is well, if you want to license it, why don't you come to Maryland?

So, I mean, there are ways also to get companies to come to your states, or subsidiaries or, you know, work that way. But I don't think biotech is so much clustered as it is. It's really global, and much of the advances are made through a tremendous amount of networking across the country on regional problems or problems that are common to certain states. And I happen to believe that there is "- we have to tip the iceberg in marine and ag, and biopatholosis. Everybody focuses on medical, but there are short, long and mid-term investments. And I would ask you not to forget those very important areas that can create jobs.

Like our aquaculture facility only requires 15 people, but the packaging processing plant to go with those 200 jobs, so there are many cascading industries that we tend to forget that go along with the marketing of biotechnology, so that's just what's happening in Maryland right now.

DR. BODMAN: Thank you for your comments. That's very helpful. I wonder if we might shift, and we will ask our last speaker, maybe we could shift to the federal "- what the future might hold? What role the federal government might play? The next speaker, we'll ask Dr. Burke, I should probably say.

MR. BENDIS: I'm a civilian.

DR. BODMAN: Mr. Burke, who has spoken to us before, and we've asked him to say a few words about what the future might hold, and what the role that this government and this department might play. Please, sir.

MR. BURKE: The task is daunting. I will try and make sense, and I offer my content in four main areas. First, something of phases and chronology. Second, something about the future. Third, something about the national possibilities of leadership and assistance. And fourth, something about the biggest imperatives at hand.

First, about phases. This word "bioscience" brings us together, and whether we come to it from the vantage point of technology transfer, or clustering, or governmental whatever, we are unified by what is fundamentally the technology. And like any technology, this one has a life span, and a kind of inevitable movement. All technologies begin with intensive research, and they move over time to more the way of products and applications, and more in the way of outcomes.

All technologies, beginning with the earliest ones have been founded on discovery, and this one is no exception. However, I submit to you that what I would call Phase I of biotechnology, that phase largely based on research and exploration, and the feathering out of possibilities is fundamentally over in its broadest possible way.

What have we learned in Phase I, which has roughly gone for 25 years? We have learned that the science can yield extraordinary outcomes. We have learned that companies can spring from this science. We have learned the difficulties and vagaries of technology transfer, and ways to finance these companies. We have learned something of regulatory policy, and daunting

ethical and societal issues. We have learned that pots of money are available to be made, and we have learned that the societal impact is extraordinary.

Essentially, having learned that, it's time for us to move on to what I would easily in an abbreviated way call Phase II of biotechnology to develop the next what, 25, 30 or 50 years. And unless we have a clear sense of some demarcation by which we are moving to the future, we will be less able to both identify, so my second area of biotech, what is the future likely to bring for biotechnology in ways that will be useful to all of us?

First, I think we're going to get a more realistic take of what it is at hand here with biotechnology. Yes, we are going to see extraordinary economic and societal gain, but as Ms. Alexander and others pointed out, we are going to see that the number of jobs, and the conventional measures of economic development will not necessarily go on to past experience. We will get a realistic sense of what can come from it.

We are going to see probably a diminution or a lessening of new places that are working to be strong lead sites for biotechnology, because as we are discussing today, the task and cost is daunting, and

other places are far ahead, and have more experience. We're going to see probably instead, this has been implied today, some greater attention to NISH and targeted biotechnology endeavors on the part of places, and regions, and cities and nations offering a realistic take on what they can do, and how they should do it.

We're also going to see in the future, I submit, the slow but probably inevitable diminution of America as the sole leading dominant nation for biotechnology. This foundational research of Phase I has, of course, percolated as it always does worldwide, and other places benefitting will assume a greater primacy, and no doubt will assume that primacy in areas that they quite frankly think are more important to them, and that seem less important to us. Meeting, perhaps, the needs of cultures, varying economies and other places worldwide.

We're going to see, of course, specific areas of implication and of intent, value-added crops, nanotechnology, biocomputers, animal biotechnology is fairly explored, including aquaculture and marine. We're also going to see a world much changed by forest biotechnology, and we are going to see increased human intervention, and increased human implications that I

submit to you in their complexity will make concern with taco shells pale by comparison.

We're also going to see increasing worldwide potential and imperatives to policy. Traditionally, we have accounted the technology as a matter of one, underlying science and research. And two, of products and commercial movement, but to those one and two, with this technology we'll be able to add a third factor, societal policy and related imperatives and issues recently worldwide.

Our attention to these societal and policy imperatives will, in fact, not just be a luxury. It will likely be a requirement for the movement of certain products, and certain identifications. We know this, of course, with stem cells and agriculture and biotechnology.

And I further submit that among the ways in which nations, states, regions, and places can be strong in this technology, leadership, and thoughtful and sensible attention to ethical, and societal and policy issues will now be a sign of leadership, as well.

What about this future? How can we move to it? They're complicated and they're not without challenge. What might the national take be, and how

might your department and other involved federal agencies help us? First, I submit this.

I spent 17 years in the Biotechnology community, and I continue to be astonished that we have never had about this, the most single and complicated technology in the history of the planet, we have never had a sign of national policy statement, that this nation is committed to the development and application of biotechnology. There would be some set statements to that. There are issues are hand, we must attend to them, stem cells, cloning or whatever. But amazingly enough, this country has never benefitted, nor has its community benefitted from a significant signal statement that this nation is committed to this technology.

Amazingly enough, we have made that statement about other areas of importance in our national history, but we have never made it about this one. So what a significant juncture, particularly at this chronology as we move to the next manifest stages, to have some kind of federal, national statement made. We are not unaware of the issues, but we are committed to deal with it, and move it on out.

Second, as part of that, we're aware that the technology will continue to yield new shifting,

unexpected applications in areas of prices and attention. Right now we know that America in particular needs, for instance, increased capabilities for workers and for those persons to support the technology, and increased and steady ways to finance companies at different stages of this development.

How useful it would be if somehow the federal government could lay out ways to be responsive to the ever-changing and unfolding needs of the biotechnology community. They will be different this year than in five years, but a kind of flexible response would be necessary.

Another imparity that could be met at the federal level, to ensure and make clear that our national government has in seamless way programs and ways to offer assistance at every juncture in the movement of technology from foundational science, not just to the funding of companies, but also to the preparation of workers, to the dealing with issues. And, in fact, the biotechnology community can trustingly and effectively go to our federal government and get assistance with everything, rather than the wholly roman empire take, which is a bunch of unrelated stuff. We are sure that

under this national statement and policy that everything is in place.

Finally, what might that mean for your Department of Commerce? Well, we're told, first, that all places can't be strong, but many places have intentions, so what if you establish the needs analysis program, and made available \$50,000 every January under some time period in your program for a place to get funding to determine realistically what is its possibilities?

How can do it meaningful research with possibilities, so that you help those persons with those tactical making task of determining what they can do, so that their ambitions are realistic, and so that their goals are more in tune with need. And perhaps you would then bring all those recipients of those \$50,000 needs assessment awards together every December at the end of the year, and see how they can dovetail together. Or what if you set up the competitiveness capacity funding program, that could in a deft, nimble way make responses to what are the prevailing current needs in America? For the next three years, it might be worth those preparations, or biomanufacturing, or other ways to assist companies. Or what if you even triggered the

national bioventures investment fund, national government, public and private partnership to assist companies?

Finally, area four, what are the biggest imparities here? We share experience. We deal with the reality of the nuts and bolts, but in the biggest possible way, what's it going to take to bring about this Phase III in the future of thoughtful and sustained biotechnology?

First, imagination. This is the imaginative process. New strategies, new ideas, new approaches. We heard of Central Maryland. Don't forget, we're humans. We do best if we're triggered by imagination.

Second, it will take synergy among all partners and among all participants. And third, our future will require synthesis. Biotechnology is the most complicated thing currently on our planet. It's a matter of science, regulations and ethics of everything. And synthesis among diverse vantage points are required, not just for the development of the clusters. Imagination, synthesis and synergy. It's our future. Welcome to it.

DR. BODMAN: Thank you, sir. Are there any comments, amplifications, differences? Yes, sir.

MR. BENDIS: Well, I can't say it as eloquently as Steve. I think I'd like to compliment some of the people at the table here, because some of the things you're talking about are beginning to happen. EDA and Dr. Sampson basically agree there is a new mantra there, and the words they are using in their programs are totally different than the words that were used before. And there's really the regionalization, return on investment, high-paying high-skilled jobs. You know, the EDA used to talk about express communities, but if you talk about all those things we're talking about now, that's how you turn around distressed communities, so some of the programs "- the first one you talked about on the needs analysis, that program basically exists today. EDA has that plan.

You can do a cluster analysis if you can show that you're going to do it on a regional basis with a proposal to the EDA. They would help fund a cluster analysis, or a needs analysis for a region. It may not be readily known to everybody, but we just applied regionally in Philadelphia, and we basically have worked with Regional Director Paul Rache there, and we've got six unique programs that meet the new language that

you're talking about, that EDA is going to be responsive to.

DR. SAMPSON: I appreciate your pointing that out, and I think that one of the things that I would like to leave with all of you is, I travel around the country quite a bit, because I do want to see what communities get it. I don't have the time, nor do I have the money to waste it on communities that don't get it. And I can't rely just exclusively on paper. There's only so much you can get from looking at proposals on paper, so I am trying to identify the communities. I was in Kansas City last week, spent a whole day in Kansas, Missouri, and many of your communities.

What I said to Dr. Duncan at that time is, there is a real disconnect between what you all are talking about, and the economic development practitioners and organizations at the regional and local level. They don't know what you're talking about, and the reason I know that is because I look at all the proposals. I evaluate every single grant proposal that comes in. It's my credibility on the line before I send it to down to, you know, the fifth floor, because I'm a professional in this area, and they don't get it. So what we've got to do, and why I appreciate Bruce so much putting this

together, we've got to do a better job of linking what you all are doing with the people who are developing and implementing economic development strategies that are out there.

MR. BENDIS: And I think you've done a great job, so "-

DR. BODMAN: Don't puff him up like that. He's hard enough to "-

(Laughter.)

DR. SAMPSON: I haven't gotten the check yet, so "-

(Laughter.)

MR. BENDIS: I think to pick up on what Steven was saying, is that I view the government's role as identifying gaps. And I also look at the government's role is that we've got one big portfolio to manage. There's a whole lot of money in it, and guess what? If you look at your personal investment portfolio today versus where it was two years ago, you have to do things differently in the way you invest your money.

We have different challenges today with government funds and the different agencies. But guess what, we talk about a new philosophy, but the implementation we use today is the same as it was 10, 15,

20 years ago, so we need to change some of the structures of the federal funding programs. We need to be more flexible with these programs to be responsive to the changing economic climate and the environments today. At SBIR, Phase I has been \$100,000 for how many years, Mark?

MR. ROHRBAUGH: For years, but we routinely now give higher amounts.

MR. BENDIS: I know, but now you can do a fast proposal, and you can get a Phase I and a Phase II together. But maybe we should look at a Phase I "- let's call it different. Let's go now to the Phase I, II, III commercialization. Let's get some new programs. Let's have a \$250,000 SBIR award. Let's have, you know, if we're going to focus on biosciences with 100,000 bucks, what's that going to do on a Phase I SBIR? It's not going to do anything. Maybe for life sciences, biosciences a half a million dollars in order to get to a quality project that we really need to get going on.

The ATP Program, we need to change the portfolio and the structure of the ATP Program too. We have to change the cycles on how long it takes to get a proposal prepared, reviewed, and funded. It might take a year before you get something out of the system. By that time, you've got 15 other people over in Germany and

Japan who are doing research from the same technology, and you're behind. So how do we get "- fast track is good, but how do we get more money into a fast track system so we can be more responsive with these emerging ideas to meet the challenges that exist today? So it's changing the way we manage our portfolio. I think we have all of the vehicles. We've got enough money, but need to reallocate the money around the portfolio to be more strategic than the way that we're doing our investments from a federal government standpoint.

The other thing is you have to require more leverage and match. The key is it can't be soft money, and a lot of people are going to hate me saying this, but the way you find the real partners out there are the people that are going to stand on the gain with you, and that's the stakes.

You know, the stakes have to come up and match dollars occasionally, rather than being soft matches, so you're going to have hard dollar matches out there for people "- because if you can get them to put dollar for dollar, you get industry to come in, you've got three times as much money to work with, rather than just federal money or public monies. So how do you find ways to really stimulate partnerships? And it doesn't have to

be all of the programs, because in your portfolio, I look at it as four different things. You have basic research, which is in two categories. Basic research for the advancement of knowledge. That is very important to the nation mission, but you have basic strategic research, which is potentially going to become applied. That takes on a different personality.

And then you have applied research programs, and then you have commercialization programs. If we look at our portfolio of programs within the federal government today, and if we look at the dollars allocated amongst them, we're heavily weighted towards the basic research for the advancement of knowledge, and we probably should be long-term into the future. But the way we allocate those other dollars, I don't know if it's being done strategically from a portfolio management basis. And we can't be all things to all people.

I mean, from a state standpoint or a regional standpoint, we can't fund everything. It's a peanut butter budget. We have to pick winners and losers sometimes, and that's why a lot of people didn't like the ATP Program. You know, you're picking winners and losers, and a lot of people didn't like that because it was big businesses involved. But I think the ATP

Programs are very strategic critical programs in the United States because a lot of foreign governments, the European Committee are doing things just like that with bigger bucks today, and we need to continue down that path but a little bit more strategically, so I'll get off the soapbox.

DR. BODMAN: Thank you, sir. Yes, Ms. Alexander.

MS. ALEXANDER: Just sort of thinking about the comment that Steven made about a statement from the federal government, and who knows exactly what that looks like? But I think it's more than that, and I think there's something besides money that, perhaps, commerce can do. And maybe this is a question as much as a statement.

Biotechnology touches many, many different federal agencies in one way or another, and I'm interested in sort of exploring what commerce can do in a leadership role with its sister and brethren government agencies in helping to set a tone, an environment at the federal level that's conducive toward biotechnology development.

There are so many places where we're funding technology, we're creating regulatory and legislative

policy. And I think coming, as someone who's worked in the industry for a number of years, somebody who worked at the NIH for a number of years, and now will be going to a different type of model, it's thinking about how do we tie these pieces together and make sure that while we have some relatively consistent favorable environment at the federal level to support biotech development, and wondering what role commerce can play in that in helping to educate other agencies, to makes sure when things are happening that are going to stall or hurt this industry broadly, ag, forestry, all of it, what's the role that can be played in the cabinet to make sure that we're going to move forward as a country, that we're not being supplanted by other countries?

DR. BODMAN: Yes, sir.

MR. RUFFIN: My name is Morrie Ruffin. I'm with Bio. Just to pick up on what Dr. Alexander said. I think one of the "- I mean, the issues for me, as it relates to this third topic, and the role of the Commerce Department and the administration is the perception that we address every day as the industry; and that is, whether the administration, frankly, is viewed as pro biotech in terms of how it is viewed both within the

industry and outside the industry. And I think that is very important.

I mean, we want this administration to be viewed as supportive of this industry, and I don't know, frankly, to be honest that we are there yet. I mean, and it's because of a lot of issues, some of which are beyond our control. But one of them, I don't know whether it was mentioned here earlier today, and I know this isn't in the purview of the Commerce Department, but we still don't have an FDA Commissioner. And without an FDA Commissioner, I mean, that is the most absolute fundamental thing we need in this industry right now today.

And I was just up on Wall Street two weeks ago going around talking to all of the analysts in the industry. It is the number one thing they focus on. We want to have successful companies in this industry. We want to grow successful companies. We want to develop clusters. We need to show the leadership there, and the perception among the investors in the industry is that there is no leadership, because there is no FDA Commissioner.

And that's just one thing I would add as we go through this, because I think it is a message that it's

very important for us as we go forward. We need the support of this administration for industry, but we are at a critical juncture in the evolution of this industry, where we have more drugs than ever moving through the clinic, and we need the resources, and thankfully due to the efforts of this administration though, we were able to get the legislation through, the Prescription Drug User Fee Act, and that has been helpful.

My sense is that, as I think Leslie was alluding to, commerce can play a leadership role in kind of setting the tone among a number of the different agencies, and it involves essentially a commitment on the part of everyone to support this industry.

We are, I think as others have mentioned, are now at a point where our primacy is being challenged, and there are governments around the world "- I was also just on a trip to Asia a couple of months ago. And I can tell you, in the commitment that is being made to build this industry in Taiwan, Singapore, Australia, India is immense. They have all the resources of the government behind them, both political and economic. And it's something that we have to be aware of. And there is a lot at stake here, because we have built a very

successful industry, but we have to preserve it at this critical juncture.

DR. BODMAN: I feel the need for us to respond, but we will restrain ourselves, and get the comments from you. Gillian, do you have a comment?

MS. WOOLLETT: Yeah. I would just say, it all comes down to essentially public perception of value of the products. If there isn't a market at the end, it doesn't matter how well any of us produce anything. And just having watched some of the recent media coverage, whether it's hormone replacement or whatever, the volatility of the public confidence is fairly conspicuous. And without things such as FDA Commissioner, or support and competence in the regulatory structure, but we have to pay for the reviews of our own products to get them to the market?

Clearly, that is not an optimal situation, but it was a necessary one to actually get medicinal products through. So I think what it comes down to is, at every level is value of the product has to be part of the debate. And just watching what's going on with prescription drugs and seniors, value is not in the debate.

What's in the debate is net cost, not costs relative to other health care or whatever, so if value gets dropped out of the debate, all these products at a medicinal level fall off the table. And when we're talking 12 to 15 year development times, 800 million per product, the very uncertainty of where things are going can be hugely destructive, and that's where I'd give the gene therapy analogy of just not knowing who is in charge, even though NIH is not a regulatory authority. In the year after Gelson, the number of INDs dropped by 50 percent for gene therapy. That can be conspicuously damaging for the long term without the ongoing support of this and future administrations.

DR. BODMAN: Thank you. Richard.

MR. SELINE: Can I throw some more fleas on the dog? The Commerce Department has always in its history, at least I have observed, Mr. Secretary, has always played a leadership role in looking at the trends of the country, and in working backwards, so there's been opportunity to talk, you know, say 20, 25 years out what this is going to look like. There's also the realities that we work in a political environment.

Let me notion a couple of things that at least we come to the table with in a bias. One is, the federal

government has tons of data about this industry, about regions, and about communities. And I will throw a couple of fleas that actually will bite here, by try to be provocative.

If I have to call for the third time over to the international trade office here to get the international trade reports on what the biotech industry does in the way of exports, and still not finding somebody who can get me an answer, and I'm a friend of the family, it's just difficult. So there are access points for federal data, whether it's census, international trade administration, NIST, NIH, NSF, a number of places. We now know through at least our work around the country, that regions are begging to have access to this knowledge, that they sometimes don't know who to call or where to go get, and it becomes a hurdle. So even when David gets a community who wants to collaborate to be able to define what his region is like and what it's about, is really, really difficult to get at.

And the nature of "that some of this data is proprietary because it has some issue of competitiveness", trust me, there are nations around the world who get at our data better than we can in our own

backyard. So I'd like us to at least some point talk about data and the information that regions need to have, that tends to be inaccessible.

The second is something Bruce, that he and I talked about, and commerce has done this in the past, Mr. Secretary. Morrie, correct me if I'm wrong, but I don't think that, at least in my knowledge, anybody has ever really brought the entire federal family together that has an impact on the broadest statement of the biotech industry, whether it's labor, or NIST, or NI "- those representatives have never come into a room to really talk about their impact on the regional development of the biotech life science industry. And we tried a little bit, but yes, there's a whole set of the world that's the regulatory, but the economic impact and competitiveness relies on us being able to say with David, Department of Labor is putting X amount of workforce grants. Most of our relationships at states now, oddly enough are through the workforce commissions, because we're trying to figure out what the next round of workforce and skill sets are going to look like. So just the ability to bring the federal family.

Third, something I think I and others have mentioned, and that is that the formulas have not caught

up with what the trend lines are looking like. Now what's interesting is, not NIST. I'm sorry.

DR. BODMAN: Mark.

MR. SELINE: One outcome immediately of this gathering, I would encourage "-

DR. BODMAN: I've lost you. What formulas? What trend lines?

MR. SELINE: The formulas that are in place today for whether they're the SBIRs, or past ATPs, or whatever the new generation of federal fundings, have really not caught up with what the trend lines look like in the area. So I'll re-emphasize Rich's point, \$100,000 for an SBIR tends to not get you where you need to go in the scale and the size of the businesses.

But, Mark, one of the things that you raise here, and that David also has raised, it would be great as an outcome of this meeting if we could get a memo that really articulates some incredible big steps that commerce and others have taken that really notion that there's something new, a new way of thinking, there's a new set of things that I heard for the very first time that Mark's talking about, some things that David's been working about, if we can get some kind of inventory of what are some of these federal strategies that are in

place to really be innovative, and I think they're encouraging.

And the last part is this president is an entrepreneur at heart. Right, David? This is a president who loves and believes in entrepreneurship more than anything, and this is an industry that next to academia relies on entrepreneurs more than anything. And there are a whole set of agencies that kind of tinker and tweak a little bit. I was with the SBA folks last week, kind of tinkered with this idea of what an entrepreneur needs. And frankly, I don't see an entrepreneur in the room.

MR. BURKE: This gentleman is "-

MR. SELINE: Okay. I'll take it. The question is, is we're talking about what we can do to help economic development, and the secretary goes in the room, the ability for us to define what an entrepreneur really needs, rather than us sitting here saying this is what we're going to give you. Here comes the hose. Get ready, we're going to make, you know "- I think we can find out what the entrepreneur really needs in the future and get those pieces of the federal family together in that area, as well.

DR. BODMAN: Dr. Rubin.

DR. RUBIN: As a member of two university faculties, I go to a lot of meetings, I must say. And my congratulations to the gentleman at the head of the table for organizing this. This has been the most interesting, and perhaps most important meeting that I've had the privilege to take part in in a long time.

Having said that, I'd like to make a finite proposal. We've heard wonderful things about what's going on around this. I mean, all of us in this room will agree, this is the most exciting industry right now, or else we wouldn't be here talking about what needs to be done. But I think there are real problems that have not been addressed here today, other than organization and money, and they have to do with public confidence. And in two or three kinds of areas.

One of them, for example, is the periodic scandal mongery in the media about exploitation of vulnerable populations during clinical research. There's a distinct lack of trained people in pharmacology, in clinical investigation where a critical importance in bringing new ideas to the point where at least in the bio drug business, if I could use that, are critically important. These are things we're going to have to address with imaginative academic programs, as well as

policy kinds of issues, that we all have a responsibility to nurture, but that's where the next generation is going to come from.

And I've had the privilege of spending most of the day here in talking to various people, and my finite proposal is I think that no individual group, academia, trade organizations or government can speak alone and have credibility in the different problems that are there. So my thought is to propose the idea of a working committee drawn from all the disciplines involved, academia, industry and government, to come up with deliberations and recommendations.

These are not necessarily money, but it will lead to money in a variety of ways. It's really the element that we haven't talked about, that I feel very strongly about because I hear it all the time as a clinical investigator, is public confidence in terms of the development programs. And developing a dialogue with the media who take every opportunity to criticize, would be a gentle word, to them would be closer to the reality of this kind of thing. And this will be as important, I would submit, to some of the other initiatives there, and I think the Commerce Department could show a great deal of leadership by involving all of us to deal with these

things in developing new educational programs and new relationships.

DR. BODMAN: Arden.

DR. BEMENT: Not very much has been said during this meeting about the role of NIST, or the role of infrastructure science in support of the industry, or in support of world trade, so I feel I need to put together a folder for all of you, and indicate the many different ways in which we are contributing.

Clearly, we're working on trade barriers through mutual recognition arrangements with National Metrology Institutes around the world, and I know that many of you are well aware of some of the issues with regard to international standards. And in that regard, NIST is the world leader in biotechnology standards and chemical standards. And we're in a training mode essentially in training other NMIs around the world in these standards areas, because they are creating trade barriers in some countries.

In the Measurement Science area, just to give you some ideas, we're working in the realm of nanobiotechnology, actually measuring properties of individual cells, individual molecules, molecules on membranes, and we even have people here that are working

in that area, which is very exciting and very important, that also in developing databases that are well evaluated in terms of three-dimensional protein structures. Our work with carb is having a very important impact on the whole field.

Now maybe we ought to be developing other databases, and in that regard, your feedback on what else we might be doing would be very helpful. I should point out, since the ATP Program came up, over time you learn how not to pick so many losers. Through our Economic Analysis Office, we learn as we go.

On the other hand, you want to take some high risks, so you're bound to have some losers. But I should say that a significant part of the ATP Program goes to support projects in the field to as much as \$1 million a year, and in some cases even higher. And this has been very exciting because I think we can take credit for some of the micro array technologies, some of the gene chips that are now into the market. And new proposals that are coming in in the current batch, which is the largest batch we've ever had. A significant number of them are exciting new concepts in the area of bioscience and biotechnology, and I'm sure they'll be part of our selection, so those are just a few examples. But I think

as you go through the folder of material, you'll find that there's a wealth of other activities that you'll very much be interested in. So my program office, my investor liaison office is here. We'll give you points of contact. We'll have the websites identified if you want to be interacting.

DR. BODMAN: You will all be beneficiaries to a far greater degree than you can imagine.

MR. MOREIRA: Tony Moreira, University of Maryland in Baltimore County. Jennie already gave us a very good description of what's happening in Maryland, so I will just expand on that.

One of the things that we do a lot in our campus is really work with the industry nationwide, but certainly focusing more on biotech companies in Maryland. And we're hearing a lot from them, a couple of things. One is, and expanding on Steve's, the need for well-trained workforce. And that's interesting to look at because industry is "- they need scientists, they need laboratory technicians. They need all that, but they also looking at manufacturing, and you used the word biomanufacturing. That's very important, because truly, we're not going to be there. It's not going to be manufacturing at some point, real products. And so being

able to have individuals that understand manufacturing side, and as a chemical engineer it took me many years to understand what bioinfection is, myself, because you normally are not trained in those areas.

And so, being able for universities to train individuals that understand biomanufacturing, as well as the regulatory side, because on top of this, the biotech industry is heavily regulated, and so being able to manufacture in compliance with all the regulations is very important. And unless you have this cross-training of large scale and regulatory interests, you're not going to be effective in this kind of industry.

And then we have to look at these in terms of any evolving industry, and those people that we train today, two or three years from now, they need to be trained in different areas because every day new developments are occurring, and new names, new bio nano infotech, whatever is coming along, and so we need to be able to respond to those. So having programs that help universities develop responsive training programs for the workforce development is very important. And universities need to be able to have the capability of doing that, of interacting with industry, otherwise we

work in a vacuum and don't really know what industry needs, so that's one aspect.

The other thing we hear from industry is, again, the need for funding even in the early stage, and that's very hard to come by. Talk about the SBIRs, ATPs, those are very, very important, and we heard just very recently a company in Maryland that's creating their own venture capital site, to help to look at other "- of course, there are interests, self-interests here, but again the need of developing other kinds of mechanisms to support companies because I hear all the time small companies that, you know, they can get 50,000, can get a 100,000, but that's a drop in the bucket. They need a few million very often to just make a dent into this.

The other point I wanted to make is also expanding on Jennie's comment, is the need for federal programs to help universities move again their technology into the commercialization. And she used an interesting word, "Translational Research", and that's, again, very important because if you have an idea, if you have something that seems to work in the laboratory, and you create and might get a patent, but until a company can see that that indeed works, that it can lead to a product, you will not have that transfer information.

And so being able to develop these concepts to a point where a company or organization will be able to see yeah, there is value here. We really "- we can move this forward, also bring further to the university because now they have a more valuable technology package that moves along. But then we also need help as an academic in understanding how this works.

We are very good with draining Pietrie's, doing research and all that, but universities have not been typically part of economic development, and so helping universities understand that. For instance, creating or supporting sabbaticals from industry people at the university campuses so that we can get this little back and forth, helping faculty spend time at industry without having to jeopardize tenure and other kinds of issues, without complex. And the universities also have to change somewhat, they have to review the ways of they do models and the way they're doing business.

There's a whole field here of opportunities for the federal government to work with universities, to work with industry in making all these elements come together. As one of the elements of the many that we heard today that are so critical for this industry, and goes "- just millions of factors that are very important

that we all bring together looking more at, on my half of the academic and the Council of Biotech Centers as the kinds of things that we are very involved with in terms of workforce development and economic, technology transfer, economic development.

DR. BODMAN: Thank you, sir. Mr. Bendis, do you have a comment?

MR. BENDIS: Yes. I'd like to reinforce what Dr. Rubin said. And it's a question of what is the take-away we take away from meetings like this, because we all have the opportunity to do many of them. And there used to be an organization, or whatever it was called, the United States Innovation Partnership, in the prior administration, and what it attempted to do was exactly what Dr. Rubin was talking about, I think Richard mentioned, and others may have participated in, that the United States Innovation Partnership was OSTP TA.

This was Dr. Mary Gooden took the lead, and really she drove "- TA drove this in the United States. We had every federal agency at the table. We had Council on Competitiveness, the State Science and Technology Institute. It was more general around competitiveness and technology. It wasn't specific to bio, but I "- there's a need for something like that today because the

platforms where implementation occurs is in the regions in the state. There's a disconnect in communication today because this meeting is one of the first things I've seen happen, and I'm sure there have been many other.

But I compliment what you've done today to bring people from regions, states, different types of organizations around a common table. We need more of that, and I'm not looking for more meetings, but this is a way that we can get people talking about how we can transform what's going on in the United States. So whether it's the United States Life Science partnership, I don't know "- you've got to "- you like bio, you like PRA Pharmaceuticals, but I think there's a specific reason this came together, it was around bio.

But a lot of people, you know, whether it's life sciences, pharmaceuticals, or bio, or whatever you want to call it, if we can demonstrate we have this partnership, that partnership is the one that demonstrates globally that the United States is behind with this statement, about how the U.S. is supporting it, and it's not just the administration. It's every agency within the administration, all of the independent organizations and industry at the table speaking for

that. I think that's a much stronger voice, so I would strongly encourage to the extent possible, that we try to re-invent something like the United States Innovation Partnership, and where there are specific industry needs, create subsectors around it to where you can focus on those emerging and those next big things around the United States where we need to keep our leadership, and we can develop leadership.

DR. BODMAN: Yes, sir.

MR. ROHRBAUGH: Mark Rohrbaugh, NIH. We've talked a lot about government funding, but I also want to point out something that has been successful, and perhaps there's a need to grow and become more innovative in this area at NIH, is in-kind assistance to companies and universities, particularly in this area where the translational area of adding value, showing proof of concept.

The Cancer Institute and Allergy and Infectious Disease, in particular have very strong programs where they will screen compounds for activity against cancer or infectious diseases, where they will assist universities and companies with toxicology, scale-up, processing, clinical lab testing, even conducting clinical trials when it's warranted for the government to

assist in those areas. So consequently, we can say that to date most, if not all, of the anti-AIDS drugs, Anti-Retroviral AIDS drugs on the market have gone through that program in one way or the other. And the majority of anti-tumor agents on the market have gone through that program, as well, even though they may not have received direct funds from the government. There was vital assistance that was provided by the government in some form of testing along the way to add value in pre-clinical and clinical trials.

DR. BODMAN: Yes, sir.

MR. HOROWITZ: Yeah. I wanted to, you know, a little bit more at the micro level. Where has the market failed for communities, and I think if you put it in that context, it makes it a little easier for folks in government to say well, there's a role. Because clearly what you don't want government to do is try to interfere with market processes. And so the question really comes down to, and I kind of make our living doing this, so I'm giving a little bit of a trade secret away, but I mean, there are really two market failures, particularly in bioscience.

One we've hit upon, which is this proof of concept, because no private venture capital is going to

pay for an uncertainty in terms of knowing when things are going to really be validated. And we're not talking validated in humans, we're talking validated in animal models, and it's a market failure. And what we work with in communities is to figure out how to create the mechanisms, and I think even more sort of revolutionary than what Richard was saying is to be honest with you, you don't get a whole lot of leverage out of the SBIR program. I think the kinds of stuff that was raised earlier is that it's one-by-one.

Well, you really need to create something that allows you to leverage, so you make a one-time investment, and in a sense you're getting a return on principal, not a return on investment, so those funds remain in place and allow them to keep going forward. And, you know, Kansas did a great job of thinking through a lot of those kinds of issues, but that's a tremendous market failure, and that is holding our country back because what you find is you have great technology, and people aren't advancing it, and that is innovation that's not being seized.

The other key market failure is really around facility financing, and it's because it's such a specialized facility, the market place really holds off.

And I'll give you a very clear example. In Montgomery County here at 270, we had the opportunity to do some work. There's about a half million square feet of space under-built right now. The reason why? Because even today, the commercial markets don't recognize that space as being good "- you know, it's too much specialized so the markets stay out of it. And clearly, the communities that are really doing well are the ones that figure out how to really build on those specialized space and come up with mechanisms. And the question becomes how do you create secondary markets? How do you think outside the box that not that the federal government is going to do it all, because it shouldn't, but it needs to create that infrastructure.

We would not "- probably most of us, or those of us who live in particular, would not own our homes if we didn't have the kind of mortgage market place that we have today. And the only way you could have that is by creating a framework at the federal level. And those are not for the well-established companies, those are for the companies that probably will never see "- you know, you'll never get to see too much, that really need that extra set of space. And to be honest with you that's, you know, in Maryland why we did so well, is we were able to

figure that out for at least a period of time how to create those funding to that kind of space. Like very few states really do it, and the market place just fails there. And I think if we can bring that kind of focus and use "- have commerce be a partner, that would be tremendous.

DR. BODMAN: Any other comments? Let me, if I may wrap this up, we'll get everybody out of here on the agreed to hour and on your way.

First, on behalf of the Department and the Secretary, I want to thank you all for coming, particularly those who came from a great distance. We're grateful, and that traveling these days is not very easy. Yesterday particularly was not a very easy travel day. We're all aware of that, so we want to thank you for the effort that many of you made to be here.

Secondly, to state the obvious, the government "- I can tell you as a newcomer. I've been here for a year, the government is not organized very well to do many of the things that you have suggested that we do. We find our "- I always find myself in awe of the resources and capabilities that exist within the government, that I had no idea were here. I learned today that NIH has a venture capital program. I spent 24

years of my life on and off as a venture capitalist. I had no idea they were doing that there. I wonder how well they're doing it, with all due respect but, you know, they're probably doing fine. But, you know, that is but small example.

I think the "- we tend to be organized in stovepipes in the government. It's not easy. We are captives of congressional committees who love to hold sway over what we do, and how we do it, and that leads to a compartmentalization that is difficult to break down, and to cause some of the interactions that you all have suggested would be useful.

The Commerce Department, as I mentioned before, is a kind of an eclectic place. There are a lot of different activities going on here. You have gotten a snippet of some of them this afternoon with Dr. Sampson on the one hand, Dr. Bement on the other hand, the folks at the technology administration, and these are but three of about a dozen parts of this place.

Overall, the way we see it, our job is to represent the private sector broadly defined within the government. That's what our job is. Our job is to try to provide for, if you will, a home for the private

sector within the government. We have good relations and are able to convene individuals from different agencies.

As the afternoon moved on, I felt, as I'm sure Bruce did, when we review this, we would have been well-served to have had other people from other departments here. I think that that "- we have been successful in that in the past. We're grateful that we've had the diversity that we've had, but it's even "- I think we would have been better served, you would have been better served if we'd had even a more broad cross section of individuals. But we can be a bit of a bully pulpit, I think, in terms of getting individuals together, and getting departments together so that we can make available to you, your colleagues, your organizations that which ought to be made available to you, a word about that.

We do have contact. The secretaries have contact with Pharma and with the large pharmaceutical industry, which are the ultimate customers of much of what your "- the newer "- the biotechnology, smaller companies, new companies product. They're not the customers for all of it, by any means, but for much of it, and that's an industry that has its own burdens today. It is an absolutely unique business in America

today. It has got a unique competitive position vis a vis almost anything else we can do in this country, even our so-called high tech software, the electronic equipment in businesses where we have a powerful position.

But we, as a country, have no more powerful position in any industry than we do in the ones you represent, and the ones, particularly the industry represented by the large drug companies, that they have a set of problems that they are confronting that I think they are struggling with related to what their broader role should be, how do they deal with disease and problems in nations that cannot afford the solution to the problem? Yet, they've got to confront it, and deal with it in a more effective way, I believe, than they have done in the past.

We have some contact with your industry broadly defined, but I would like to suggest that perhaps through the technology administration, and through the people on my "- at my side here, that we could do a more effective job of hearing and specifically trying to provide, for example, data and information to the extent that there's data and information, that there are data and is information available in the government that your

clients or your regions are not getting access to. We surely ought to be able to deal with that, and so I would think by having a link-up, and a means of communication here, we could certainly do our best to try to identify and free-up the flow of information that is appropriate.

We cannot pry out confidential information. We would not do that, and I know you wouldn't't ask us to do that, but we ought to be able to free-up information that's your property, and we're, you know, very aware of that.

I would also say that I think we can be a convener, and a drawer-together of, if there "- if it is appropriate to have a group or subgroup, Dr. Rubin mentioned such a thing. Others of you have alluded to it. If there is an appetite for that, we would certainly be pleased to perform that role, and to see what we can do to be helpful.

This department, I don't know about past administrations which were alluded to. I can tell you that both the secretary and I come from the private sector. Neither of us have ever been government before. We both ran companies, and we are here to try to be helpful. You know, it's the old story that having spent time in the private sector, coming to Washington to try

to save the world. The best quote I heard on that was one of the Congressmen who had been there said, "He came to Washington to save the world, and now he was just trying to get out of town with his reputation in tact." And at times I feel a little bit that way myself, but you know, you do not, as a group, represent, you know, a consistent set of interests.

Some of you represent individual cities and regions, others particular industries, others have corporate interests, yet you all have this common link to this extraordinary newly emerging industry that probably will dominate the science of our country over the next generation, maybe longer. And I think we're aware of that, and our job here is to try to provide a home for the commercial aspects of that in an appropriate way, and we will do it. We will do our darnedest to be responsive and to be helpful where asked, but we do need to know what to do, because I do think we have not had sufficiently deep or broad communication, or understanding.

And in part, that's because of the way the government is organized. You've got to clear relations with NIH and with, you know, the great organization that that represents, and the source of funding for all kinds

of things that they do, and there are obviously other parts of the government that you deal with. But perhaps we can play our role in helping deal with some of these commercial interests, and we will do our best to do that.

With that, we would conclude the meeting. I noticed there were a few business cards being exchanged. I wanted to note that any commercial deals that are made, the Commerce Department gets 10 percent.

(Laughter.)

DR. BODMAN: And with that, we would call this meeting to a close.

(Off the record 4:00:51 p.m.)

