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Proceedings By:

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P R O C E E D I N G S (9:05 a.m.)

Agenda Item: Welcome and Introductions

DR. GANSLER: This is not university time, but real time. After being in industry and government and having now started living in a university, I am used to meetings not starting on time, but we have a very full day, and it is worthwhile to get started.

I am Jack Gansler. Along with Alice Gast who is here in the front row, we are the co-chairs of this committee. We want to thank you and welcome you to what is the National Academies' Committee on a New Government-University Partnership for Science and Security. How is that for a nice long name, but a very important topic, obviously.

This is the second regional meeting of our committee. We are particularly grateful to Georgia Tech for hosting this meeting, along with Emory University. Also, I should say the Southeast Regional Center of Excellence for Biodefense and Emerging Infections. That is an even bigger title.

We have been charged by a variety of sponsors for this, the National Science Foundation, National Institutes

of Health, Office of Science and Technology Policy and the House Science Committee. Our objective here, what we have been charged with doing, is holding a very broad and open discussion, I should emphasize that, of the key issues at the heart of this balance between science and security, and how to balance those.

We are holding three regional meetings. This is the second one. The first one we held at MIT last month, and then we will be holding a third one at Stanford. Then we will culminate this activity with a convocation in Washington in early 2007, at which we will present what we heard and a set of options and recommendations associated with that.

These regional meetings were specifically the request that we had in terms of the methodology to be used. As I said, these are intended to be open, so we want to encourage comments and discussion from the speakers, the attendees and particularly the fellow committee members.

I have to emphasize, and I have been told to make sure I emphasize this, that we have not drawn any conclusions. The reason for these is to hear from all of the participants. The speakers we asked to try to frame

the challenges that we face in this science and security area and we particularly would welcome your proposed solutions. We are trying to get ideas from you, not just to define the problem. We are very interested in trying to get a balanced set of presentations from the national security community and the university community about topics such as controls on dissemination and publication, restrictions on participation, management of biological agents. These are the kind of issues that are challenging to both the Administration and the legislation, but also very challenging right now to the universities.

We are going to go through the normal Academy process in terms of our deliberations, both in terms of our own committee and then a rigorous outside review of our findings, and we will then finally put out a report at the end of that time period.

I should emphasize that this is an open session for both days. The public are here, and we also welcome the press here. So just be aware of that. An unedited transcript of the meeting is going to then be posted on the Academy's website in a few weeks, so this is all being recorded as well.

Before we get started, what I thought I might do is introduce the members of the committee, beginning with Alice. Raise your hand so the people know who you are. So when the committee speak up, they will know they are speaking as committee people. LouAnn Burnett. I should point out, Alice is right now the Vice President of Research at MIT, and shortly to become the President of LeHigh University. LouAnn is from Vanderbilt University.

John Gordon, retired Air Force General and among other miscellaneous jobs with the intelligence community as well as the U.S. Air Force, and now retired. Former Senator Gary Hart, now at the University of Colorado. Michael Imperiale. Michael is with the University of Michigan Medical School. Julie Norris. She is the director emeritus of the officer sponsor programs at MIT. I should point out that several of our members were unable to come today, Arnie Bienenstock, Karen Cook, Richard Meserve and Elizabeth Parker.

Finally, in addition to our host institutions, let me thank Jilda Diehl Garton and Michael Green of Georgia Tech, as well as Ruth Birkeleman of Emory, who really put a lot of help into providing this organization

for the two-day sessions.

Now it is my pleasure to introduce Jilda, who is then going to introduce the president.

Agenda Item: Opening Remarks

DR. DIEHL GARTON: Thank you. It is my pleasure to welcome all of you to Georgia Tech and to Atlanta, and thank you for coming.

It is my very great pleasure this morning to introduce the first speaker, Dr. G. Wayne Clough. Dr. Clough is the tenth president of Georgia Institute of Technology, and I am told the first alumnus to serve as president. For those of you who don't know, Dr. Clough is a civil engineer. He earned his bachelors and masters degrees in civil engineering from Georgia Tech, and later earned his Ph.D in civil engineering from the University of California in Berkeley. After serving as a number of faculty positions at Duke, Stanford, Virginia Tech and University of Washington, he became the president of Georgia Institute of Technology in 1994.

These last 12 years have been a pretty impressive time at Georgia Tech, and we have made some remarkable strides. In 1996, I think most of you know that Georgia

Tech served as the Olympic Village for the centennial Olympic Games. That was just ten years ago, it is hard to believe. We have also during this time increased our research expenditures from $212 million to $425 million. Over a billion dollars in private gifts have been received, and a statewide engineering program has been created down at Georgia Tech-Savannah. An ambitious building program of over $900 million of building has been completed, including this facility, and I believe we have got about $300 million more in the planning and design phase. In 1999, Georgia Tech received the Hesburg Award, the nation's top recognition for support of undergraduate education.

Dr. Clough serves on the national stage, as most of you know, as well as on the Georgia Tech platform. Dr. Clough was named by President George Bush to the President's Council of Advisors on Science and Technology Policy, and in 2004 he was nominated to the National Science Board. I believe Dr. Clough is the only person to serve simultaneously on both PCAST and the NSB.

Dr. Clough's other service activities include serving as the vice chair of the U.S. Council on Competitiveness, where he co-chaired the 2004 National

Innovation Initiative. He is also serving right now on the National Academies' Katrina Commission, looking at what happened down in New Orleans and Louisiana and Mississippi and the failure of the flood walls there. He currently serves as the chair of the Engineer 2020 project for the National Academy of Education.

Dr. Clough is also a member of the Executive Committee of the Metro Atlanta Chamber of Commerce and the trustees of the Georgia Research Alliance. He also serves on the board of advisors for Noro-Mosley, one of the Southeast's largest venture capital firms, and he serves on the board of directors of TSYS of Columbia, Georgia. Finally, he is also serving as a consultant to the San Francisco Bay Area Rapid Transit System for its ongoing work in seismic retrofit operations, which fits in his civil engineering background very nicely.

With that, I will turn it over to Dr. G. Wayne Clough.

DR. CLOUGH: Good morning, and thank you, Jilda, for that very fine introduction. I appreciate that. We are really honored to have all of you here. I thank you for taking on this task. It is a very important one for

our nation, for all of our universities.

Jilda said some nice things about accomplishments here at Georgia Tech while I have been here. It helps if you hire people who are smarter than you are like Jilda, and then good things will happen, and that is why it is happening.

The work that you are about today obviously is very important to all of us. I am shortly to take a trip to Ireland, where we will open up a new office in conjunction with the Georgia Tech Research Institute. The very topic you are talking about has come up multiple times in regards to our work overseas. In December I was in Shanghai, where we established the joint degree program at Shanghai Jiao Tong University. Before I left, I had to have a briefing on deemed exports and all of the issues associated with deemed exports. So it affects us in every way we interact internationally.

Sometime in the fall I will be in Beijing, where we have a joint relationship with Peking University, and once again we have to spend a great deal of time on the deemed exports issue. And of course, we have lots of international students here at Georgia Tech, about 3500,

and have a strong interest in that area too, as well as having many, many scholars here.

It is my pleasure to welcome you, not only on behalf of Georgia Tech, but Emory University which is co-hosting, and the Southeastern Regional Center of Excellence for Biodefense and Emerging Infections.

Collaboration with Emory University is not new to us. Emory and Georgia Tech have a very deep relationship, going back some 20 years. We have combined forces in the area of medical research, bringing Georgia Tech's strength in computing, engineering and science with Emory's great medical school. We created the joint biomedical engineering department, which we think is one of the first in the nation where a private university and a public university work closely together in co-funding such an activity, and we are proud that has been recognized today as one of the top five such departments in the country.

As you know, those kinds of relationships are not easy to develop. They take time, and they take a lot of willing participation by both sides. I tell folks that after 20 years of working on this and reaching a pinnacle when we see the kind of relationship we have with all of

our faculty, I knew it was working when both parking departments agreed to one approach to parking. That was the toughest of all.

We are also co-hosting this with the Southeastern Regional Center of Excellence for Biodefense and Emerging Infections. That is the new kid on the block. That was formed in 2003 under the leadership of Duke University and a group of research universities in the Southeast, and focuses on translational research designed to provide vaccines and medicines and diagnostic tests for emerging diseases and bioterrorism threats. So we are pleased to join with those two entities in co-hosting.

This is an interesting topic that you have in front of you. I think it dates back a ways. Three years ago in 2003, I had the pleasure on the 200th anniversary of the inauguration of the historic cross-country journey of Merriweather Lewis and William Clark to take a boat trip to simulate part of that trip that they had. It was a lot easier for us; we were able to drink martinis where they were starving, but at the same time we had an opportunity to reflect on what that meant.

As we went along on our trip, I read their

journals. It reminded me that this was a voyage of discovery, and it was driven in large part by Jefferson's interest in science. The trip reinforced this idea of the rich heritage our nation has of exploration, discovery and risk taking, and sharing that knowledge with others. Beginning with our earliest pioneers, Americans have always looked for new frontiers and imagined a better future based on sharing of information.

I have had the privilege, as Jilda noted, of serving on the President's Council of Advisors on Science and Technology. The same year I took that boat trip commemorating the 200th anniversary of the Lewis and Clark expedition, I also served on the PCAST panel that looked at the subject of science and technology in combatting terrorism. This panel is a reminder that many of the fundamental characteristics that drive exploration and discovery have the potential to be at odds with issues related to homeland security. Even as our future prosperity depends increasingly, however, on scientific exploration and discovery, we are facing a need to rebalance freedom and risk taking on the one hand against national security on the other.

Fundamental research, which in the United States is conducted primarily at our great research universities, thrives in an environment of openness and collaboration. The national security Directive 189 from back in the 1980s recognized this by saying, no restriction may be placed on the conduct of reporting federally funded fundamental research that has not received a national security classification.

However, of course after the attacks of 9/11, the federal government began to tighten its restrictions on federally funded research, and we in the university systems began to express concerns.

That brings me to the third thing that happened in 2003. That was, the AAAS organization conducted a study to see what they thought the impact of these new restricted clauses would be. What they found was that in some cases, universities decided to forego federal money altogether rather than accept restrictions. Our friends at MIT, for example, turned down more than $400,000 in federal funding because it would have required the federal government to approve all of the employees on the project.

However, in most cases our universities have

responded, and Georgia Tech is one of those, engaging in a case by case tedious basis to negotiate and modify the language to be more acceptable. AAU and COGR weighed in as well, stressing that university research is based on a free exchange of knowledge. Unless it was classified, fundamental research at universities should remain unrestricted.

The federal government spends well over $25 billion a year in funding university research. These funds are distributed by a wide range of agencies and departments, including NASA, NIH, NSF, NRC, DARPA and NIST and a list of acronyms. As Senator Hart well knows, there are 13-some Congressional committees that have oversight for all of these things.

Some of the agencies that we deal with have taken the initiative on their own or felt they were required to take the initiative to add new restrictions on research contracts. These restrictions that include a designation that research is sensitive but unclassified, or that foreign nationals are restricted from participating. The Department of Homeland Security, responding to their own needs, have also joined the fray with restrictions specific

to its research.

Right now, I would suggest there are too many cooks in the kitchen stirring the stew. What it boils down to is that we have no consistent policy. This is one of the problems that we have; we don't know which answer is the one we should use. What the Department of Energy finds acceptable today, the Department of Homeland Security may reject tomorrow. What NSF considers legitimate may be unacceptable to the Department of Defense.

We were of course gratified to read in last Wednesday's Federal Register that the Department of Commerce has acknowledged the concerns raised in more than 300 comment letters from institutions like this one and others, and modified its proposal for additional restrictions regarding deemed exports. But the devil remains in the details. When a funding agency imposes a restriction on the use of foreign nationals in research, we are forced to exclude some students and visiting scholars from these projects.

All of us can see how this may be seen as justifiable to the public, in the interest of national security. But taken to an extreme or a modest extreme, it

may leave us in an isolated position in the world of science and engineering. We all know the figures. Over half of those earning Ph.Ds in this country in engineering today are not born in this country. Not only are our universities dependent on this remarkable talent pool, so are our industries and corporations and, as you know, many of them are trying to demand that when an international student gets a Ph.D here, they get a green card. That is at least one suggestion by corporations.

If you combine these issues of restrictions with those about the difficulty of obtaining visas or visiting processes, we as a nation are at risk of insulating ourselves from the very talent that we need to succeed in a more competitive global economy. The competition for that challenge in the coming years will be intense. Nations like China and India are deliberately investing and building world-class universities.

Thirty years ago, the United States was conferring 54 percent of the world's Ph.D degrees, but by 2001 our share dropped worldwide to 41 percent. China, which was virtually offering no Ph.Ds as recently as 20 years ago, now produces 12 percent, and that is rising.

Doctoral degrees in national like India and China also have -- doctoral degree recipients have a growing range of opportunities for employment at home. As nations like these develop world-class universities and skilled work forces, high tech corporations pay attention, and they locate there because of the talent.

Microsoft's fastest-growing R&D facility is not in Seattle, it is in Beijing. GE's Jack Welch Research Center in Bangalore, India employs 2,500 scientists, and GE is building a $250 million medical research facility in New Delhi. Our nation's economic competitiveness is going to be put to the test by these new developments, and more is to come, not less.

Last January I was privileged to attend the U.S. University President's Summit on International Education, which was convened by Secretaries of State Condoleezza Rice and Secretary of Education Margaret Spelling. President Bush and Laura Bush also participated. The two Secretaries and President and Mrs. Bush are to be congratulated for making it clear at that meeting that this nation needs to encourage international students to come to study here and for U.S. students to go abroad and study and learn about

other cultures. The meeting was also valuable in that it allowed an open exchange on matters of concern about visa processes and deemed exports.

It was a good step forward, perhaps the first we have seen where we literally had a chance to speak to each other. The university presidents made it clear that broad areas of research such as nanotechnology should not be restricted, since to do so cuts us off from important developments that will be coming from other nations.

When we were there, we talked about nanotechnology. Fluid dynamics was another one that was being proposed to be restricted, which is kind of crazy, because as we know, other nations are investing as much in these areas of research as we are. We certainly understand that in nanotechnology. As Chuck Vest put it, president emeritus of MIT, he said we should work to build high fences as needed only around the narrowest areas of research that are truly critical to our nation's security, high fences around very small areas.

We know how to do that. Some of our institutions do research that is already classified. We can do that.

But if you try to protect nanotechnology, then you are

cutting yourself off from the world.

We clearly need to take a comprehensive look at the type and level of restriction that is truly essential for national security, and then forge a new agreement between universities and the government on the balance point between openness on the one hand and security on the other as it relates to university research.

So I want to thank the National Academies for taking the initiative to create this Committee on a New Government-University Partnership for Science and Security. As noted, this is the second of three regional meetings to discuss the issues related to these important issues. I join the National Academies in believing that these regional meetings are an important step in beginning the process of forging new partnerships between the government and our nation's research universities that will serve the needs of our science and community security for the 21st century. I think that is very important.

So I congratulate you on undertaking this activity and taking time out of your busy schedule to do this, and we look forward to working with you in any way we can to help your activities. We hope you have a good time

in Atlanta. I understand the weather is going to be perfect, so please enjoy it while you're here, and spend a little money.

Agenda Item: Keynote Address: Challenges and Opportunities for the Research University in National Security

DR. GAST: Maybe you will be able to direct us to the bookshop so we can spend some money at Georgia Tech while we're here. I would like to join Jack and thank you for hosting this event. Thank you all for the hard work in putting this together. We are very glad to be here today.

It is my great pleasure to have the opportunity to introduce our keynote lecturer, the Honorable Frank Gaffney. He is the founder and president of the Center for Security Policy in Washington, D.C. This center is a not-for-profit, nonpartisan educational corporation that was established in 1988.

As with our tradition, we optimize our time here for discussion, so I won't read to you his fascinating biography. But you all have the biographies in your material. I would just like to say that you probably are

already likely to have read his words in many forums and many op-ed columns, or heard his voice on the radio or seen him on television. So with no further ado, I would like to welcome him to the podium for his address on challenges and opportunities for the research university in national security.

MR. GAFFNEY: Thank you so much. Good morning. It is a pleasure to be here with some old friends and sparring partners, as well as, I imagine, some new ones. It is vital that we be talking at this moment in time about the issues that this particular panel has been asked to address, and indeed that the community that is represented so well here is clearly seized with as well.

I guess my job is to somewhat set the predicate for a conversation which it sounds as though it might largely involve not so much the national security, but how do we get around the problems that it constitutes. I am going to talk about the problems confronting the national security in the hopes that that will both inform these other considerations and deliberations, and also I hope strengthen the recognition that the kinds of

recommendations that this panel is going to be making, and

that indeed, all of us want to see adopted must, must, be cognizant of some very hard realities.

This morning's Journal Constitution offers some interesting up to the second reminders of the nature of the challenge we are facing immediately. Reports that Georgia citizens have perhaps had an association with Canadian terrorists who had obtained three tons of ammonium nitrate which they intended to use certainly in Canada and possibly elsewhere to blow things up, is one indicator. Another is, over the weekend the news was trickling in about the possibility that another danger was very narrowly averted, a sarin gas attack in London's underground. These are just symptoms of course of the immediate problem.

It is a problem that I believe is truly global in character, and that represents a threat that is almost unimaginable, namely, the emergence once again in our time of yet another totalitarian ideology whose ambitions are quite literally to destroy what I call the free world. That means us, of course, as the leaders of the free world.

This ideology has not been universally named. Some people confuse it with symptoms like the ones I just described, terror. But in fact, I believe it is a coherent

ideology. There are different strains within it, but for want of a better term, I call it Islamofascism. I use that term advisedly, because I am suggesting that it is indeed a political movement, not a religious one, one that masquerades as a religion, which makes it frankly vastly more difficult for liberal democracies like ours to contend with. But it is at its core about power, not about faith. It is being made vastly more dangerous to us by the support it enjoys from states that sponsor and enable it.

Challenges here, too. One of those states of course is Iran, with whom we are now dancing in the hopes of dissuading them through a series of inducements to give up something that they are quite committed to having, which is nuclear capabilities.

The other which is even tricker is a so-called friend in this war, namely, Saudi Arabia, a nation that is awash, as is Iran, with the proceeds of oil payments from the West, and that is using those proceeds perhaps in places like this, but certainly elsewhere in academia, and indeed elsewhere in our society, and surely elsewhere in the world, to promote this very ideology of Islamofascism, greatly complicating of course what we think and say about

these sponsors, let alone about the ideology they are advancing.

That is the near term problem. Unfortunately there is a longer term problem. It is comprised of those who may not be Islamofascist themselves, but who certainly seem to be quite happy to have our resources and energies preoccupied with dealing with that threat while they work to supplant us economically and perhaps militarily.

The most worrying of these is Communist China. We have just heard about the relationship between this institution and Communist China, and it is true of many, of course, both in academia and in the corporate world.

How do we understand what China is about? A recent contribution was made by the Pentagon, which has produced in just the past weeks the most detailed and I think sobering series of analyses of what China is doing in a number of different areas. It notes that the Chinese themselves refer to the United States as the main enemy. They talk about war with the United States being inevitable. Do they mean it? I don't know, but as with the Islamofascists, I am inclined not to ignore what they are saying, to themselves, to their political cadre and to

their military.

Then there is the matter of economic power, power that I will be coming back to in a moment, made possible in no small measure by us. There is the question of its industrial capacity, being built at a truly mind-boggling pace. We have heard about the academic infrastructure being built up and the products of it in a very competitive way. There is also the matter of China's wealth also being applied to purchase our debt. The largest owner of America's T-bills is Communist China.

There are matters of espionage. Gordon knows a great deal more about this than I, but a number of studies over the years have documented the role that Chinese front companies, technology theft operations, academicians and outright espionage collection operatives are doing to build up both the tech base and the military capabilities of China. Then not least, there is the military buildup itself, much of it enabled by Vladimir Putin's Russia, but to some extent benefitting from the sorts of technology flows and opportunities here, in Europe and elsewhere that China is very aggressively exploiting.

So there are two problems, the immediate threat

posed by Islamofascism, the longer term threat posed by Communist China, giving rise to what we have called in a new book the war for the free world.

A further complicating factor which I think operates very much in areas that you are going to be addressing in the course of the next two days is something that for want of a better term I think might be called post nationalism. Our ability to contend with these challenges will in no small measure be affected by an attitude that we very much believe is a truly worldwide phenomenon, indeed, it is called globalization by most of us, and yet, it is not entirely clear that it is being pursued in a post nationalist way by our competitors.

I was struck in reading through this document about rising above the gathering storm, a title that I will come back to in a minute. It says a lot about the way we are approaching this problem, but we assume everyone else is approaching it in the same way, that this globalization is not only truly global, but that we are all in it for the same general reasons and purposes. I'm not sure that is true, on closer inspection.

Indeed, in the key issues paper that is in the

packets for your consideration, there is this quote which was alluded to a moment ago, the need for unfettered communication and collaboration in an increasingly global and competitive world is predicated on the idea that basically there are shared values, shared interests, shared techniques being applied to a better world economically and presumably in other areas as well.

Yet, I think even fairly superficial examination of what is happening in some of the areas that presumably being referred to as this country's competitors, that is not necessarily so, Communist China being an example in the extreme of a nation that is certainly exploiting globalization but seems to be doing so for very much nationalist purposes, building up nationalist capabilities.

I would argue that even some of our friends in the free world are similarly seemingly exploiting globalization at our expense for purposes that have more to do with building up national or in the case of the European Union, transnational communities, capabilities.

It is certainly true that we in this country benefit from some of this globalization. Most obviously in the case of the academic community, those graduates that

you are cranking out who stay in this country and who bring great talent and energy, as have preceding generations of immigrants done, are incredible assets, assuming -- and I hesitate to say this, but I think it needs to be said -- assuming they are not working for somebody else.

Even, I think it can be argued, those who go home that you have trained in our finest academic institutions, have a contribution to make to a better world, including to our interests, to the extent that they are in fact bringing with them an understanding of our country, an affinity for our country, a desire to improve the conditions in their own country in ways that are not threatening to us, bringing about middle class growth and creation of new consumer markets and the like in their societies as trading partners for us. That is all to the good.

But let's be honest. It is not up to us as to whether or not such products of American academia, with all that they are taking in terms of the training and skills and knowledge that is imparted to them here, will redound to our mutual benefit. There are factors at work, I have mentioned nationalism overseas as one. Another is the mindset that is evident in at least some of these quarters,

one might argue India and Japan as well as Communist China and the EU, a certain zero sum mindset seems to be operating, with strategic repercussions and economic ones.

In some cases as I have indicated, there are simply downright hostile intentions on the part of their governments. To the extent that their governments have means of either inducing or compelling such students, such Ph.Ds, such postdocs to perform services for the state at our expense, that, ladies and gentlemen, is a problem.

In short, we need to be clear about whether globalization is more of a one-way street than we are led to believe, that it is not being practiced in ways that assuredly help us and instead may in many cases be practiced in ways that compound today's national security problems and confront us with far more serious military and economic ones in the future.

I have been asked to talk about opportunities, not just challenges. I would like to give you some food for thought in this department. Truth be told, I'm not sure all of this is in the realm of the hard sciences, which I gather is the major focus of these deliberations, but I think we are all in this together, and the soft

sciences, the hard sciences, the academic institutions and the country they all serve is what I would like to speak to in terms of the opportunities at hand.

The larger point is, I think we have got to be clear as a people who the enemy is, and that we are in fact once again at war. It is a global war, as I have indicated. It is a war with both near term and potentially longer term dimensions, and it has to affect the calculations that you are thinking about, and the decisions or recommendations that you will be making about how you draw that line, that balance between national security and openness, the possibilities of globalization ueber alles governing in the Academy at least.

I believe there is a critical role for the Academy in understanding who this enemy is. Clearly the skill sets especially in regional studies and languages, the cultures of the regions and nations that we are confronting, is critically important to be bringing to bear as part of the national effort to protect ourselves and promote the free world's larger interests.

There are clearly opportunities that abound to insure that the U.S. military is equipped to deal not

simply with today's challenges, but tomorrow's. Some of those are likely to be very different from today's. There is a very real danger, particularly in a time of constrained resources, that we will persuade ourselves that the kind of fight that we have right now is the one that we have to be preoccupied with and equipped for forever. It is a variation on the old line about generals fighting the last war. As Jack Gansler knows very well, we are in a dynamic situation strategically, and for reasons that I have alluded to, particularly from China. That is likely to become more dynamic rather than less in the future.

For example, in areas such as cyber warfare, the possibility of conflict involving or actually taking place in space. In particular, a problem that I am frankly seized with and think is of enormous consequence for this country, we call it in War Footing the mega threat you never heard of, the possibility that someone may use strategically an attack involving something called electromagnetic pulse, possibly as a blue ribbon commission reported to Congress two years ago, by delivering a single nuclear weapon and detonating it high above the country in space, raining down on this country an enormous burst of

electromagnetic energy, possibly as much as a million times the power of the most powerful radio signal on earth, with what the commission described as catastrophic consequences for the nation, because such a burst of energy would devastate our electrical grid and damage if not destroy virtually every piece of electronic gear that is not protected against it. That, ladies and gentlemen, is a 21st century disaster. If you have a hard time getting your head around it, think about Katrina as a microcosm of what this might involve.

I mention this because this is an area in which both our military and frankly every bit as much as our civilian economy urgently need the skills and insights and help of the research institutions.

Another subject of great opportunity is the need, now increasingly appreciated by the public and some of Senator Hart's former colleagues, for energy security. There are tremendous opportunities here. My personal belief is that this is of such urgency that the opportunities may lie mostly in applying existing technologies as much as in making the breakthroughs that will enable future technologies to be brought to bear. But

this is at the top of the agenda, I believe, and has to be for obvious reasons.

Another area in which there are opportunities, we need the help of the academic community in areas that to be honest with you, most people in this community I sense find anathema. That is in the homeland security arenas of collecting intelligence and monitoring activities of people who have -- again, for reasons I have alluded to -- been able not only to set up shop and to pursue jihadist programs and activities abroad, but also to do so in this country, which raises of course a host of thorny issues about, are we in fact not only circumscribing unduly academic freedom, but are we engaging in other infringements on civil liberties.

I believe however that we are in fact at war. The enemy has unfortunately been able to some extent to penetrate our society itself, and it is incumbent upon us to help our government. We offer in the War Footing some ideas about how we can do it as individuals, but particularly those of you who do understand technologies that John has worked with for many years, to improve our capacity to identify and counter the sorts of threats that

I spoke of at the very beginning of these remarks, and worse, before they eventuate.

There is the issue of political warfare, again, a soft science rather than a hard one, I suppose. I am of the view that if we wish to avoid having to fight enemies present and prospective the old-fashioned way, the way I think all of us prefer not to have to engage in at huge cost in lives and treasure, it behooves us to understand and be able to utilize other techniques to influence the shape or the future direction of some of these regimes that do wish us ill.

There are lots of ways in which that can be done. In fact, we in the United States engage in political warfare every day. It is just that generally speaking, it is directed at each other, trying to figure out who is going to represent us, who will wield power, and which policies they will adopt, basically the same techniques, if we understand the enemy and its weaknesses and are willing to bring these techniques to bear, can be utilized to avoid war while providing for our security.

Lastly, there are some issues about economic competitiveness. This is of course very much on the minds

of all of you, and I'm not sure I can shed a great deal of light as to what this requires. All I can tell you is, I have lived through a succession of efforts to eliminate controls on the export of sensitive technologies. The argument is always made as it just was that as long as we have really, really high fences around the few things that are really, really important, we will be okay.

I don't believe that is true, ladies and gentlemen. I don't think you need to look much beyond the point that was made in the same breath by the previous speaker. Let's leave nanotechnology out of those high fences.

Well, Jack Gansler I'm sure could attest to this better than I; nanotechnology has almost unimaginably large national security implications. So the moment you start saying, I'm sorry, that is not going to be part of what we control or at least try to insure is handled in a secure fashion, you are setting yourself up for the sorts of economic problems, yes, but I believe also serious national security problems down the road.

I will conclude by just saying, the world will become sadly a more dangerous place before it becomes a

safer one for this country and its interests. That is because we are in fact engaged in a war, a global war against people who, no kidding, wish to destroy us. And as I said, they are being enabled by people who may not seemingly wish to destroy us, exactly, for example, the Chinese clearly have an interest in perpetuating our market and cratering the value of all those T-bills. Yet, they also I think clearly hope to supplant us. Sun Tsu argued that it is better to defeat an enemy without having to wage war against them, and I think that is the model that the present Communist regime is pursuing as well.

These conditions that I have tried to touch on very superficially here, I'm afraid, clearly create grave challenges, challenges to a freedom loving people, challenges to our national security establishment and challenges not least to academic institutions that support both. They also clearly create opportunities. I think it is vital that as we seize and exploit the real opportunities, we not exacerbate the very serious challenges posed currently and in the future to the free world.

I think it is discussion time. Thank you.

DR. GAST: I would like to open the floor for discussion, and I would like to start by hearing from members of the committee, if we can.

DR. GANSLER: Frank, you started off by talking about the newspaper today, the Canadian issue and then you brought up the sarin issue. Certainly in the case of the Canadian one, and the sarin issue in Japan, these were essentially natives of those countries, Canadian citizens being born in most cases, and the same thing for the Japanese case in the sarin. We have had other instances, Oklahoma City, for example.

So the question I would raise, at our MIT session, what we found was numerous members of the Administration suggesting that the current export control system is based on the old Cold War model, build walls. As you point out, in today's Internet environment and communications satellites, global transportation and so forth, that model doesn't work. They suggest that we might consider a totally new export control model that would address such issues as recognizing that terrorism may not be all international, that there may be domestic issues. In fact, if you look at the terrorism data around the

world, something like seven times as many of them have been domestic as international. I just wonder if you would comment on that for us.

MR. GAFFNEY: Look, this is a huge problem, no getting around it. Not only are we seeing people that we don't know have an association with terror, but I think there is some reason to believe people involved with terror -- and again, this is the near term problem as opposed to the longer term problem -- that they are effectively seeking out and recruiting people who some have called lily whites, people who would not specifically be suspected or profiled, if you will.

I am entirely open, and I think most of us in the national security community would be entirely open, to fresh thinking about how you address this kind of problem within our own borders, a problem particularly compounded by the nature of the recruitment that I think is being done largely out of sight, recruitment that is of people who might be collectors of technology or intelligence or those engaged in corporate espionage or more directly operating against our military.

But I think it has to be rooted in the

proposition that this is a serious problem, and not simply an inconvenience that we have to try to work around to the maximum extent possible, as was pointed out in that key issues paper, try to have unfettered communications and collaboration.

Unfettered communications and collaboration, I submit to you, is simply not on in this kind of environment, any more than it would have been in the last terrible conflict we had against a global totalitarian ideology bent on our destruction, of the hot war kind in World War II, or for that matter in the Cold War conflicts with the Soviets.

DR. IMPERIALE: Are you suggesting that we have to have a fundamental change in the way that academia thinks about how it operates in terms of openness? In the engineering fields, are we used to having this kind of thing, but say in the life sciences, for example, we are not use to that. Then if we have to make those kinds of changes, one concern that will come up is, are people going to be inhibited from then going down those paths, and that will hurt us in the long run. So what are your thoughts about that?

MR. GAFFNEY: I am better at challenges and broad-brush opportunities than I am to tell you how to fix this problem. In fact, I ran into an old colleague, Judge William Webster, in the airport yesterday, and I told him I was coming down here to talk to you all about this, and he said, we have been wrestling with this forever. I observed that I am sure that smart people would have solved this problem before now, if it lent itself to easy solution or maybe any solution.

I do think it is imperative that people in the life sciences community and academia more generally be encouraged to think differently about the problem. It is one thing to believe that as long as the world is a benign place and that globalization has really supplanted the old national interests and impulses, that science can be unfettered and communications can be completely open, and collaboration can be unconstrained. The only problem with that is, I don't think that is the world we are living in.

What worries me most is the point I tried to make third there, that I fear we are operating as though that were true, and nobody else is, at least none of the people who count. You hate to be duped. That is in a way worse

than just being stupid, people taking advantage of your stupidity, is such that most of us recoil from the prospect that that could be true. I think the technical term for this is cognitive dissonance; you don't want to see it, so you don't see it.

I'm not suggesting that anybody here is stupid, mind you. I just think we do indulge, we have been encouraged to indulge. I think this issue in terms of academia is practically trivial compared to the attitude that has now taken hold in corporate America. In fact, a lot of corporate America doesn't want to be called corporate America anymore. They are now world companies. American national interests are in many cases seen as inconveniences or irrelevancies to the pursuit of the profit in global trade.

I have to tell you that we have just had announced the appointment as the chief financial officer for the United States government of a guy who has probably done more as a world corporate maven to promote Communist China's power, Henry Paulson. This is not a trivial issue, which I think simply underscores and adds urgency to encouraging what I would hope would come out of this, which

is some appreciation of the continuing importance of patriotism. This nation will not survive if we take its survival for granted, and the role of the academic institutions and corporations for that matter and government in insuring our future survival, to say nothing of success, argues for some rethinking.

MR. HART: If war with China is pretty much inevitable, why is our current Administration not discouraging capitalist America from helping build up the Chinese economy and rejecting Chinese investment in our mounting debt?

MR. GAFFNEY: First of all, I don't know that war with China is inevitable. I'm simply saying they say it is, and that ought to be something we take into consideration.

MR. HART: And there are people here who say it is.

MR. GAFFNEY: Secondly, I think they are behaving in ways that make it pretty clear they are positioning themselves to defeat us militarily if it comes to that.

This is an immediate issue, as I say. The Chinese have the ability to project out 75 years. I'm not

sure it is going to take that long for this to come to a head one way or the other, but when we are looking at quarter by quarter long range plans, it is an asymmetric problem, to say the least.

I don't know the answer to your question, Senator. I think that the United States government can't quite figure out what its attitude is towards China, is the short answer. You have the Pentagon report, which paints a pretty bleak picture, coming out within days of Henry Paulson being appointed to run the Treasury Department.

The U.S. government clearly has no intention of discouraging the Chinese from continuing to buy our T-bills. They are enabling much of what we currently are doing to maintain our standard of living while deficit spending. On the other hand, and there is that other hand, I think there is a growing appreciation that the kind of wholesale liquidation of America's industrial capacity that is underway is far advanced, much of it having now migrated to places like China, is a national security problem as well as an economic prosperity problem. The idea of the United States really being reduced to being a service economy is perhaps okay, as long as other people don't beat

you at the service game, too, just as they have been beating us at the industrial game.

I think if nothing else came out of this kind of conversation, it would be wonderful if we started doing some fresh thinking about where China is going and what the implications might be if we are globalizing at the same time that they are pursuing a nationalist program with great help from our one-way street in the globalization area, militarily and economically, both important.

DR. GORDON: Frank, I did hear your disclaimer about broad policy issues. You mentioned the importance of nanotechnology in international security. How do you think we should approach that? What provisions, what ideas, what directions? Can you just talk about that a little bit?

MR. GAFFNEY: Again, I really don't know the answer to this. I do think that probably it resides, if the answer is to be found, in the kind of collaboration that you are trying to foster. The last of those key issues was what kind of ongoing relationship can there be between industry and academia and the national security community.

Again, you have spent a lifetime in this field,

John. I would only say, I think if everybody is basically approaching it from the point of view that there are truly national security imperatives in play, that there are equities for the country that are likely to prove determinative, if not against that near term threat, the future ones, that we can find a way to come together around this, that we can find ways at the very least to do something that I would like to see done more systematically on a host of different fields, notably export controls.

It has always seemed to me that somebody ought to be obliged when they are making the argument for higher fences and narrower focus, or more specifically on de-controlling one of the few now remaining technologies that are controlled, there ought to be an impact statement. We ought to be asking people to evaluate -- we understand what the possible benefits might be, but what are the possible consequences.

An example, just to dwell on this point for a second and then come back to the nanotechnology issue. There was a time during the Cold War when we made a very concerted effort to try to constrict the exports of advanced machine tools. A Japanese company and a Norwegian

company violated those rules and transferred machine tools to the Soviet Union, which promptly used them to manufacture propellers, very quiet propellers for their submarines, which in turn meant that the enormous investment that the United States Navy had made in acoustic anti-submarine warfare was dramatically degraded.

I can't remember the exact number, but it was something like $45 million that these two companies garnered. The Navy confronted a billion dollar problem of trying to reconstitute the capabilities that it had against the Soviets.

That is then, that is the Cold War, that is not now. Yet, I think stuff like that happens today, too. We have become so accustomed to basically saying, it is good for business and business is going to make the world a better place because we are all in this together, and we all are going to be globalizers pursuing the same basic purposes. Those kinds of impacts are not being given adequate weight and considered as I think they should be in answering questions like yours.

I guess I would just say, to get people in the nanotechnology field together and say, the upside of you

having unfettered communications and collaboration with your Chinese counterparts or your Indian counterparts or your European counterparts is that theoretically you will be being kept apprised of their breakthroughs every bit as much as you are keeping them apprised of ours.

But maybe that is not true, A, and B, maybe the implications, given what nanotechnology could represent in terms of national security applications, the impacts of trying to keep that kind of flow of information at least from here to there, could be quite considerable from a national security point of view.

So if that is true, how do we sort this, so that we are getting the best minds applied to the subject, we are learning as much as we can, we are instructing our people as well as we can, and we are not doing grievous harm to the country and its future national security and its economic interests as well.

DR. NORRIS: I would like to follow up on that just a moment. When you finished your prepared remarks, you finished with a summary about, we really are in some type of a global war. You said there were a number of challenges, and you cited some specifically that might

apply to academic institutions, but you ended by saying that there were also opportunities, and one should look at exploiting the opportunities without exacerbating the challenges.

That is a very delicate balance. I was wondering if you had any thoughts about how one would go about approaching that balance.

MR. GAFFNEY: I probably have not succeeded very well in describing what I am thinking about this, if I haven't gotten that answered before now. I guess I am saying, reduced to its essence, my guess is that most people addressing that balance will come out rather better from my point of view in figuring out what opportunities can be safely and aggressively pursued without exacerbating the challenges, if they are clear about the challenges, if they understand the context in which this debate has to happen.

I have to tell you, reading through this and reading through some of the other materials for this panel's deliberations, I sense that the starting point really is, how do we contend with these nattering people who don't get it, that the world really is a free market of

ideas and we just need to be in it to the fullest?

I keep coming back to that quote about unfettered communication and collaboration. That says it all to me. Not that it is not an ideal; I subscribe to the ideal, and if the world were truly different than it is, it might even be possible that we would benefit as fully from it as everybody else is.

I worry because here in academia in particular -- in fact, we have got a particularly controversial chapter in the book about academia -- looking specifically at more the soft sciences part of this than the hard, but the fact that we as a people are paying something on the order of $120 million a year to support regional studies programs at America's finest academic institutions. We rely upon those institutions to produce people with the language skills and the cultural understanding and the regional specializations that are directly relevant to John's old line of work and to the military's day to day operations and to the common weal.

A non-trivial percentage of the people doing the teaching at that $120 million a year clip are people who are very hostile to this country, and what it stands for,

and the rightness of its cause. The fact that the people that they are teaching about are actually part of the problem, as opposed to clients or people who they want to get visas from so they can continue their research.

This is a real problem, and it compounds the larger one that I was trying to get at, which is, if you really don't think that we are at war, A, or if we are at war it really is only against these rascals who are trying to get an ammonium nitrate bomb here or there, and it is a nasty bit of business and it is a good thing when we stop them, but if it blows up a Murrah Building, for example, stuff happens, as they say, then you are not going to be remotely able to draw this balance the right way, to my way of thinking.

If you take aboard, conversely, some of these points about near and longer term security challenges, you still may have a hard time answering some of the questions that your colleagues have posed, but I think you are going to do a better job of it, and I think academia is going to be part of the solution, which is obviously critically important.

DR. GAST: Frank, I would like to follow up a

little bit on that. It seems that we have a little bit of a natural experiment that we can look back at from the Cold War. We know what the isolation of attitudes in the Soviet Union did to the Soviet Academy, and many brilliant scientists and the work that was done there, and how total isolation and real separation from the rest of the world was not beneficial to them.

So we clearly have to find a balance. It is clear that the world needs international and global participation on tough challenges such as infectious disease, the fact that the SARS epidemic started and proceeded because of secrecy and was only solved by a multinational collaboration that was able to move forward because of the cooperation across borders.

So it doesn't seem that science and technology can be cordoned off in the way it may have been years before when there was less communication and less international participation. So I am concerned about the other direction, if we do become isolationist and put too many barriers up, how have we harmed not only our own infrastructure and our ability to be among the best, but for the sake of the world.

MR. GAFFNEY: It is a real concern. I think it is a completely hypothetical concern, because I don't believe that even if I were saying go to an isolationist posture it could be done.

I was talking about export controls earlier. One of the things that I am sorry to say was done at the beginning of the Clinton Administration was, they essentially eviscerated the mechanism by which export controls were maintained on a multilateral basis. So we are not going back to that. You couldn't rebuild it if you wanted to. Similarly, I think the kinds of attitudes that I have just talked about in terms of formerly corporate America are not going to be reversed, they are simply not. Many of them have now so intensely invested overseas that they really do have alternative focuses as well as interests that no matter what we said would surely impinge upon their willingness to play ball.

I guess really, all I am asking for is a balance, but the balance be preserved or maybe reinforced in a way that will enable us to have true national security equities taken into account both in academia and in the corporate world and by the government, when virtually all of the

present practices and certainly inclinations are moving in the direction of let 'er rip.

That probably sounds like a gross exaggeration to people like you, who are still confronting what remains of export controls and what remains of some of these scrutinies that are being applied, and you will be hearing from other people who can both elaborate on what they think is still happening and why.

All I am saying is, I really believe that this is a sufficiently urgent national problem as well as a national security problem, that having your help in drawing that balance, with the idea in mind that there really are national security imperatives still requiring them, that I think will insure that we come out at least closer to where I think we should be than we will otherwise.

DR. BURNETT: You are clearly advocating a dialogue, and I think that is what the committee has been hearing. One of the things that I think we hear from the other side of this is the need for an impact statement from security folks, and yet, we run up against the barrier of, specific examples are classified. We have also heard at our MIT meeting from someone who said, you should insist on

some dialogue with some of those examples maybe diluted down or filtered somehow. Do you have some suggestions as to how that can happen?

MR. GAFFNEY: Again, John and Jack have been much more intimately involved with some of the practical aspects of this than I am, and much more recently than I.

Personally, I think there ought to be some conversation, at least in a somewhat diluted, as you say, form of how this stuff does bite from a national security point of view. As I said, I don't think this can be imposed any longer. Even if it were a good idea, I just don't think it is likely to happen. So it has to be in part a partnership in which people in the academic world willingly cooperate.

There has been a huge furor in Washington in recent weeks over this question of the NSA enlisting the help of some American corporations in monitoring patterns of calls, in the hopes of finding the proverbial needle in the haystack of people who interact with suspected terrorists and who are in this country. You have had people in Congress demanding that these corporate heads be drawn and quartered, or at least brought up for a public

dressing down.

I happen to think if it is true, and there has been a lot of thrashing about even whether it is true, but if it is true, I happen to think that is a very laudable thing for these guys to be doing, because I think it represents the kind of partnership with our government in trying to deal with the problem, drawing a balance between privacy and civil liberties on the one hand and national security on the other, to try to avoid the problems that we have seen in the past and that could frankly be infinitely worse in the future, if one or more of these characters turns out to, get their hands on biotechnology or chemical weapons or other things that could inflict casualties.

So I guess my answer to you is this. This is not a problem that we lack the brainpower to address. That is the good news. There is clearly plenty of brainpower. It is a question in part of will. I think that will is a function as much as anything of a perception of the danger. To the extent that many in academia and for that matter many in the country at large remain unpersuaded of the magnitude of the problem, and the fact that that problem is indeed material not just to somebody else somewhere else,

but to each of us and by the way, if we get it wrong, not just to each of us, but to our children and probably to our grandchildren, then I think that brainpower can be applied in creative and constructive ways that yes, may mean that there is some constraint on unfettered communication and collaboration but no, it is not going to be the end of all collaboration and communication. It is just going to strike that balance.

I guess I would close by saying I am excited about the fact that this panel is working the problem and that it is clearly facilitating these kinds of conversations with people who in addition to your own brainpower, bringing a lot of hard experience to the matter, but that nonetheless can come up with, if it can be come up with, some better ways to draw that balance, informed by the reality of the problem.

DR. GAST: I would like to open it up for more questions and discussion. I would like you to please let us know who you are and where you are from.

DR. HARRIS: I am Elisa Harris from the University of Maryland. Hello, Frank.

MR. GAFFNEY: An old sparring partner.

DR. HARRIS: Indeed. If I understood you correctly, you were critical of countries like China and Japan and the European Union for pursuing their national interests economically and militarily, and not operating in a post nationalist type of way. But at the same time, the whole focus of your remarks this morning have been about U.S. national security. I haven't heard you even utter the phrase international security.

So I wonder, do you think there is such a thing as international security, or there are international security interests? Are there opportunities for international collaboration in addressing some of these security threats that you have talked about, including what I think we are going to be talking about a great deal this afternoon, dual use threats?

MR. GAFFNEY: I appreciate the question, because it may be a confusion that I left in other peoples' minds as well. It is not so much that I was being critical of China and Japan and the EU for pursuing national interests. It is that I am critical of this country for operating as though they are not, as we pursue this notion that we are all just pursuing international security together, when I

think a pretty persuasive argument can be made that we may be doing that to a considerable degree in the belief that that is good for us, ignoring the fact that others are doing the other in ways that might not be so good for us.

It seems to me you just have to play it one way or the other. You can't do it both. You can't be continuing to perpetuate an arrangement that I think is having a deleterious effect on both our economic power and our national security by essentially trying to the maximum degree you can to train Chinese scientists, for example, and engineers, and equip their universities to do it cheaper than we can do it, which inevitably will put these academic institutions into much the same jeopardy that their commercial counterparts have gotten themselves into, by doing exactly the same thing.

As long as the Chinese are pursuing a nationalist zero sum policy that yes, for the moment has certain attributes like buying our T-bills and engaging in trade in terms that enable us to buy goods that we might not otherwise buy, but that nonetheless has a long term purpose, maybe it is 50 years, maybe it is 100 years, maybe it is ten, that could be quite detrimental to our national

interests.

So I guess my bottom line is, I would love to live in a world in which international security is genuinely assured, and we can continue to enjoy all of the freedoms and security that we have become accustomed to. I don't believe that is the world we are in. I don't see it in prospect. I think that the kinds of issues that we are talking about here today make a material difference as to whether it gets worse or whether it gets better.

DR. BERTSCH: Gary Bertsch from the University of Georgia. Although I am a Georgia man, I think I should come to the defense of our Georgia Tech president and his use of the term unfettered. He did use that term, but I believe he also called attention to the importance of high fences around certain areas. So I don't think you should assume that he or others when they use the term unfettered suggest that this should be completely unfettered in strategic areas. I don't believe he meant that.

I also think that much of what you have had to say, Frank, and I followed carefully your thoughtful work in this area for 20 years, but it assumes things that are not really possible. It assumes that we can control -- and

we have leadership in technology that puts us in a position where we can do these things that you suggest, when in truth, technology and science is international, and we are part of this international process.

Everyone who knows export controls these days say they have to be multilateral or they are meaningless. The United States can propose the most thoughtful export control policy unilaterally, but if it can't implement it without the cooperation of other countries that have the same science and technology, then we have great problems.

So I think you are quite right by saying we have to identify the challenge, the true problem, and I think you have contributed a lot of important issues in your comments. But I also think that we can't under value and under emphasize the economic, scientific and political foreign relations elements of our national security.

I thank you for your comments, but I think we have to challenge some of the things that you have shared with us this morning.

MR. GAFFNEY: Well, I would be in the wrong place if I didn't expect challenges. Just as a point of clarification again, I don't think I attributed to Georgia

Tech the term unfettered communication and collaboration. That is in this issue paper. I don't know who is the author of it. My impression is, it is the grist for the mill for this panel. But it talks about the need for it, and I'm not sure that is inconsistent with what we heard here a moment ago.

I think I have already talked about my feeling that this idea that you can trade off narrower and narrower and narrower areas for higher and higher and higher fences has not proven to be effective. In fact, I would argue the proof of my point, that this tragedy of having the Clinton Administration deliberately eliminate the mechanism whereby multilateral export controls were imposed on a multilateral basis. That is to say, we were able to actually exercise enormous suasion over other peoples' export policies under what was then called the Coordinating Committee on Multilateral Export Controls. As an early agenda item, the Clinton Administration decided to get rid of that institution and replaced it with something that talked about higher fences and smaller things, and it was all basically from that point on unilateral. It is still more talk, but the opportunity to influence real influence and

control on who exported what was gone.

I hope I have left you with the impression that I believe this is a hard problem. I certainly don't want to say that I think either A, I have got all the answers or B, that the answers are self evident. I think we are in a world in which we have gone a long way towards saying anything goes.

I guess my response to that difference of opinion is, I think that is not safe. How much we can draw the balance differently will depend upon a couple of things. I kept coming back to this point about a broader understanding of the magnitude of the danger.

I think another part of this will ultimately be, to what extent do we appeal to something -- going back to Elisa's question, do we appeal to a national sense of purpose and identity. When I was looking through your key issues, there was reference there to energizing research as a national priority. I think that is a terrific idea. But to the extent that we are increasingly energizing research for the purposes of figuring out how to cross pollinate with other countries in pursuit of this idea that that is the way the world will get better and science will work and

we will all get more return on investment, I think if we are as I suggest we are, in an environment where people are playing us as we do that, exploiting U.S. government research dollars in ways that benefit them disproportionately, buying up companies that we have invested in as a matter of national interest or national security in some cases, often for pennies on the dollar, and then hollowing them out. This is one of my beefs about the so-called Committee on Foreign Investment in the United States; there is another place where there is no impact statement. We have done no after-action or postmortem if you will on what has happened when companies that we have invested in to insure we had a national capability -- I am thinking of one called Silicon Graphics that had as a subsidiary a venture that made spy satellite camera lenses, but it made lithography machines that we use to create high quality chips. We invested, I can't remember, but it was tens if not hundreds of millions of dollars in making sure that that was the state of the art, that company, with the active support of a big multinational company called Intel, the United States government went along with the idea of having Silicon Graphics bought up for frankly a fraction of

its worth by a Dutch company, which promised to leave it all there, and then hollowed it out, leaving basically a shell, and little if any national capability to manufacture those machines which are critical to the chip industry.

That is just one example, but it is an example that I think is dispositive about the attitude we bring to this. Am I saying, let's go to a world in which we are isolationists and we are not going to share anything, and we are going to make investments exclusively for our benefit? No. As I said in response to your question, we couldn't do it if we wanted to. It is a question of balance, and the balance is currently drawn way too far, I'm afraid, in the other direction, if only because of the mind set that we are bringing to the drawing board.

DR. GAST: Frank, we are due for a break. Thank you very much.

MR. GAFFNEY: The pleasure is mine. Thank you very much.

DR. GAST: We will reconvene in ten minutes, please.

(Brief recess.)

DR. GANSLER: A couple of administrative points

that I forgot to mention in the beginning that I got stung for. I should have asked you to make sure you turn off your cells and Blackberries and all that sort of stuff. Everybody knows everyone is important here if you get lots of calls, but we would rather you didn't interrupt the speakers.

The other point I should have made, if you have any administrative questions or complaints or anything, make sure you give them to Anne-Marie, not to Alice and I.

Agenda Item: Sensitive But Unclassified Information: Challenges for the Government

What we have obviously been trying to do in this session and the other two sessions -- and Anne-Marie can give you a list of both the dates and the speakers that we have had and that we will have at Stanford -- we have been trying very hard to get a clear balance of perspectives across this full spectrum of people who have views on this important topic of science and security, both from the government and independent thinkers, from universities. We are very concerned about dual use, and we are going to have some sessions on that today as well. So we are trying to get a full set of inputs in our deliberations.

One very important part of that is in terms of the Department of Homeland Security and the steps that are being taken. Our next speaker, Grace Mastalli, is representing the Department of Homeland Security, but also I should emphasize has an extensive background with Justice and elsewhere that she brings to this.

Again, I'm not going to read all the bios because you have all of those. I just wanted to let you know that Grace is not just bringing the Department of Homeland Security to this, but also a very extensive background, having worked in a variety of areas related to this problem as well.

So with that, Grace.

MS. MASTALLI: Thank you. Classified information and sensitive but unclassified information. I am here to get your help. In addition to other things, I am the co-chair of an interagency government-wide working group tasked with solving the problems of both sharing and securing sensitive or controlled unclassified information.

The current activity is driven by Presidential guidelines issued on December 16, 2005, in support of the creation of an electronic information sharing environment

focused on sharing terrorism related information. Our task however of the interagency working group and of the Attorney General and the Secretary of Homeland Security and the Director of National Intelligence under these guidelines is far broader than terrorism information, and addresses all information.

To give you a little bit of a context, if you have not heard of the information sharing environment, it is intended to create an interoperable electronic information sharing environment for federal, state, local and private sector partners to share all kinds of information to combat terrorism, to preserve homeland security and support law enforcement.

The basic concept is somewhat better information sharing, depending on the level of security required, to leverage all existing capabilities and to create some form of government structure to manage the information sharing environment. It will include classified, sensitive but unclassified or what we call controlled unclassified information, and unclassified information.

The other guidelines, there are five in total, common standards for information sharing largely come in

data standards, Dublin Core, XML, those kinds of data standards, as well as meta data tagging standards, a common framework for sharing with federal and non-federal partners, which is a euphemism for, there are still more silos and stovepipes among federal, state and local partners than is good for the country in many ways.

Number three, guideline three, is to standardize sensitive but unclassified procedures. Number four, an issue you will touch on this afternoon or tomorrow, is also facilitate information sharing with foreign partners. Five, which covers all of the other activities and is an overarching goal, to protect privacy and the other legal rights.

Guideline three, that which I am going to talk about today, first directed that there be an inventory of all federal sensitive but unclassified, marking, handling caveats, guidance and procedures. Fortunately for the working group and for the program manager who is tasked with it, a substantial amount of work was being done in this area already by the GAO, by the Congressional Research Service, by the National Security Archives, a private institute associated with George Washington University, and

others. The initial response to the call from our working group to all of the agencies in the federal government was, oh no, not another data call, didn't we just tell somebody else about this? And why does it matter? We eventually completed and continue to update an interactive data web base that contains all of the controls, markings and categories and security safeguards that we were able to identify being in use by federal agencies. I am sure we missed a lot. Altogether too many agencies said, we don't have this. Then I would turn around and open the mail or the e-mail, and there would be a document from someone in that agency with the school based intervention marking or handling caveat affixed to it.

I want to emphasize the time frame here and the way the guidelines divided the activity, which is one of the challenges that the federal government is facing right now. By June 15, 90 days after the inventory was completed, the Attorney General and the Secretary of Homeland Security are to provide the President with recommendations for the standardization of controlled unclassified information procedures for homeland security, terrorism and law enforcement information.

Our working group spent months trying to figure out what didn't fall into one of those categories. We are absolutely positive that there is some information that under no stretch of the imagination could relate to homeland security, terrorism or law enforcement, but we pretty much couldn't figure out any one form of data that we could agree would never need to be shared and would never fall into one of those categories, which is a shame, because we have until December to come up with procedures for all the other information. That is not out job, because after the Attorney General and the Secretary recommend the procedures for homeland security, terrorism and law enforcement information, then the Director of National Intelligence, the DNI, has to come up with procedures for all of the other kinds.

So if you think about it, it seems counterintuitive. Why would DNI come up with procedures for non-intelligence, non-homeland security, non-terrorism, non-law enforcement information? But that is what the guidelines require, and those are the constraints for working with it.

The goal is, within a week from now to come up

with recommendations in a report on how to improve the management of SBU and other unclassified information that requires control, potential ways of harmonizing and consolidating the information. The Homeland Security Council approved the plan.

This is the findings from the inventory. We took a fairly academic, if you will forgive me, approach to it. We gathered as much data as possible. We conducted an extensive literature review, and then we tried to analyze what we had and come up with some broad conclusions and findings.

Our database has 164 different entries, which is every marking that was reported by every organization. CDC reported more than 17 SBU markings. Two agencies said they had no markings. I have examples from both agencies of markings. Five markings are no longer in use according to the agencies, but still exist on the books in procedures and rules and regulations. Four markings were recorded by non-governmental agencies or were construed to exist by people reading the Homeland Security Act. I tell you as a person who has been trying to prevent sensitive homeland security information from becoming a marking for four years

now, it is not a marking. There is a statute that could be interpreted as requiring that marking, but it really just requires procedures for protecting that category of information.

Of the 98 distinctly different markings, we found ten general categories of information. The two largest are for official use only or sensitive but unclassified. There is also law enforcement sensitive, and there are probably 19 or 20 sub-categories of law enforcement sensitive: Internal use, security, statistical, proprietary, deliberative, privileged, export control, non-public, and then there are 17 that are required markings created by Congress in its wisdom, or controls that do not mandate markings, but explicitly require controls.

Sensitive homeland security information is grounded in statute but is not a marking, because it has not been implemented as having a separate marking.

We were surprised, because we thought that if there were markings, they would all have safeguarding, access, dissemination, and we could look at those two kinds of controls to consolidate, what were the safeguarding requirements, what were the access restrictions. They

don't, we were wrong. Some of them have it, some of them don't.

When I talk about safeguarding requirements, it is something like a special access requirement. You have to have a certain clearance, a background. It has to be wrapped or encrypted or something. Others are the no contractors, no partners, no law enforcement categories. And there is a great deal of information that we are responsible for looking at that may be terrorism or homeland security information that we would never anticipate being shared in a large information sharing environment such as the kind of information many of you working for Homeland Security may have generated that is patent, homeland security proprietary, special processes, commercially protected information. But those categories are part of what we are looking at as well.

It is a really complicated problem. This is just a notional look at our analysis. There are different dissemination schemes, different requirements. The VA by the way, which recently lost my husband as a retired Navy officer, and many other active veterans' information, including your social security number, does not according

to their report have any sensitive but unclassified or uncontrolled information safeguards or dissemination controls. This might have been part of the problem.

There are statutory requirements that have to be considered, security requirements, privacy, FOIA, state sunshine rules, all have to be taken into account as we develop the new procedures. There are statutory markings. There are hundreds and millions and billions, I don't have a high enough number, of data of reports, hard copy, electronic media, all formats, that have some of these legacy markings. Many of these will be never shared or accessed by anyone. Others will be. Part of what we have to consider is, what do you do with all of the myriad legacy markings when you are trying to create an electronic sharing environment and not drive the federal government any deeper into deficit. Again, this is to understand a little bit of what we are wrestling with.

The big three legal constraints. There is a relationship, but it is not a direct relationship between the Freedom of Information Act and controlled unclassified information. The agencies don't agree. Some agencies say, you use the CUI marking if something is not covered by a

FOIA exemption and you still don't want it to be disclosed. Other agencies say you should never use an SBU or CUI marking unless you are fairly confident that it can be protected under one of the FOIA exemptions. Inconsistency among the federal agencies on these issues is rife.

There are a number of statutes that drive or resulted in the creation of markings. The list here is just a sample.

So what are we doing? We have an interagency group co-chaired by myself and Brent McIntosh, who has my former job at the Justice Department. He is the Deputy Attorney General for the Office of Legal Policy. We accomplished the first task which was due March 15, which was the inventory of 165 categories, 17 statutory, many duplicates.

When I say duplicates, I mean a marking that says SSI, which since I come from Homeland Security and work in counterterrorism, thought meant sensitive security information. It does in some agencies. It means something totally different in other agencies, and there are many agencies that use the marking, all different meanings.

The SBU marking is the second most commonly used,

but the safeguarding requirements and security requirements and access controls associated with them differ dramatically among the agencies.

Law enforcement sensitive. I spent much of my career in law enforcement. People have defended it a being important because everybody knows what it means. Nobody knows what it means. Until last year, not even the Justice Department attempted to rationalize what law enforcement sensitive meant among the Justice Department law enforcement agencies. So DEA stopped using law enforcement sensitive and now uses DEA sensitive because they disagreed; a new marking.

The biggest problem with information sharing for any purpose with any kind of controls is, the people who get the information need to know what a marking means, what is expected of them, what they can and cannot do with it, who is allowed to see it, who is not, how long does the protection last, if all of the markings are similar but all of the meanings are different. You never have that. In the law enforcement arena, it used to be a joke that law enforcement sensitive was put on everything because it might be. But then it wasn't secured in any particular

fashion except in those organizations and agencies that required that you have a gun in order to look at it, which I as a former prosecutor had a problem with.

We have been trying to meet with the experts as well as read the work. When we undertook this, we knew that there had been a lot of work done, particularly in the classified venue, about that delicate balance point that Frank Gaffney was talking about between security and openness. What I didn't realize until I printed out all of the reports was that the stack of them were taller -- and I am not kidding -- than I am, including reports going back to 1922 forward. Many solutions have been proposed, many have not been adopted. The problem of how you deal with controlled unclassified information has grown exponentially in the last 20 or 30 years, and even faster have such markings and concerns proliferated since shortly before 9/11, not at 9/11, but the real exponential growth started about 1997.

Meeting with substantive experts. Who are the experts? Anybody involved in information management, information security, whether they look at it from the technical standpoint of electronic security controls or

managing privacy act implementation, whether it be HIPAA or another act related to privacy, and those in the classified community who have been managing the much smaller, much more contained, much more manageable system of controlled information.

Being here today is part of our research effort, because the academic community and researchers both within government and outside of government have probably been responsible for the creation of more controlled unclassified markings than the rest of the federal government, which is kind of scary, because the rest of the federal government has way too many, with state and local partners and preparing lots of analysis, options papers, et cetera.

We have been pressed and have pressed back on simply coming up with something in response to Congressional pressure. Some of you may have read -- Ambassador McNamara, who is the new program manager for the information sharing environment, testified before Congress about two weeks ago, and got beat up rather badly because he didn't have a solution ready to roll out to solve this problem. So he came back and beat up me and my co-chair

and said, we need a solution, and we said yes, what should it be? Give me an options paper, and I'll choose one. We said, we can do that, but whatever you choose will be the wrong answer.

This is truly complicated. It takes consultation with those that have to work with the process. We will give you the procedures, we will meet the requirement, but it would be a mistake and a disservice to either wipe the slate clean, as tempting as it might be, or to simply pick an option and impose it overnight. Fortunately, they said okay, give us the recommendations, but give them to us by June 7, and we will move ahead.

This just lists our bureaucratic activity. The report which is in draft right now has findings regarding the policies, lexicon. Perhaps the most important is, there needs to be governance. As we are doing this in the federal government with our federal, state and local partners, we have discovered that the corporate world have been proliferating their own. So there is now New York State secret. It is an unclassified market, but that is what it says. There are dozens of examples; New York just popped to mind.

All of the issues that have been wrestled with in the classified community have come up dealing with the unclassified information, which brings me to a critical point that I realized is little understood when we are talking here. What is controlled unclassified information, and if it is so darn important, why isn't it classified?

If you will let me be a lawyer for a minute, it is because Executive Order 12958, which is currently being looked at in a number of venues to determine whether or not changes are needed in it, very clearly defines what is classified information. A whole gamut of highly sensitive information, including yours and my social security numbers, will never be classified under the existing structure.

Classified information is something that falls under one or more categories of Section 1.5 of that executive order, which is a national security executive order. It requires to be classified that information fall into one of those categories, be identified specifically as causing damage to the national security if not protected. It might affect my financial security or my privacy or any of a host of other interests and not fall under

classification.

This is very little understood. I was stunned when meeting with a group of very high level senior officials, almost all of whom John Gordon knows, who said when being brief on controlled unclassified information, if it is important it would be classified, forget it, why waste our time on this. Maybe the solution is for the definition of classified information to be changed and for some information that is not classified be classified, but I doubt if that is a politically wise approach at this point. Yet, as a former prosecutor, I know that some grand jury information, if I was going to share it with anyone outside of the grand jury room, I had to give the judge the name of my chain of command and my staff that were going to have access to that information so he could control it by name and know who to hold responsible if information coming out of that grand jury room hit the newspapers.

Some material in law enforcement is life and death sensitive. Witness security. You all heard of the witness protection program. Who would enter it if the federal government had no way of protecting your new identity? But that information could never be classified

under the current classified structure of the executive order.

So it is controlled and protected as controlled unclassified information. It is marked sensitive but unclassified, for official use only, law enforcement sensitive, and any of a host of other things. There are lots of kinds of information of varying degrees of sensitivity, some as I said truly life and death, that are not appropriate and cannot legally be classified. They all fall into the pot of information we are looking at.

So does information that one federal agency said should be marked with an SBU marking if its release might embarrass anyone. In complete violation of law openness, they published a federal regulation that said, use this marking if the information the release of which would embarrass the agency or officials. Clearly not good policy.

This summarizes the recommendations I expect our working group to be making in very broad strokes. First, we are proposing a federal-wide moratorium on any new markings. Our database grows weekly because someone comes up with a new marking for their particular problem,

probably more often than weekly, but we only identify it on a weekly basis.

We propose an immediate governance, interim governance mechanism to be set up to carry on the work of the working group and to implement the recommendations, including completing the analysis, an impact analysis, and cost-benefit analyses of the options that we have identified for fixing this problem, as well as consult more broadly with all of the affected communities of interest.

The recommendations will include a clear statement of the relationship to FOIA, to wit, there is basically no relationship between a marking and FOIA, although you may be aware when you mark something that something is subject to withholding under one or more exemptions of the Freedom of Information Act. That determination should be made when there is a request for the document, not by somebody who generated the document and wants it protected. The protection they want will be provided by the marking they apply to it. The decision on whether or not to release or disclose belongs in a separate category in consultation perhaps. But FOIA decisions should be made by FOIA experts, not by people who may not

want to have their work product see the light of day.

We propose both a reduction in the markings and a permanent registry and governance system. So if a document comes across your desk, you in academe, the general public or elsewhere could look up on an Internet-based registry what that means. Maybe you shouldn't have it. Maybe you are required to put it in a safe. You would be amazed what comes through fax and e-mail. My own agency has a written requirement that for official use only information may not be e-mailed unencrypted, but we have no capacity in most of the department to encrypt it, so we have a standing guidance in writing from the same people who write the management directive saying it must be encrypted that says, if you can't encrypt it and you need to send it, send it unencrypted.

Our principles are principles for minimizing, clarifying and defining markings for standardizing the safeguards, for standardizing the dissemination regimes, and for considering when protections should be terminated. Some protections, for instance, in competitions for grants or contracts are sensitive during the period of the consideration of the application, and are routinely

available after the decision is made. Most of the federal government has no way of removing markings or making a determination that something once marked with any of the plethora of markings should now have that marking removed, and it should go into the public domain.

What has happened is, the proliferation of markings is so great, the concern for security having driven it has been totally counterproductive to the goals of protecting truly sensitive information well, and having openness and the ability to share other information.

We are trying to put together in the next week a budgeted time line, direct guidance on what is improper use of any marking. My example of the agency that said they could mark things if their release might cause embarrassment to the agency being the prime example of why markings should never be used.

Another huge issue and one that many of you have wrestled with is, we are in a public-private partnership, you are working with the science and technology directorate of DHS or the intelligence analysis office or whatever. I have controlled unclassified information. To do your job, whether it be as a researcher or a contractor, I need to

share that with you. How do I control and assure that your handling of it comports with the requirements?

The answer heretofore has been nondisclosure agreements. There are no standard nondisclosure agreements, as I'm sure you all know. One of the things that we are looking at is the kind of language that once we standardize this, would similarly be standardized to go into contracts, nondisclosure agreements or other documents, so that what you agree to do for DHS you would agree to do for the Department of State.

We are looking at how governance works in other venues. Some people have recommended that the existing classified world governance mechanisms simply be given the task. The working group thinks that is a bad idea, although those governance mechanisms, the information security oversight office in the National Archives and CAPCO in ODNI deal with much more limited scopes of information. A great deal of our work is toward making more of this information available for appropriately fettered chairing and collaboration, as opposed to making it unavailable. The fear of pseudo classification being simply a way of achieving more government secrecy for no

reason creates a public perception and political problem. So we are looking at the models of what they do, recommending against them being assigned a task.

We are looking at legislative proposals and others. The materials which I will leave behind so they can be distributed -- although my colleagues would all mark this for official use only, you must know -- summarizes the recommendations.

The bottom line here is that it is a huge problem that has been looked at over and over again by commissions, including several the Senator was involved with, the weapons of mass destruction commission identified it. There is no easy solution.

I was concerned with the suggestion this morning that we needed select issues with areas with very high fences, because that is how CDC came up with 17 different markings. There has to be a way to protect information and to facilitate openness and sharing that makes sense in the current electronic world. We are trying to work toward it. We don't have all the answers. I think we have some good ideas, but we need to make sure that we are considering the perspectives of all of those, including those of you in

this room who will be affected by any decisions that are implemented.

DR. GANSLER: As you notice, we are running a little bit behind, but we do want to make sure --

MS. MASTALLI: My boss says I talk too much.

DR. GANSLER: That's all right. We want to make sure that we have a few minutes for discussion with Grace.

Let me start it off, Grace. One of the things that you did not mention at all is penalties for violation, and also the ability of the people who are impacted, for example, the university professor who has done his research, and then someone puts a stamp, sensitive but unclassified, on it afterwards, what protest procedures. Will you look at that as well as part of this commission?

MS. MASTALLI: It was in the footnotes that I ran through very fast because I was running out of time. Enforcement regimes, sanctions, is part of what we are looking at. There would be different ones for those who are federal employees as oppose to those who are not.

DR. GANSLER: And the same thing with the opportunity to disagree?

MS. MASTALLI: Redress and appeal. For those of

you who don't know, in the classified world anybody who thinks something has been misclassified can request from their agency that it be looked at and reconsidered. We are looking at a lot of models for that, as well as for external --

DR. GANSLER: Sounds like a nice challenge for the next two days.

DR. IMPERIALE: I understand the need to protect information like social security numbers and identities of witnesses and so forth. But it seems to me that the kind of information that we are charged with discussing here really is that sort of information that impacts the national security. So given that, can't one make the argument that for the types of things we are talking about, it should either be open or classified?

MS. MASTALLI: I think that is true of some of the things you work on. I gave you a very short summary, the classified options. I am not familiar enough with the work that each of you do to say some of it should be classified.

But remember, even within the classified world, there are degrees of classification. It is something that

many commissions have looked at as to whether it is the right answer or not. The classified world, you often think of things as a pyramid, in fact I often draw a pyramid on the board. At the top of the pyramid are special access programs, very limited access, with lists of people who can see it. Then you have top secret special compartmented information, and then you have secret, and below that you have confidential.

Confidential is a classification. The distinction between secret and confidential information is often lost on me, since the security requirements are the same, but that would work for information that under the existing executive order should be classified. But remember, when it is classified, you than have the additional requirements associated with it, which are currently causing academe, the corporate world and the government major problems. You have to have a background investigation. Depending on the level of security of the information you have access to, it can be a very complex and intrusive background investigation.

We have a huge backlog of security clearance requests right now in the federal government. So the

minute you move information from the unclassified world to the sensitive world, you bring with it a large number of security requirements for secure networks, for SCIFs, for facilities, for limited access and boy, do you limit for the most part your ability to work collaboratively with non-Americans.

DR. IMPERIALE: So I don't understand. If you say something is sensitive but unclassified, aren't you also limiting it? Where is the line? Maybe that is what you guys are supposed to be coming up with.

MS. MASTALLI: The point that I was trying to make and did not articulate very well is that we currently have two parallel systems of protecting information. The classified system that only applies to a narrow category of information directed related to the national security and falling into one of the categories, the release or inappropriate disclosure of which would damage national security. The person applying that marking, making the classification, needs to be able to articulate how the release of that information would damage national security.

Then you have in the parallel much larger controlled unclassified that includes corporate

information, privacy information, research information. One of the reasons why there are many statutory systems like protected critical infrastructure information is that those who own the critical infrastructure did not trust the federal government to appropriately protect the vulnerabilities that they might want to report to the federal government, unless they had a separate statutory scheme.

You may need to have access to that. Arguably, some of that information could be classified, but then most of the people who needed to work on it wouldn't have access to it.

DR. GANSLER: It is a dilemma. We did hear in one of our other meetings, the Commerce Department said they were explicitly using sensitive but unclassified in order to protect national security. That was their statement. That is what I think Mike is referring to.

MS. MASTALLI: It is used for that purpose.

DR. IMPERIALE: Then it should be classified according to that executive directive.

MS. MASTALLI: No, it is not mandatory. A determination is made, and it is still made by a human

being, not a machine, on a risk management determination on whether something should be classified or not.

DR. GORDON: Grace, this is a mechanical question. How now does the Ted McNamara organization, the program manager, fit into this system? Who works for who? What are those relationships?

MS. MASTALLI: It is very awkward, actually. The inventory was given to the program manager. The program manager's office was not up and running, so we created this interagency working group and conducted the inventory so that once the program manager's office became functional they would have the task completed by March 15.

The second part of the task was the report on the recommendations for this huge slice of homeland security information, terrorism and law enforcement. That duty still remains with the Attorney General and the Secretary.

One of our recommendations is that there be a dedicated staff that is funded and does this work full time. Currently the interagency working group are people like myself that have major responsibilities in a host of other areas, and a couple of contractors that we scratched together to provide fulltime support.

It clearly needs a small dedicated staff. I would imagine that the initial cost would be greater than the long term management of it, just to set up and implement the reforms. But then there needs to be a permanent governance function, just as there is an information management office in the Justice Department for privacy and OMB for intelligence at NARA. There needs to be a permanent governance mechanism.

We could fix this permanently tomorrow, and it would go out of place in response to changes in needs or inevitable work-arounds as soon as it went in place. It does not have as a result of that. One of the recommendations that we have made to the PCC, a term you are familiar with, is that it does not belong in the intelligence community. The vast majority of this information is not intelligence and it is not national security information. It is everything else. It is civil liberties issues, it is privacy issues, it is proprietary. It has a national security impact, but most of the issues we fear will get shorter shrift while dealing with building the classified sharing environment, for example.

DR. GORDON: By sensitive information sharing

environment, it is simply everybody's favorite second-tier issue. It is the one that the seniors say I am going to work on tomorrow. It is really important, but I am not going to have time to work on it today. We have been doing this for a couple of years.

MS. MASTALLI: And the situation has actually gotten worse rather than getting better. We have moved backwards in some respects. One of the things that we have to try to come up with in the next few days is a recommendation of where it should be. I would welcome your suggestions.

MR. HART: We have spent a lot of time learning how the present regime works or doesn't work in terms of dissemination of scientific information. What we have to do also is come up with recommendations. What would be most helpful is, based on what you know, to give us two or three very, very specific and concrete recommendations for how the regime ought to work.

MS. MASTALLI: It ought to work in terms of being simple and understandable, yet provide flexibility for the special circumstances. I could give you five options that we have developed that are variants on what is already in

place that might work. Part of what we have suggested and how to be able to do is to do some validation and some pilot testing in different communities on the options before any are adopted across the enterprise.

DR. GANSLER: When the drafts came out for the sensitive but unclassified, it was very clear that even though you had a spokesperson from an agency, that within the agency there were dramatic differences.

in the Defense Department, for example, the IG said, go to this extreme, and all of the research community wrote nasty letters about, this is ridiculous, don't go to do that at all, trying to balance that.

MR. HART: Mr. Gaffney earlier suggested we were giving away the store in terms of national security secrets and so on. How do you reconcile that with the fact that the quantity of classification of documents in the last five years has skyrocketed?

MS. MASTALLI: Not at DHS. I think that people -- and we are talking about people, the institutions are made up of people -- respond to the concerns that they hear. If they are working on something that falls into the category, you are in a risk management mode. If everything

around you is suggesting that the risk is higher than ever, it is human and natural to therefore try to manage that risk and to move it into the classified realm.

There are some things that have to be classified, and there are some things that are statutory within the CIA and so forth that are protected by being classified. But a fair amount is people trying to apply informed risk management. If everything around you is suggesting the risk is higher than ever, or if you are sitting back and trying to -- one of the things we learned, we sat down with all of the agencies and had them bring in their security officers and information management people and said, we need to come up with a better common regime for protecting sensitive but unclassified information.

They all wanted to move it up to the highest level of classification equivalence because if you were managing risk and your job and your success determines on perfectly managing risk, which is of course impossible, you are going to opt for more classification, for more controls.

Now, my job is information sharing. I believe that I have to be able to create trust, that I can protect

information, whether it is industrial information or others' agencies information, in order for sharing to happen, because if I can't protect that which is highly sensitive and important to you, you won't give it to me.

But the delicate balance is, you need to have the protections in order to have the sharing, but you need a whole lot more sharing and collaboration than is currently occurring.

MR. HART: Is the risk five or ten times greater today than it was in the height of the Cold War? Because that is about the quantity of the classification that is going on.

MS. MASTALLI: I don't think the comparisons, the metrics, work. I think we need different metrics. We need performance management that causes change in the behaviors regarding risk management and classification or other markings.

DR. GANSLER: We are running behind, but I do want to allow the audience to have a couple of questions. Steve, we are not going to hold you to your time; we will let you run over a little. Any questions from the audience?

DR. HARRIS: As you work to try to harmonize the whole approach to controlled but unclassified information across the government and between the government and non-governmental entities, I wonder if you have as your ultimate goal being able to reduce the approach down to a single page as exists for classified information.

I had classification authority in the government. I had next to my computer a one-page document that I looked at 50 times a day when I created something. It was a checklist. If in my mind I answered yes to that question, I knew what to do.

Do you think that you can reduce the instructions to all the stakeholders down to that simple form that exists, and I think in many ways works pretty effectively for classified information?

MS. MASTALLI: That is absolutely our goal. The question is whether or not we can achieve it.

DR. GANSLER: Thank you very much, that is really helpful. We obviously wish you good luck in this interesting challenge you have. Do you want to introduce Steve?

Agenda Item: Classified Research on University

Campus

DR. IMPERIALE: Our next topic, we are going to move onto classified information, and our speaker is going to be Dr. Steve Cross, who is a vice president here at Georgia Tech. Dr. Cross spent much of his career in the military and working with DARPA, and so he sees things on both sides. He has been here on the academic side now for the past three years. He is going to talk to us about Georgia Tech handles classified research. As always, you can read the rest of his biography in your packets.

DR. CROSS: Jack, I know we are behind, but it is still good morning. So good morning. I know i am the proverbial obstacle between you and lunch, so I'll not take the full half hour, I hope. But I have been a full professor long enough now that maybe I will use my whole time, we'll see.

I am real pleased to have an opportunity to talk to you on this topic. I will only talk about the classified research. That is where the dissemination of research results is restricted because of national security implications. Others here from Georgia Tech, Jo de Garton, Pamela Arie from our legal office, are well qualified to

share our approaches with export control or other topics that you may be interested in discussing.

Just a statement up front. It was mentioned, I am fairly new to Georgia Tech, so I am very enthusiastic about being here, and I don't want that to come across that I am suggesting that our approach is right or better. It is our approach. What I am sharing with you is our approach to this and how we go about doing it, and not to make any value judgments.

So the purpose of my talk is to describe our position on classified research. There are really two key points in this talk. The first one is that at Georgia Tech we have no policies that prohibit faculty members or students from engaging in any kind of research they want to pursue. The second point, and I think this is a very important point for you deliberations here, is, we consider ourselves to have a very high standard in terms of self regulation. We certainly cooperate openly with the government, but we hold ourselves to a very high standard, and I will show you how we go about doing that as well as I get through the talk.

A brief snapshot of Georgia Tech. I told you I

was going to be enthusiastic and brag a little bit about this place, but I want to spend the bulk of my time in the next couple of minutes talking about these four topics, and then I will summarize briefly.

At Georgia Tech we have a vision, and we take this vision very seriously. We want to be a place that defines the technological research university in the 21st century, and we educate the leaders in a technology driven world. This includes leaders in our government, in our U.S. industries as well as internationally.

This is the bragging chart, only one bragging chart, but basically what this says is, we have really, really good students, and we do lots of research, the last fiscal year, $425 million in expenditures. Our faculty are really good, but we also value service. Wayne Clough told you about some of the national panels he is on, the National Science Board, the Council on Competitiveness, PCAST, et cetera. We also have 22 of our faculty on loan to the government through the Inter-Personnel Act. A lot of our alumni serve in government positions, for instance, John Young, who is the current Director of Defense Research and Engineering. So we are very proud of this service here

in this university.

This is a fun chart, just to make sure we are all awake just before lunch. This is probably a fun way to show what Georgia Tech is like. We have the colleges. We have six colleges. It is a very interdisciplinary place, very interconnected. We have a School of Public Policy, and it works very closely with all of the technology areas, the same with our business school. We have interdisciplinary centers that are not in any one college, for instance, a Microelectronics Research Center.

I head the Georgia Tech Research Institute, which is our applied research arm at the university. Most of the classified r is done in GTRI, but it is not solely done there. We have an economic part of the university. The buildings that we are in here are a large part of that, and also, our distance learning professional education, specifically this building is devoted to that. So this university is very interconnected.

It is probably one of the differences between this university and some other universities. A university like MIT that has classified research that is done at its Lincoln Laboratory, federally funded research and

development center 15 miles from the main campus, is different from GTRI, which is an integral part of the university, considered to be a college level unit. It is not an FFRDC, it is just part of the university.

This is a chart I just pulled out of the president's state of the institute address that he does every year, where he updates us on how we have been implementing our strategic plan. This is just one example of a project that we take great pride in that we worked on for the Office of Naval Research, where we brought together many of the technologies, some of them resulting from classified research programs, to prototype a new vehicle very quickly that is meeting a definite need in Iraq for our soldiers there.

Definitions I just put in for completeness for the talk. Let me get to the main topics at hand. The role of classified research, how we facilitate and manage that research, the benefits we derive from that research, and our thoughts on stricter interpretation of the directives, policies, regulations, et cetera, the role of classified research within Georgia Tech. We already mentioned that we have no policy that prevents or discourages faculty or

students from pursuing classified research. It is an integral part of our heritage.

The kind of research projects that we get involved in are very exciting, very rich, very complex scale. It introduces problems that we might not otherwise be able to address. We have also had many opportunities over time where we have been able to spin out knowledge and products from this research that we have been able to use in unclassified projects for the benefit of society. This is all consistent with our strategy at Georgia Tech. We want to be a place that provides objective analysis on problems of national importance, and we want to help provide an educated workforce for our nation.

An example of one program we are creating with my colleague, Bill Wepfer, who will be on a panel tomorrow, Bill runs this global learning center which does our business learning and professional education. He has a professional masters degree in systems engineering. Other universities have been exploring this, Stephens Institute, MIT, et cetera. It comes out of a need both of the government and industry in this country to have a trained engineering workforce, so this is a program we are setting

up to meet that need. Even in that program we are willing to entertain having a classified component to that program if it makes sense for the constituents.

Some statistics. I said there are no more bragging points; I lied, there is. The first one is a bragging point. Somebody might ask how many classified research projects do we have here, and how many people are engaged in them. About 200 projects are classified, about eight percent of the overall research that is done. Of students, about 2.5 percent of the students have security clearances. Most of these are through our cooperative education program, a few are graduate students, then quite a large percent of the faculty. We have about 2,000 faculty if you include all the research faculty and the tenure track faculty, and almost 800 of those have security clearances. The faculty that is assigned to GTRI is 576. You can see there are about 240 more faculty than the rest of the university that have clearances.

How do we facilitate and manage this research? The president retains a top secret clearance. He is briefed periodically on the research. I retain the clearance. Our vice provost for research retains

clearances. People in our office that sponsor research retain clearances. We also have a SCIF there to maintain classified proposals and reports. We have a senior administrator in the university that is called director of research security. He provides all the oversight consistent with the national industry security program, the NISP. He reports to the president and he also reports to me. This is all fine. It takes commitment of everyone and it takes money. I will show you what it takes.

We have 27 fulltime people at the university. It is much different than it was at Carnegie Mellon University. I was at Carnegie Mellon for ten years after I retired from the military, and there we did classified research in a semi-autonomous unit called the Software Engineering Institute, and our entire staff at the university was two people. Here we have 27 people.

There are 32 different closed areas that you have to have badges to get into. We have the sensitive compartmentalized information facilities, special access programs. The budget is right up there. Next year for our budget we have budgeted $2.5 million for this entire program, which is a significant amount of money, but it is

still less than one percent of the overall research revenues for the university. So our contention is, we think we do this well, and we budget accordingly for it. Our audits from the government indicate that we do it well as well.

Benefits derived from the research. At the end of the talk I have all of the URLs; you can go get more information about these things. One of the things that we run is a defense industry short course, for instance, on radar courses. They are classified courses there, but we have been able to generate from that many unclassified courses. As you walk around this building, you will see that it is over subscribed in terms of the course programs that we have.

Second bullet, international guard Falcon View. Falcon View is a very popular mission planning system used in the DoD. Taking products out of that, we have been able to build some really interesting useful visualization systems for homeland security, for local agencies.

Flapless wing aircraft research, an interesting area of research. We have been able to take knowledge that we derived out of that, and last year we did tests that

were done by the Department of Transportation to show six percent fuel efficiency on large semis going at top speed on the freeways. So an interesting spinoff there.

Frank mentioned electromagnetic research, a very important area of research. This is very big at Georgia Tech with our electrical computer engineering department and our laboratories at GTRI. We have been able to take that knowledge and set up some first class testing facilities for implantable medical devices.

As a matter of fact, one of the things we run here at Georgia Tech is the Underwriter Laboratories, if you will, for the National Arthritis Foundation, so we do all the testing of those kind of devices. I won't belabor the point there.

Our thoughts on stricter interpretation of directives, policies and regulations. I will just quote from Wayne's talk this morning. This is another talk he gave recently. I will just underline the key points to us. We believe there can be a balance between the free expression of ideas and these very important national security interests. We believe we have a model here that demonstrates that.

In terms of all the things that are going on in the policy arena for tighter export control, loosening export control and all the things that we read about in Commerce Business Daily and Chronicle of Higher Education, et cetera, we believe we have demonstrated at effective approach to self regulation of classified research. I would suggest that that is true in export controls and other areas as well.

For instance, we have human subject or animal testing, there is another set of regulations there that we think we have a very good track record of adhering to.

We do have concerns about labeling things as unclassified but sensitive. As Wayne Clough mentioned this morning, what we do is, we address those on a case by case basis. We either negotiate those out or we just don't do the work. As a matter of fact, there was a project just last week that we wanted to do that we stepped away from for that reason.

So I am in complete agreement with this report that was published by the Center for Strategic and International Studies and their quote there. This is one my real foot stompers, that the community itself has to be,

because of its ethics and its integrity, strongly committed to self regulation.

We have to be willing to cooperate with the government. As we showed here, many of us at Georgia Tech are the government right now, so we want to cooperate with them, but in an open, trusted communication, and we have to be willing to go the extra mile to a higher standard than is required, and we believe we do that here.

In summary, finishing almost on time, we don't prohibit research that people want to do. Truth in advertising here. Of course, there is the unwritten policy of publish or perish for junior faculty members, so that is going to discourage a young assistant professor in electrical engineering from exploring classified research, but that is not a policy, that is just the way it is in academia.

We view it as very important as part of the overall corporate view of the university. We can support crucial problems of national importance, educating the workforce for industry in this country, and for government, and the knowledge that we gain from these very interesting problems that we can apply to other societal problems of

interest. We think we have an effective approach for doing that.

That is the end of my sales pitch. Now I am happy to turn it over for questions, or to go to lunch. Thank you.

DR. IMPERIALE: Thank you, Steve, and thanks for leaving time for questions. Maybe I could just ask a quick one. From a practical point of view, if you have a laboratory in which classified research is being done, and let's say there are two students working on that project and ten other students who are working on unclassified projects, do you require those other ten students to get clearance, or do you restrict the flow of information within the lab?

DR. CROSS: No, we don't require the students to get clearances. We compartmentalize off the research into another area. Part of the self regulation we do is, we make sure that everybody that has a clearance is briefed and knows what the responsibilities for protecting that information is. So we certainly don't discourage those students from talking to the other students. We trust them, if they have the clearance, that they are going to be

able to know what they can share and what they can't share.

DR. GORDON: I don't quite understand the self regulation point you are making. The example you just gave was about classified. What are the regulations that surround classified data to start with?

DR. CROSS: We are audited every year by the government under those regulations, but we also have a professional security staff here that helps us make sure that we are an exemplar of implementing those regulations. That is what I mean by the self regulation. We also hold everybody that has a clearance to a very high standard in terms of honoring the commitments that they have under that classified research that they are doing.

DR. GORDON: I think it is fine. I just don't recall self regulation for following the rules of the government system.

DR. GAST: I think it is very impressive, what you are doing. I just wanted a little clarification. We all worry about the cost of compliance, and you have the additional costs, your $2.5 million for the pursuit of the classified research.

Your implication in the numbers was that that is

a small fraction of your overall budget. That sort of implies a cross subsidy, that your non-classified research volume is subsidizing your complying with classification. I wonder how you view that, feel about it, keep the buckets of money straight. Of your eight percent, was that projects or volume wise that was classified?

DR. CROSS: It is eight percent of the overall projects that are classified as opposed to volume, so it is not eight percent of the research revenue that is classified.

To be honest about this, the other way I could have sliced it is to show the number of classified projects that are done within the Georgia Tech Research Institute, the applied research arm of the university, and broken out the overhead funding that way. If I do, it comes out to be about 1.75 percent, I believe, so it is still a fairly small number.

What that number doesn't reflect is the cost of people with the clearances, for the briefings they go through, for the cost of support from the Office of Sponsored Research for reviewing a proposal, and getting the form filled out for classified research, et cetera.

I don't have a way to estimate what that unaudible funding is, but it can't be too large. It may be low hundred thousands or something for everybody's time that was put on it. It is still a reasonable low number, I think.

DR. GANSLER: So what percentage of the dollars do you do for classified versus unclassified?

DR. CROSS: I would have to get that number for you. I don't have that readily available. But we can get that if the committee wants it.

DR. IMPERIALE: Are there other questions from the committee?

MR. HART: Based on your experience, if there were to be an influx of some size, not giant, but a substantial increase in the number of Chinese foreign students studying at Georgia Tech, what kind of security complications would that cause for you?

DR. CROSS: Actually we have a large number of Chinese scholars at the university now.

MR. HART: Does Mr. Gaffney know that?

DR. CROSS: I think there are several hundred here. For fundamental research it shouldn't present a

problem at all. I know our dean at the College of Sciences was very upset a year ago when one of his Chinese doctoral students went back to China for the holidays, and wasn't allowed back in the country to defend his dissertation. So that was a very difficult thing.

We wouldn't allow anybody who wouldn't qualify for a security clearance to come and work on the classified work. It is compartmentalized and separate, so it is not a problem.

One of the things that you get into in the gray areas, what about the Chinese student who is studying electromagnetics and electrical engineering? You can get into a classified area pretty quickly there. There are professors there that have clearances that teach the courses, and those courses are listed in the catalog, so they are part of the fundamental research.

Even though I perhaps didn't use the term self regulation correctly, that is part of what we mean. We hold ourselves accountable for this, and it works. So we wouldn't restrict the students coming here. We think it is a pretty good university to go to. We want the best students to come here.

DR. GANSLER: Steve, have you noticed any increase in the amount of concern or literally subpoenas or any other things such as the Chinese example you just gave, any significant increases over the last few years in terms of restrictions on foreign students in one way or another?

DR. CROSS: It has been a hotly discussed topic within the university for the past couple of years. I don't have exact numbers for you, Jack, in terms of the numbers of students, but we have been very concerned that international students haven't been able to come here to pursue some of the research.

There is another element about Georgia Tech that is very interesting. We have operated a campus in Metz, France since 1989. I don't have the specifics on this, I would ask Jo to maybe answer this later. There is some cases where there is research we can do that might be considered sensitive here that we can do there without any restrictions on it.

But we have been very concerned about the -- if you look at the definition of sensitive research and the constraints that puts on international students coming to study, having that reviewed before a research project could

be initiated, we have been very concerned about that. Our president has been very active nationally speaking on that as well.

DR. GAST: Steve, I wanted to get your thoughts on something I grapple with. I often have faculty whose work is becoming -- or the area is becoming classified; DARPA is taking the program over into classified work, and they want to keep abreast of the work and they want to keep doing it, but they want to do open fundamental research. They are trying to decide whether they should get a security clearance.

I always have mixed feelings about that. As long as they don't have the security clearance and they are pursuing open and fundamental work, even if they in some sense in the course of that research accidentally talk about and discuss and work on things that in some peoples' view would fall over the line, they are not obligated to have made a decision in their brain on what part is classified and what part is open.

So I am wondering how you counsel faculty members when maybe a fraction of the research group is behind the door and another fraction is outside, and how they can

partition their work and keep this. It is a large number of faculty doing this, and I presume many of them have mixed classified and unclassified research programs.

DR. CROSS: I was told you ask very hard questions. The only thing we know to do in this situation is to have a very trusted relationship with the government sponsored the research, and to discuss it openly in the applications of that. That is the first thing I would advise the faculty member to do, because we are all in the same team here.

This is actually happening in many of the aerodynamic areas as we speak. We need to help that professor compartmentalize the research that is classified, that will help that person get a security clearance if they need that. That is about the best I can answer off the top of my head.

DR. IMPERIALE: Questions from the rest of the audience?

DR. CROSS: This is where my students throw things at me. Yes, sir.

PARTICIPANT: How are current U.S. export controls, particularly deemed exports, impacting your

research programs?

DR. CROSS: This one is probably one I will defer to Jo de Garton if she can help me with this one. The question is, how are deemed export controls impacting our researchers at Georgia Tech.

DR. DE GARTON: Steve, I think the deemed export regulations are impacting Georgia Tech's researchers pretty much the way they are everybody else. Where we have the fundamental research exclusions we rely on doing our work under that exclusion, and the country of origin for that foreign national is generally not a concern.

Where we have any restrictions for national clauses of the 7,000 clause that Julie knows well, or we have proprietary information that is being shared with us by a company, we have a sensitive but unclassified clause in the contract, that sort of thing, then we are dealing with deemed exports and we are having to look at the countries of origin for the contract performers.

As you just noted, we have a lot of Chinese students, we have a lot of international students in general, so we do have to look at who is doing the work. We are also spending a lot of our time looking at the

projects that people coming to Georgia Tech or international scholars coming to Georgia Tech will be working on if they are H1B visa holders, because we do need to look at the kinds of equipment that they will have access to, what kind of use technology they will be gaining access to when they are doing their research here at Georgia Tech. We are developing even more procedures for ongoing review, just for deemed export purposes.

But I don't think that we are unique. I think we are handling it pretty much the way almost eery other university is approaching it.

DR. CROSS: My short answer is that it is taking a lot of Jilda's time and a lot of Sissy's time over here.

PARTICIPANT: How do you do it? How do you organize your operations to pick up the things that need the export controls to make sure that you do meet the requirements? Do you have a central office that things go through, or do you rely on your sponsored research offices in the various schools to pick it up? How do you grab hold of the information so that the right eyes can look at it to make sure that you are doing what you have to do?

DR. CROSS: It has always been that way here. We

are a small place, and we are a network community, so we have a very good working relationship with the Office of Sponsored Programs, Jilda, the legal office, Sissy, and we talk about these things in the inception of the contract and as the contract is working through. That is how we do it.

Whether that would scale to an extremely large university, whether it would scale to a university that didn't have the core values that we have, where we stress the interdisciplinary nature of the university and open communication throughout, I don't know. I don't think it would work just by having checklists of rules put out. We have to talk and trust and work with each other. That is probably not a very satisfying answer, but that is the way it is here.

DR. GAST: One thing that concerns me, it is not just the contract performers you have to look at with these deemed export issues. It is people who go to research group meetings and seminars. That is where you get to the fundamental openness of academia, where these doors are open, people can walk in, you don't find out their country of origin when they sit down in an auditorium. So I would

wonder how you would work on that.

DR. GARTON: I think you are talking about the deemed export provisions. That is particularly an issue when we have graduate students or undergraduates working on a project that has foreign national restrictions. Very often we will find that that is not a project that is appropriate to staff with students that would be exchanging that kind of information. If it is a graduate student you have to worry about deemed exports to members of that person's graduate committee, and you would have to worry about the seminars and that sort of stuff, and making sure that export controlled information was not then shared.

Part of the trick of it is looking at what is actually the export controlled information, and what part of that project can be conducted under the fundamental research exclusion. That is what we spend an awful lot of our time doing, is sorting out what is subject to the fundamental research exclusion and what is truly export controlled, either technology or use technology.

That is why it takes so much time to administer overhead in terms of personnel. And of course, that relies then on the faculty and on the school chairs, because they

are the people that have to understand this stuff and have to be there to implement it. The central office folks are not there to implement it. So that is a huge education problem.

But the way we approach it is to separate out that which is supposed to be controlled from the fundamental research project, and then if it can't be, then that is not going to be a project that is appropriate for students to staff.

DR. GAST: This gets back to the question of the bright line. It shows you the classified is much easier to deal with, because you know it is classified. It is the things that are in this gray area. One of our concerns with SBU is that work that is put together from open non-sensitive information that once it is compiled is now considered sensitive, during the course of a fundamental research program, it has become SBU. Then you have a kind of moving target.

DR. GARTON: That is exactly right. It is theoretically possible for something that is a fundamental research project to result in a classified result, although I don't know of any examples of that ever happening. You

do? Then it is classified and you can't tell us. But that is the result.

What we end up doing in some of these cases where you have sensitive but unclassified, you are treating it de facto as though it were classified, with a lot of the elements of control that you would have for classified projects, even if it is on a smaller scale than an entire SCIF or something like that.

DR. CROSS: You know this, but two trends that seem to be prevalent today is one, the time scale of how research is advancing, and the other one is how much of the research is being done internationally.

IBM just released their global innovation report, where they surveyed 796 CEOs. One of the things that it suggests in there is that 75 percent of the research is going to be funded outside the U.S. in the next several years. So maybe besides export control we need import facilitation, I don't know.

DR. GANSLER: I think the other trend is one that Gary pointed out, which is the increasing amount of classification and the increasing amount of this sensitive but unclassified. So those two trends in a sense are

counter to the globalization of the technology. And that is the balance that we are trying to look at.

DR. CROSS: Right, and the issue we have on the sensitive is the restriction on the international student, and also the review of results before publication, which is also onerous in academia.

DR. IMPERIALE: Any additional questions or comments? Then lunch is going to be served one floor down from here, and we will reconvene at 1:30.

(The meeting recessed for lunch at 12:25 p.m., to reconvene at 1:30 p.m.)

A F T E R N O O N S E S S I O N (1:34 p.m.)

Agenda Item: Dual Use Sciences Research: Government Perspectives

DR. BERKELMAN: I am Ruth Berkelman from Emory University. I am happy to moderate this afternoon's session. We are going to be focusing on life science research and dual use. A large portion of federal research funding is focused on the life sciences, and there have been a lot of life scientists beginning to deliberate about these issues.

If you are not aware of some of the reports that have come out of the National Academies, I thought I would just show them to you. This has been known as the Fink report, for Gerald Fink, who headed the Committee on Biotechnology Research in an Age of Terrorism. Another National Academies report, Seeking Security: Open Access in Genome Databases. There has been a third one recently, Globalization, Biosecurity and the Future of the Life Sciences.

All of these focus on educating scientists, making them more aware of the issues of dual use, what should be considered before research is started is very

much in the Fink report and the other reports. The most recent report on globalization and biosecurity and the future of the life sciences also takes on the fact that this is a far broader threat than one simply of select agents.

We are going to focus though this afternoon on the government perspective. We have got four individuals here. I have asked them all to come on up. They are all restricted in terms of the number of minutes for their comments, so we will have plenty of time for discussion.

I am going to go ahead and introduce all four now. Their biographies are in their packet. Dennis Dixon is going to be leading us off. He is the Chief of the Bacterial and Mycology Branch at NIAID, the National Institute of Allergies and Infectious Diseases at NIH. Followed by Dr. Lisa Lee, Assistant Science Officer out of the Office of the Chief Science Officer at CDC here in Atlanta. We are glad to have Gretchen Lorenzi, an intelligence analyst from the FBI here, no need to say what FBI stands for, and Carol Linden, who is currently a senior scientist in the Office of Research and Development, Science and Technology Directorate at the Department of

Homeland Security.

I will ask Dennis if he will lead off.

DR. DIXON: Thank you, and thanks to all of you for coming back from lunch on time. I am pleased to be here and to learn along with you in this rapidly evolving area of science and policy. I will be giving you my own personal perspective as a program manager of the NIH.

The context for my presentation will be helpful, just to know what my comments are grounded in, and what component of the government I come from. I am from the National Institutes of Health, which is part of Health and Human Services, and I am in the National Institute of Allergies and Infectious Diseases, where the preponderance of dual use biological research is centered at the NIH. I am an extramural program manager. I interface with people such as yourselves in the community and in other sibling components of the federal government on these issues.

One of the reasons I am here is because I have had experience in select agent management over the year. I was one of the NIH representatives involved in the formulation of the implementation arm of the select agent rule the last time through and the most recent select agent

provisions. I am serving on several working groups of the National Science Advisory Board on Biosecurity, which is clearly in tune with what is being discussed here today. I am not their official spokesperson; I will merely try and give you my perspective on having watched this group take on the enormous task that evolved out of the Fink report. I think that we can all be assured that they are taking the issue so seriously, and are making outstanding progress in coming up with some very workable possibilities.

I don't do all of the agents of dual use. The ones I have purview over are listed here. I put up the path that I have already explained. I am in the HHS, NIH, and my Institute is Allergy and Infectious Diseases. I am in the Division of Microbiology and Infectious Diseases, where most of the dual use microbes are based.

The ones in red are the select agents in my branch. I don't do all the anthrax research, I do the front-end, upstream basic research, early applied research and early clinical research, such as the phase I trials on monoclonals for countermeasures. We span category A, category B and category C agents, if you are familiar with that artificial characterization of the bugs that fall

under the dual use spotlight.

I put up our webpage at NIAID on the priority pathogens, to let you see the spectrum of microbes over which we have the mission to advance the state of knowledge for the public health and to develop countermeasures, better drugs, better vaccines, better detection measures. We can only do this through advancing the security clearance knowledge together, and by doing that quickly so that the information that comes out of that can be put to good use before it can be put to bad use. So we are highly dependent upon the processes that govern their use.

As a program manager at NIH, I am one of those entrusted to be a good steward of taxpayer dollars, to insure that the risk-benefit analysis is managed to the right scale, minimizing risks to the use of public health funds.

The way we do this typically is to adhere to federal law. We make the acceptance of any financial award contingent upon an acceptance to adhere to all applicable federal statutes, regulations, policies, including the relevant select agent rule. I am going to focus in on select agents, because that is clearly the most relevant to

the issue at hand, where there is a good example of a process that is working quite well.

I think most people here are familiar with the background legislation, the Public Health Security, Bioterrorism and Response Act of 2002, behind the implementation arms of the select agent rules. They require all facilities and individuals to be registered with the appropriate federal agency, CDC or USDA, and that the regulations apply to possession, use and transfer of the agents, and that registration is managed by the CDC and the USDA.

We require our community to be in compliance with that regulation, and we defer to the institutional officials to interact appropriately with the CDC or the USDA for their management, and we are in communication with those entities to close the loop, as it were, on what is going on.

As an example, we came up with this term of award that we explicitly apply to the relevant grants that may be using select agents. That is, an award to conduct research with such agents need to be in compliance with the federal regulation, that they need to have completed registration

with the CDC or USDA, and that they need to do that before any NIH funds are used, and if the use is denied, they need to desist in the use of federal funds for work with those agents. They need to desist working with those agents, period, because it is the federal law.

What do program officers do to monitor this? We are networking with the academic and corporate recipients of the fund that we administer. We are calling this to their attention as program managers. We are applying the terms by interacting with the grants management arm of the NIH to see that this is inserted as a term and condition of award, and we help with guidance to what the rule requires, but we always defer to the CDC for what they need to do in specific situations for being in compliance with the law.

Jumping now pretty quickly to the National Science Advisory Board for Biosecurity, this is the chartered group that grew out of the recommendations from the so-called Fink report. I think you will see that a lot of the recommendations are coming into play there. You can go to the website. I would encourage this panel to follow that group and to be in awareness. Certainly we have overlapping categories with Michael Imperiale, who is a

member of the NSABB.

Dr. Fauci, our Institute Director at NIAID, is the NIH ex officio member. Ex officio members are nonvoting members, but we are there to interact with the community. As you can see, this group is entrusted to, in the first bullet, to a system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns; coming up with guidelines as to how one identifies dual use research, guidelines that become codes for the conduct for the scientists, and materials to outreach to the community for education.

A comment now on the five effector arms of NSABB. These are the working groups that are wrestling with the very sorts of issues that this panel is reviewing, although I think you have a much heavier emphasis on things such as deemed export and foreign nationals that has not yet been discussed by NSABB.

I am picking two working groups that I have had experience in working on, the dual use criteria one, chaired by Dr Dennis Caspar, and the communication working group, chaired by Dr. Paul Kahn.

I sense from the community that I network with that there is a great deal of anxiety over what will happen next in terms of giving us guidance that may be perceived as a bureaucratic impediment to biological research. This is a new era we are moving into. My final slide is going to be coming back to the recombinant DNA advisory committee and the RAC.

Taking us to the analogy of the mid-70s, when recombinant DNA was first operative, first recognized, first put into use, and the scientific community on their own imposed a scientific moratorium until they determined how they could self police and come up with a set of guidances that helped to govern the daily activities and operations. That later went on to have formal bodies managed by in this case NIH's Office of Biotechnology Activities, but was grounded in an awareness of cultural responsibility.

I think that is how we at the NIH and others throughout the scientific community see this, as a matter of cultural responsibility. One thing that we are wrestling with is, how do you change the way people think, how do you move into a new area where new concerns have

been recognized, so that everybody does get it, so that everybody does approach it with the same degree of seriousness. It is hard to change peoples' behavior. Guidances are very helpful in that case.

Just to comment here on dual use research. I know another concern is, if something gets labeled dual use research, what does that mean? What I am showing you now are very minimal modifications to the public document that is on the NSABB website that shows what was presented here in the last open public meeting of that advisory committee.

Dual use research of concern is what they selected for the subset of research. It is argued by some of the people on NSABB that just about any life sciences research could be misapplied by someone for something, so therefore, the goal is to concentrate on that where there is a realistic possibility of that happening. By falling into that definition, it does not mean that the research can't take place. It means that it needs to follow the processes developed to guide dual use research.

From one of the slides presented by Dennis Caspar, you can see that they expressed the primary goal of identifying dual use research of concern, to minimize the

potential for misuse. Constantly throughout the deliberations is this risk-benefit analysis that is weighed on a case by case basis, such that individual progress in science is not limited, and that the important benefits can accrue.

I am just going to show you now, and not go through A through H, because A through H represents the quote, seven experiments of concern, unquote from the Fink report. The NSABB dual use working group or the criteria working group has a draft -- that is key to point out -- draft document that has come into fruition now, that is going to be tested, refined and modified from here out as feedback is gained from the community and from other knowledgeable parties.

That draft gets at such things as trying to evade immunization, trying to evade a therapeutic, trying to evade some other modality for a countermeasure, enhancing pathogenicity, enhancing transmissibility or enhancing disseminability of an agent that the Fink report highlighted.

So when you have research experiments that are proposed that do that, then the individual investigator is

the first point for starting to think about these things. Many investigators already have done this throughout the course of their careers, but perhaps not everyone. So this is to bring it up to the forefront. Everyone who has the privilege of conducting life sciences research needs to be running through these scenarios when crafting their experiments, the same way we do about animal use, human subjects use, where there are guidances in how we approach these areas of importance to society, to determine if the knowledge derived or the product derived from that research could pose a risk to the public health, agriculture, plants, animals, environment, materiel.

Right now, the thinking is that the individual would work through that list. They would come up with yeses or noes, and then there would be a knowledgeable institutional official to verify that yes, that is under the radar screen -- those all are no -- or if it is a yes, then that individual helps advise on whether the level of concern of that experiment requires a full institutional review in some form not yet completely defined or identified, but some form of oversight. One can think of an analogy to the recombinant DNA advisory committee that

refers to the IDC for this purpose, to give guidance on that work going forward and how it goes forward and what the conditions need to be, which is risk-benefit analysis driven. So I think this is a pretty reasonable approach that can be taken to get people thinking about these for the issues that we heard from Mr. Gaffney this morning, for example.

That individual oversight would start with the human individual, that would then have an institutional review. There might be institutional guidance and oversight and ultimately federal guidance and oversight, such as in the RAC. When something reaches the highest level of concern, it needs to have approval at the highest level. Not everything goes to the highest level, some things are dealt with -- most things are dealt with at the level of the institution.

I am going rather quickly because I know you are watching the time here. I just wanted to give you another example of another working group, and that is the communications working group, because it does deal with this issue of unclassified information and sensitive information.

The working group has the charge of identifying issues and options for responsible communication of dual use research, and to develop principles, tools and to facilitate careful and consistent decision making on how to communicate this responsibly.

The working group and the NSABB overall recognizes that the overarching principle in science has been that communication is vital to scientific progress. If there is time left over, I'll take the quiz to see if you can identify all the people here. I will tell you that the one on the left is Pasteur, the one on the right is Watson and Crick, and see if you can get the ones in the middle.

This was unfettered information, since the overarching principle is to communicate to the fullest extent possible. I don't think that says unfettered. I think it says to the fullest extent possible, and that restriction is the rare exception.

NSABB as invoked, in going through the 1918 influenza virus that was reconstructed at the CDC in collaboration with other virologists in the world, on whether that paper should be published. That was not a

real easy decision. It took a lot of deliberation. Yet the decision ultimately was for that to go forward. But along with that communication went two editorials, putting this in context, and comments back and forth between people who had looked at the paper and those who had written the paper. A thoughtful, deliberative process before just dumping the information into the literature. That is not unfettered, that is carefully thought through and monitored.

So risk-benefit analysis is really what we are talking about in terms of communication flow in science, something that hasn't always been first and foremost in the minds of the scientists in the community or the individual investigator that needs to be as we move forward.

The risk-benefit analysis might be at the beginning of the project, as you are starting to think about taking it to an abstract for a scientific meeting, or communicating it amongst colleagues; are there potential risks to the public health from the information. That ultimately gets people to thinking about other risks to the experiments that I might not have thought about in my zeal to get there quickly and get a new scientific finding. And

could this information be intentionally misused, and if the risk has been identified, is it near term, late term and so forth.

I am showing you just a snippet of material that is available on the website. The tools have been constructed in draft form that are going to undergo interaction and discussion with journal editors and community representatives such as yourselves in discourse with the communications working group to try and refine tools such that individuals will have some guidance on how to proceed, and that journals are already invoking. We are taking great insight from the scientific journals such as the American Society for Microbiology, who put things into place such as the security review to invoke when the editors through the normal peer review process encounter things that raise their eyebrows.

Content is reviewed, every step along the way from the investigator's head through the publication in the journal, is this okay, if it is, does it require some additional context so that people don't misconstrue what is being said. Does it require some modification, such that the true intent comes forward in the right light. Does it

need some delay so that we can determine whether or not there needs to be additional voices heard, delay the context such as accompanying editorials, as was done in the 1918 influenza communication. And are there any limits on the distribution.

I found this chart a little difficult to follow until I started to look at it from the perspective of each column of the checkmark represents maybe a different case study that one would look at. The first case study might be a very straightforward paper that you communicated as is immediately, with no limits on the distribution. The next case study is the next column, where you might say, they didn't make this particularly clear, it almost looks like they are advocating trying to make this as pathogenic as possible so that you can do all these things with it. Let's balance that so that your true message comes through the way you intend, and then communicate that immediately, so forth and so on.

My final point here is to day that NSABB is giving some good deliberation to similar and overlapping issues to what you are, but I think overall we can learn some lessons from the past and think back to the analogy of

recombinant DNA, which was looked at before the term dual use came about, as a technology or a way to invoke dual use types of concerns, involving the community from the ground up.

This comes from a memoir from former NIH director, Donald Frederickson, who reminisced the RAC, and there is a nice treatise here I have cited at the bottom, perspectives in biology and medicine, 2001. Throughout the evolution of the process that gave rise to the recombinant DNA advisory committee, which is now a chartered group, his concern and those in the scientific community was scientists taking this seriously as scientists, coming up with guidance documents that all would accept and adhere to and follow, and to approach this wherever possible from the perspective of guidelines, not regulations, and pointing out that from that vision from the Silimar has come a new science and a new medicine and a new industry of genomics and proteomics. The societal management of all of this is going to be both a premiere challenge and a premiere opportunity of the coming millennium.

I will stop there, and turn this back over to Ruth.

DR. BERKELMAN: I would like to say that we have lots of time for very burning questions. If not, we are going to continue with all four speakers, and then open it up. Not seeing any.

DR. LEE: Good afternoon. Thank you all for hanging in there and, as Dr. Dixon said, for coming back after lunch. I am Lisa Lee, the Assistant Science Officer in the Office of the Chief Science Officer at CDC. I am going to try to give us maybe a 30,000-foot view of what CDC is dealing with in terms of dual use research.

Before I start talking about where we are with it, I do just want to be clear about our assumptions here. We believe that peer review, incremental knowledge and transparency are critical to the advancement of science, and that discourse through the body of scientific literature is intrinsic to the development of our knowledge.

We also believe that public health research done by public health scientists is intended for the advancement of health and well-being, despite how others may choose to use that.

Some of the things in terms of where we are with

dual use research. To set the context for this a little bit, CDC's mandate is to protect the public's health. So if we have to deal with a bioterrorism event, we have to be prepared with the necessary scientific information to respond in order to protect the public's health. So our dilemma around dual use research is how do we maintain cutting edge scientific output that will allow us to maintain our role in protecting the public's health should an event occur, without compromising public health or national security. This is our primary question.

I want to talk a little bit about the science that is done at CDC. We have over 9,400 employees and about 5,000 contractors that do work for the scientific enterprise at CDC. Nearly 75 percent of the employees at CDC have college degrees, 55 percent have advanced college degrees. We have over 170 occupations.

We have got scientists from all arenas doing work at CDC. Our average age of the workforce is 45 years, so many of us have been doing science long before 9/11, and remember the good old days. Each year we publish about a thousand articles in peer reviewed journals.

We do a little bit of basic research at CDC. We

know that basic research leads us to very practical and applied research. Given our imperative at CDC to create and disseminate science and other innovations that will protect the public's health, our research portfolio tends to be weighted heavily toward more applied research. This means that we do research that is closest to the end users of the research, which makes dual use research a top concern for us.

Some recent examples were already mentioned, one of them of dual use research done at CDC, the ones with the biggest kick in terms of interest, the 1918 influenza virus. That was Tumpey et al. who published that in Science in 2005, generated the virus bearing all 18 gene segments using reverse genetics, and found that the virus was able to replicate in the absence of trypsin, which is the key thing that made it such a lethal virus.

Another recent example is a paper that has just been submitted by Esposito et al. That is working with smallpox sequencing of virus. This is an instance in the instance of dual use research where it is an etiologic agent with low risk but high consequence potential. So this is a very real issue for us that we are dealing with

every day at CDC.

What are we doing about this? One of the things that we have been working very deliberately on over the last year is to prepare for the NSABB policy that we NSABB expects to be out by the end of this year. As Dr. Dixon explained, we are looking at this policy to help us define DUR, to help us assess the risk-benefit of communicating and actually doing dual use research, how we should communicate things that are considered dual use research of concern, and very important for us is training our scientists around dual use issues, how we are going to get to every single scientist who does work at CDC, or who will do work that is potentially of dual use.

Finally, what are our administrative responsibilities, how do we keep track of the fact that we are reviewing research that might be considered dual use. We are hoping that the NSABB policy will help guide us on all of these topics.

In the meantime though, we have felt an urgent need to pull together our top science advisors and associate directors for science at CDC to help guide us in how to get through until we get the NSABB policy, but also

to assess our internal infrastructure and be ready to implement this policy as soon as it comes out from the board.

What are our tasks? Our working group tasks include several things. One that is really important for us is training of our scientific staff. We want to be able to help clarify for scientific staff differences between DUR and SBU information, what that means to them as scientists, either at the bench or at the computer.

We recognize that we have a vast staff to train. We have got to reach our scientists at the bench level, so to speak, their supervisors, our scientific leaders, as well as our center directors and other people involved in clearing scientific products.

Our task for the working group also includes our definition of DUR in the context of what NSABB will tell us, but we recognize that the kinds of research we do at CDC that might be considered dual use research of concern are bigger and more broad than just biologic research. We have got chemical, we have got modeling that happens, the article in PNAST that showed the modeling the botulism in the milk supply kinds of things; we do a lot of that

modeling kind of work at CDC. Also, nanotechnology. We talked about that this morning, and the fact that there are many applications that could potentially be quite useful for us, but also could be used in quite harmful ways.

Then finally, the other task of our work group, the third big task of our work group is how we are going to actually implement this weighing of risks and benefits. We are relying heavily on NSABB guidance, personal tools for that. Some great draft tools have already been developed, and we are hoping to be able to tweak those to use those to our best advantage at CDC.

We know that we have both an internal research portfolio and an extramural portfolio at CDC. This will apply to any research done, whether internally or externally, that federal money touches. So we are developing processes now to address the extramural dual use research potential, and we are assessing the infrastructure and processes for review for our own internal research. That includes possibly convening a new body like an IBC or do we have existing mechanisms that we could roll this review process into, or maybe the policy from NSABB will tell us specifically what that kind of group needs to look

like. So we are in the process of assessing what we have available to us and what we might need.

I want to just end with two kinds of challenges for us. One is one that is unique to CDC, which is, how can we maintain our cutting edge scientific output that will allow us to fulfill our responsibilities to protect the public health without compromising public health and national security, something with which we will struggle as we work through this.

Then a couple of things that we have been thinking about that are challenges for the entire scientific enterprise. One is, how do we determine the risk-benefit ratio that indicates that something either should be published as is, should be altered slightly in some way before publication, or should frankly not be published at all. There is not a formula from which we get a P value of less than .05 and we can say yes or no, publish or don't publish. This is the art of scientific judgment, and how do we as a scientific enterprise and a scientific community deal with that.

There are lots of nuances. That is a very loaded question.

I think that we will carefully consider that, not just CDC,

but the whole enterprise, over the next several months.

Finally, the thing that somebody touched on earlier this morning that in my heart I think is a huge challenge for us as scientists: How do we encourage the best and the brightest to do the kind of research that we need to answer critical questions that might be considered dual use, that might not be able to be published, and ask these best and brightest scientists to forego the fundamental reward of being published.

With that, if there is anything clarifying or burning, I will answer that now. Otherwise I will let the other folks speak.

DR. GORDON: Lisa, can you take the temperature of your researchers and scientists with respect to what they think is coming from NSABB? Is it unnecessary or too much or too little? How would you characterize that, if you can?

DR. LEE: I think that the pulse of our scientists is that this seems like a reasonable approach, particularly because the whole sense from NSABB originating from the Fink report has been that this is about capable scientists able to make great ethical decisions. We make

ethical decisions all the time about h human subjects, about animal subjects, about all kinds of research, and this is just another topic about which we can make thoughtful decisions.

With guidance from NSABB to help us make those thoughtful decisions, it seems like a reasonable approach, partly because as I said the drive to leave it to the scientists, the self regulation, et cetera. But the other thing is that it is clear from NSABB and also from the Fink report that we are not trying to censor, we are not trying to not publish things, we are not trying not to do the research. We are trying to balance this critical research with how we communicate that. I think generally, scientists are respectful of the need to do that.

DR. BERKELMAN: Thank you. I think we will go on. Someone else had a burning question? I think we will go on to Gretchen Lorenzi at the FBI.

Thank you, Dr. Lee. While we are waiting for this to get started, I will say that I was at the meeting of the experts -- I think several people here were -- at the biologic and toxic weapons convention. One of the issues from the United Kingdom that came up was that they

were educating all of their scientists in their government on codes of conduct. That was coming out of the Chief Science Officer.

DR. LEE: We will be in the same boat shortly, and actually are preparing now with many other areas in CDC, our training folks too, to begin to implement such a process. So it will be quite an endeavor.

MS. LORENZI: I am Gretchen Lorenzi. I am an intelligence analyst with the FBI. I am part of the weapons of mass destruction countermeasures unit, but my background helps frame why I would be the one standing here in front of you. I have a bachelors in chemistry and a Ph.D in pharmaceutical sciences, so I manage a new program at the FBI which is called the science and technology outreach program, or STOP, because we love acronyms. So it is in that capacity that I am here.

But I am going to focus these comments on what I have been asked to talk about, which is dual use research. I think the one element that I bring to this panel, which has considerably more expertise in many ways than I do, is that I have a law enforcement perspective. So all of my comments are going to be very heavily slanted toward how

law enforcement looks at this issue.

Just quickly, the key issues in general in dual use are that both for chemical and biological research, the materials, the technical skills and the equivalent all can be used nefariously if desired. So that creates a difficulty from the law enforcement perspective in recognizing where the line is drawn between something that is being used as it was intended. So you could come across something that looks very innocent but instead has a hostile intent, and it starts to fall to the intent of that use when you are looking at it from a law enforcement standpoint.

Then also, the idea that research undertaken even with the loftiest of goals could end up being misapplied. So even though something is being designed for the right reasons, it can be used incorrectly.

Compounding all this is the fact that science is advancing dramatically. There is a globalization of technology in general and biotechnology specifically. That makes the law enforcement aspect, the terrorism prevention aspect, even more complicated. As the technology advances, while that does benefit society, it also benefits the

terrorist camp, so that is another part that we have to weigh in as we look at science marching forward. Also, the idea that within a legitimate scientific lab, be it in industry or academia, that terrorism could be being masked either within a front company or a lone actor acting within a lab.

So when we look at this from a law enforcement perspective, I am going to keep stressing that, we hit the balance. This whole day, the theme seems to have been about the balance, but our balance is between preventing terrorists from gaining a chemical or biological weapon capability and hindering the progress of science. We don't even mean that as members of the community who benefit from improved medicines and the ability to respond.

These are our new first responders. These are special agents out in the field from the FBI. The one on the right is my immediate supervisor. This is them entering an anthrax contaminated building. It is the American Media building in Boca Raton, Florida. He is actually that much shorter than his colleagues. I did ask that a lot. And no, the duct tape isn't holding the suit together. It turns out they could watch themselves in real

time on CNN, and it was a way to identify which moon suit was being shown at that time because they were in the American Media building, so there were TVs everywhere.

But as you can see, there is a huge amount of technology that we rely on and that is being developed by science. The suits, the detectors they are carrying, the filters, they are wearing the antibiotics they are taking. So in a very direct way, law enforcement does rely on the progress of science, and it is not inherently interested in stopping that.

I know we are not going into codes of conduct here. I am only bringing it up because of the value that they have from the law enforcement perspective. One of what is believed to be the key ways to prevent terrorists using a scientist without their knowledge to gain skills, expertise or materials is through improved awareness in the science community, so codes of conduct are really an important way to improve awareness across the board. As Dennis pointed out, one of the big issues is, how do you change a culture, how do you make them step up to that responsibility. So we are just trying to have codes of conduct help us in a prevention role. Law enforcement is

interested in helping to facilitate that culture of responsibility. That means that individual scientists can start stepping up to their responsibility of the knowledge that they have, workplaces can start to enact codes. This helps to minimize the potential for misuse.

From a law enforcement perspective, the biggest problem of dual use is basically trying to sort out the good guys from the bad guys. I think most of our law enforcement agents could walk in and say, this is a piece of laboratory equipment, I might not be prepared to handle this, but they don't know for sure whether this fermenter is fermenting beer, if it is a bio reactor that is legitimately being used for research, or if it is something that was legitimate and has been converted to a nefarious use.

You could also see a fermenter that looks like this. This is basically a home brew setup that was set up in someone's back yard. Every single piece of equipment on there could be bought at Home Depot. So not only do our law enforcement officers have to recognize a spectrum of the same type of equipment, going from more complicated to -- I'm not sure you could get less complicated, but

somewhat less complicated than the cooler system that you see; they also have to see that within that spectrum, every level of those could be your next-door neighbor who is working on his home brew, versus somebody who is trying to cook up something in their basement. That is a tricky problem for law enforcement, because there are probably not a lot of detection movements for a biological or chemical attack, so we are looking at capitalizing on as many of those as possible.

When you look at what to do about dual use, I think we can probably all agree that the idea of directly policing science is not viable, and it is not likely to be effective. Law enforcement doesn't have the resources to be trying to hunt down things that are going on within labs. It is unlikely to be effective. It is a bad use of resources. It is not like trying to infiltrate the mob; it is trying to work a the community that is the vast, vast majority that is working to improve our society. So it is not a good use of our resources to be actively trying to bind that one deviant within there. We are more likely to get in the way, slow down scientific research and hinder the progress.

That said, something has to be done. We definitely support the establishment of the increased culture of responsibility within science as a better mechanism than direct policing to prevent the harmful use of science.

The FBI probably has been somewhat behind in how it deals with the prevention of chemical and biological terrorism. it is a very difficult problem. One of the things that it has been doing is trying to identify the vulnerabilities.

There are a number of vulnerabilities. Because of this audience and this talk, I am just going to focus on the one. That is that university labs represent a critical vulnerability as far as a potential terrorism incident. That is because -- and I know that there are exceptions in labs to each of these rules and to all of these comments, but many university laboratories have very open access. They tend to have a less stable staff, meaning that postdocs come through, graduate students come through, and they could potentially harbor a lone actor, your single disgruntled researcher or indoctrinated researcher, and that is going to be a difficult person for law enforcement

to find. Additionally, university labs have a very rapidly evolving technology which their staff has access to.

The flip side to that, and not to make it all sound bad, the really great thing about the science community is that it has an inherent ability to detect and prevent chemical or biological attacks. Law enforcement will never have that same capability, because we are not there. That is partially because scientists are trained in a culture that encourages collaboration and discussion and review, in the way that a scientist as part of the training process is taught that when you hit a stumbling block, you can usually reach out to another graduate student or a postdoc and get some answers in order to move forward.

A potential terrorist who is possibly trained in science is likely to have that same inclination if they hit a stumbling block. If they do try to reach out into the science community for help with techniques or materials, that is a possible detection event, and one of the very few that we get ahead of a terrorist incident.

Additionally, within science it is true in many fields that as your field of interest gets more narrow,

that even though they might be globally distributed, the other researchers in your field become a small town. You know the main players, you know who is publishing. You might not know every member of their lab, but there is some sort of pedigree there that you can follow. So it i snot unthinkable to see that you can be approached by somebody, even in a place as random as an academic meeting, and a scientist could leave with the impression that that question seemed out of place because you don't recognize the person or the laboratory that that question was coming from.

Which brings me to the need for partnerships between law enforcement and universities. I have to say that it is really quite an opportunity to speak on behalf of law enforcement about partnerships. I recognize that when you start on the topic of university-government partnerships, the FBI is usually not at the top of your list. But we are working at it because it is really important. The days of those communities not being able to interact well really are behind us. We have to start creating ways to bridge those two communities.

The FBI has a couple of programs that we have

started, the science and technology outreach program basically is aimed at recognizing that the science community has an ability to deal with and take responsibility for its own vulnerabilities, but that the FBI can be an asset in that fight. We can help with awareness, we can help with providing information, we can work with any institution that is interested in learning more from a security perspective from us. So there is a mutual interest there that we are willing to work with academics on.

We also have the domain program, which works with helping identify where there are critical infrastructure areas of vulnerability. For those of you within the regions here, I have our domain coordinator from Georgia; it is Rick Heugh. He is a point that anyone could go to if they had questions within this region on how the academics or industry can work with the FBI more closely.

I do believe there is a shared mutual interest between law enforcement and the universities. Nobody wants their communities or families to be vulnerable to a biological attack, and it is on that common ground that we really need to move forward.

Just a final thought on partnership. This is maybe just to point out where I think law enforcement needs to push forward with the help and advice of the science community.

I'm sure all of you have read the ASM's code of conduct from April of last year, but the last sentence from the paragraph I just showed was that ASM membership will cal to the attention of the public or appropriate authorities misuses of microbiology. I read things like that, and sometimes it makes me wonder if law enforcement is really holding up our end of that deal, are we meeting that need, a need that has been identified from within the science community.

The answer is that the FBI is incredibly good at setting up reporting structures. We have got phone numbers and websites and informants of sources and agents distributed everywhere, but I am not at all convinced that yet we have established anything that a scientist would be interested in interacting with. I think that is a really important hurdle in how we look at ways that partnerships could try to move forward, is to try to see if there is a way to get a reporting structure, so that if a scientist

had something they were concerned about, there is a way for them to reach out and be a part of the prevention mission.

DR. BERKELMAN: Thank you. Seeing no burning questions, Dr. Carol Linden. Oh, there is one at the back.

PARTICIPANT: (Comments off mike.)

MS. LORENZI: Am I as FBI are known? The answer is that the FBI I'm sure would like to be a part of that structure. However, that is not essential. I think what is essential is that there is a way for a scientist who felt something of concern to reach out, and that through some process that could be acted on.

I personally recognize that it is very unlikely that scientists will ever directly cal the FBI. I actually had an incident of suspicion happen to me just since I have been doing this. I am a rare part of the FBI who has my phone number and e-mail publicly distributed quite regularly as associated with the FBI, so I get a lot of calls and e-mails. I had a suspicious incident happen to me. It was asking what the correct reporting structure is. They were like, you report it and you open a case. I was like, I'm not sure I am really comfortable with that, and I sit right next to the guys who do it. I am friends with

them, I have lunch with them.

But I think there is this inherent -- a law abiding citizen does not want to reach out to the FBI, and I recognize that. As much as I would like to think that that is not true and that we could set up something that gets it reported directly in, I think people are likely to report to a friendly face, and if that is something that needs to be more local to them, then that is a structure that we need to develop. But it is an important enough issue to say let's find a solution that works, no matter where we fall into it.

DR. BERKELMAN: So in the absence of a structure, we will be calling you?

DR. LEE: You are welcome to call. I am happy to receive any issues of concern that you have, as are my FBI agent representatives that are here with me. Of course that is always an option. I always tell people to feel free to reach out to the people that they know. My issue is to make sure, if you do feel something that you are uncomfortable with, people need to know that they have a responsibility to reach out and act on that.

DR. BERKELMAN: In all seriousness, you have

given us a very thought-provoking talk here, to think about the ways in which scientists would be comfortable reaching out to the FBI is something I think we really do need to pay attention to.

DR. LEE: And I would very much appreciate comments on that.

MR. HEUGH: I am Rick Heugh. I am a Special Agent with the FBI here in Atlanta. The FBI has 56 field offices across the country, and every one of them has a main coordinator. The main coordinator's job is to reach out to DoD, classified contractors, other business communities if they have some high level proprietary stuff that you might want to protect, and academia. So the main coordinator in your territory should be going to all the major universities in his territory, reaching out to somebody in the university.

Different universities reach out to different people. Some might go to the police, some might go through the research institutes and touch bases with their security officers. So they know they have a point of contact within PTRI, for example. PTRI, they know if they have an incident they can reach out to me, so they know somebody

here that they can go to. Wherever you come from, hopefully they will set up the same kind of relationship with your university, and the university can pump it out to all the scientists and say, if you have an issue, report it to whoever the designated point of contact is at the university, and that person can reach out to us. So it doesn't have to be Professor Johnson calling me. I don't mind if he does, it's great, but if they feel more comfortable contacting somebody in their own university structure, then they can reach out to me, that is how we are trying to set it up right now.

DR. BERKELMAN: I think I must also applaud the fact that you as a scientist are in the FBI. I think that helps as well on the liaison front. Dr. Carol Linden.

DR. LINDEN: Good afternoon. I would like to thank the Academy and the hosts here for the opportunity to speak today on dual use -- I will put in parentheses of concern, because that is really what we are talking about, life sciences research.

I would like to talk a little bit as an introductory piece about government biodefense programs, because I don't think folks have that whole picture put

together, and then what is the problem, and maybe some thoughts on what we can do about it, although I think we are all admiring the problem, but I'm not sure we are making a lot of progress in figuring out what to do about it.

There is a document called Biodefense for the 21st Century. It is also known as Homeland Security Directive Number Ten, which was published a little bit over two years ago. This document for the most part is completely unclassified. You can find it on websites and read it. It assigns specific roles and responsibilities to federal agencies throughout the government for biodefense.

I just pulled out two what I think are very important and key quotes from the introduction. It commits the United States to use all means necessary -- you can read this for yourself -- to protect ourselves against biological weapons and attacks perpetuated against our homeland and our global interests, and it also reiterates the commitment to the Department of Defense to protect military forces, and also to protect critical domestic and overseas installations.

This is important language in terms of policy

guiding programs at very high levels. The document goes on to lay out four pillars of biodefense that are depicted here: Threat awareness, prevention and protection, surveillance and detection, and response and recovery. Without a lot of imagination, you can parse what federal agencies are aligned with each one of these. In some cases there will be one agency for example that has the lead role or serves in a coordinating role, and oftentimes that is the Department of Homeland Security, or there are agencies that have specific mission roles, for example, Health and Human Services has the lead in the mission for medical countermeasures, the State Department has the lead in the mission for diplomacy, the law enforcement community has the lead for interdiction and attribution, and so forth.

So who has in the government biodefense research programs? I put research on here that there are other things that are construed as biodefense programs that aren't really germane to our discussion today. I have got these listed pretty much in order of the magnitude of the funding associated with the government organization. Dr. Dixon's organization, the National Institute of Allergies and Infectious Diseases, conducts their biodefense research

program, which is to the tune of about $500 million or so, something like that, the whole program.

DR. DIXON: The whole biodefense budget is close to two billion.

DR. LINDEN: Two billion in NIAID?

DR. DIXON: In NIH, and most of it is in NIAID.

DR. LINDEN: They definitely lead the parade in terms of the funding. The program is parsed into the five major domains shown here. I will add that much of the work, in fact, the bulk of the work that is done in this program is extramural, i.e., it is conducted by awarding grants and contracts and other kinds of funding relationships to universities primarily, but also the biotechnology companies and other performers.

Next is the Department of Defense with the chemical and biological defense program. It used to be the only show in town, and now is dwarfed by the domestic program. Their program is divided up into physical countermeasures, looking at detectors and decontamination, things of that sort, and medical countermeasures, which is the piece of the program that usually attracts the most attention, with the development of vaccines, drugs and

diagnostics Much of that work is done within federal or DoD laboratories, but some of it is also contracted out to academia and biotechnology companies.

Last but not least, the new kid on the block, the Department of Homeland Security has a biological countermeasures program. The thrust areas are listed here. DHS doesn't do any medical research, but we do have responsibility for agricultural security because we own and operate the Plum Island Animal Disease Center.

We also work very closely with the law enforcement community, specifically with the FBI, on bio forensics and threat awareness. Much of that work is conducted either through contractual relationships with industry and academia or in the DOE national laboratories, or in the few DHS laboratories that are coming into existence.

So why is some of this research controversial? We have been talking a lot about dual use research, dual use issues of concern. You already saw a listing of the seven criteria for these types of experiments that evolved from the Fink report.

I characterize this a little bit differently here

on this slide. It is controversial, because it involves research on hazardous pathogens, and these pathogens themselves raise safety and security concerns, especially safety concerns for the people working with them as well as the folks around them.

In some cases, the development of protective measures involves testing against the threat in quotes, whether it is realistic or simulated. I have often been asked over the years, how do you know if something works, whether that is a detection system or a vaccine or whatever, how do you know that works unless you really test it against a threat?

Well, you don't have to go quite that far. There are ways that you can test to see whether your system works, but some of those things raise a lot of concerns.

Our national directives and policy tell us to do research in threat awareness to better understand the current and future biological threats. We understand that Mother Nature has done a really good job in creating nasty bugs that can be used to hurt us. Anthrax has been around since Biblical times at least. But there are concerns especially using the emerging biotechnologies that there

could be future threats that are things that Mother Nature never created or would create.

The biological weapons convention has been alluded to once before this afternoon. it is intent based. I will show you the actual language in a moment. It permits work for prophylactic, protective or other peaceful purposes. Unlike other arms control conventions, it does not involve counting things like nuclear warheads or missile delivery systems or tanks in Europe.

Last but not least, the dual use issues. There is biological research with legitimate scientific purpose, but the results could be used to harm either public health or national security. That is the thing that we are trying to wrestle with. The bad guys might use our results to hurt us, the bugs might get out, and there is also a set of other issues which I term political issues which go along the lines of, we are putting so much money and expanding our efforts so greatly in this arena that we are actually going to cause proliferation of capabilities to do bad things, because we are training so many people to work with hazardous biological materials.

This is the language from the biological weapons

convention. Dual use issues and BWC issues are not one and the same. I just put this up here to illustrate that point, that they are closely related. It has to do with intent. There is nothing in the language of the treaty that prohibits a particular bug or a particular type of work. What it prohibits is using it to harm other people, hostile purposes, armed conflict, no justification for useful purposes.

What we can do about this? A few thoughts for your consideration. We need to develop and implement mechanisms for ourselves to ask and answer questions like the ones I have listed here: Are we doing the right things, the right things being not only the right things scientifically, but the right things to be consistent with our national policies, the right things to address the right kinds of questions that we think we see both scientifically and politically. Are we doing things right? Are we going about it correctly? Are we doing it in a scientifically robust way? Are we doing them for permissible reasons? Do we have robust safety, security and bio surety measures that we can put in place? We can use these measures to control and document sensitive

materials, to control information and to classify it when it is necessary.

I had a discussion with some Georgia Tech folks here at lunch today, and it was stated this morning, Grace Mastalli clarified that the existing classification guidelines or regulations really pertain specifically to direct impacts on national security. So what we are all grappling with here is this other kind of impact on things that are related to national security but not necessarily direct impact.

Developing a security conscious workforce. I think that is something that is going to take a long time. It has taken me a long time. I evolved out of the academic community, as did everybody else with a Ph.D in the life sciences, and it takes awhile to develop an awareness and an appreciation of what security issues are.

Codes of conduct have been mentioned several times already. I think it is the way to go. We need to develop at the grass roots and build into every scientist that comes out of academia the belief that it is wrong to do bad things with bugs. To the extent that we can disseminate that globally, because we do have foreign

graduate students and students in all of our laboratories at every level, starting with high school exchange programs on through undergraduate and graduate and post graduate levels, to the extent that those folks go home trained in our principles, I think that is going to be a good thing that will eventually help in the widest sense to discourage problems with biology.

We have also made reference in previous presentations to existing regulatory and professional standards for the conduct of biological research. These include regulations, some of which are regulations, some of which are guidelines, that essentially have the de facto force of regulations at this point. Those include things like animal welfare, human subjects, the recombinant DNA guidelines. Note the use of the word guidelines there. That is what the official rule is, but even at the local level -- for example, I think in the city of Cambridge, Massachusetts they require that people follow the recombinant DNA guidelines in order to do business in Cambridge, Massachusetts. So it essentially has almost the force of law, even though it is written as a guideline and written to apply only to places receiving federal funding.

Select agent regulations are in fact a regulation found in the Code of Federal Regulations. Biological safety guidelines, again, a guideline, but is the de facto standard of practice throughout the scientific community, and transportation of etiologic agents again is a regulation.

But each one of these, and there are others, include elements of why you are doing what you are doing, why are you sending that to so-and-so, and how you are doing it, are you doing it safely, is it packaged correctly, why do you want this bug in your laboratory, why do you want to use these animals in your research. You have to answer all these questions throughout when you are dealing with all these different issues.

Quality scientific and management practices include an element of oversight. I think this is a segue from the last discussion about who do you talk to if you think there is a problem. There should be within any organization, whether it is a university or a biotechnology company of whatever, government organization, management oversight of what is going on. I would be hard pressed to come up with an example of a place where there isn't any,

but we need to perhaps with the assistance of the NSABB or the community at large develop a culture of having this oversight and sense of responsibility for what is going on.

I have just listed here a few examples: Competitive review for funding, management review and oversight, which is probably more intense in say a government laboratory than it would be in an academic laboratory, scientific peer review of publications, the fundamental premise of academic freedom and robustness, and last but definitely not least, consensus behavior of professional organizations. Gretchen Lorenzi just showed you in the last presentation a quotation from the American Society for Microbiology Code of Conduct.

There are laws also that pertain to this. I think this is part of an education campaign that has go to go on. I bet if you went out into practically any biological research laboratory, especially academia, I'm not picking on academia, but I just think this would be less well known there, there are laws that actually implement the biological weapons convention, the two pertinent ones are listed here, the Biological Weapons Antiterrorism Act of 1989, which is this hideously large

thing. The pertinent portion is found in Title 18. The specs are listed up here, you can look it up on the web. Then the Patriot Act, which many people are also familiar with, which I think did have some direct repercussions in academia especially, because it has to do with an impact of foreign nationals coming into the laboratories to work also.

We have already talked about the NSABB. I just listed their charter here, because we are definitely all looking to this organization for guidance to come out soon.

We think we can reduce the perceived risk of dual use components of biodefense programs by doing the things I have listed here and discussed briefly. Complying with all the relevant regulations and national guidance, complying with federal laws, following the guidelines that get developed by the NSABB when they do get developed, supporting the development and application of codes of conduct. I have already laid down my personal marker on that. I think eventually it will help. I don't think it is going to help tomorrow necessarily, but I think over the years, if we lead the parade and set the standard of responsible conduct for doing this type of research, and I

think we will have many allies in this in other countries, this will become the standard throughout the world.

Last but definitely not least, exercising active management oversight of what is going on.

Thank you. I think we have time for a few questions.

DR. GANSLER: Carol, could you give an example of this case that you mentioned? You said related to national security but not national security.

DR. LINDEN: I think Grace talked about that earlier today a little bit when she was talking about the sensitive but unclassified information. I am thinking about things like, for example, somebody undertakes a modeling study and puts together from end to end an analysis, a what-if kind of scenario. The answer to what if is, ew, this is really bad. You want that information to get into the hands of the right people so that they can help address the problem and fix the vulnerabilities, but you also don't want that information to get into the hands of the wrong people, because it essentially serves as a template or a cookbook for how to do something really awful.

I sure don't have the answer of how exactly we should go about controlling that information. I know there was a case -- I brought this up at lunch in the discussion, there was a graduate student, I think it was at George Mason University, --

DR. GANSLER: The electric grid.

DR. LINDEN: Right, the electric grid. If I remember correctly, I believe that the way that was handled was that the bulk of his work was published in this dissertation, but there was a piece of it that was held out and either classified or just held out. I'm sorry, I don't remember the details.

But these kinds of things are serious. We need that kind of in-depth analysis to identify where our vulnerabilities are so that we can address them, but we certainly don't want to put that information into the hands of somebody who could pick it up and go, oh goody, now I know how to do this.

MR. HART: I feel obliged to point out the gender imbalance on this panel. I do so for the benefit of former Harvard president Larry Summers.

This is directed at the panel generally, if you

don't mind. We have struggled to define the what and to learn about your organizations and institutions and what you are presently doing is enormously helpful to us.

Once again, let me reiterate, we are tasked with the obligation of saying how. Either today or in the future, if you can provide us with recommendations as to the general objective of finding a balance between security and liberty or terrorism and science, how do we do it? What are we not doing today that we ought to do, specifically? Or what are we doing today that we shouldn't do? That is what we are looking for.

This is all very, very helpful, to know what is going on as background. We have to now assimilate that and go forward to try to make the system work better.

One final thought. While we are struggling with a national policy on sharing scientific information or not, shouldn't we also be thinking about international cooperation? Mr. Gaffney referred repeatedly to an amorphous enemy. Let's take for example pandemic naturally proliferated avian flu or whatever. Shouldn't we be thinking about ways to integrate national health services around the world into some sort of connection of

international health services to prepare ourselves for that natural attack, which is more likely than not, given globalization and so on?

DR. DIXON: Senator Hart is certainly exactly right, in that there are two key components, the what and the how. Just in listening to the NSABB communications, I know that they are focused now on the what, and they have made that explicitly clear. They are trying to set the definitions and identify the problem first, and then move into the implementation arm of more the part that you are getting at.

It certainly does get difficult there. I can think in terms of the select agent situation, where we defined the what and had the list of agents, and then the how got very difficult, because people were trying to fit the biological world into the physical world constraints. In the physical world when people are looking at radioactivity, there is a specific quantitative threshold that one can cross over. That became problematic in the how for the biological agents and how many, because all you need is one replicating cell, and you have an infinite source of material. I know there were difficulties in

trying to balance the regulation with the guidance there, because there were some that felt every time you did an experiment, you had to take an inventory of the number of colonies. If you were doing metagenesis experiments, you could have thousands of things. You would spend nothing but your time counting the colonies. When people finally moved toward more of a guidance on your seed stock that has to be inventoried, and then you have control of access to laboratories that you don't let the subcultures escape from.

So that is a hard part to work out, and I think that is what we are going to be embarking on for the second phase.

DR. BERKELMAN: I want to speak a second to the issue of the international, and maybe somebody on the panel wants to as well. My understanding right now is with the current threat of pandemic flu and avian influenza in many countries, as well as human influenza in many of those as well, that there is varying cooperation around the world with the World Health Organization. I don't know how clearly the World Health Organization is getting out to the scientists in our communities which countries are

cooperating.

I just throw it out that it might be useful to think about whether scientists in academia with relations in these countries couldn't be asking why, why aren't you sharing isolates, what do we need to do to get all of the scientific community on board with this issue. I don't know. i

DR. IMPERIALE: I have a question for Gretchen. One of the issues we are grappling with is educating foreign students. My question is from the FBI point of view. Are you guys more worried about foreign student in the U.S. or U.S. citizens? Jack spoke about a piece of data this morning that most terrorist attacks by a seven to one ratio have been by people who were citizens of those countries.

So what is your sense of that? How much should we be worrying about foreign students versus our own citizens?

MS. LORENZI: I would say that on an awareness level, I am very careful not to target either international or domestic students, and for that exact reason. While the media plays up a lot about international students, and we

definitely have foreign states of concern, realistically if you go on the Internet and Google you can pull up 450 active domestic hate groups in the United States. If one of them was deciding to infiltrate a graduate program and place somebody in a lab to get them access to equipment and materials, they are probably more likely to pull that off without detection than a foreign state would.

I don't know that I am really qualified to weigh in on which I think is more likely to happen first or next or most over time, but I think that as far as preparedness, when we start looking at the culture of responsibility issues, the better we train all students in the whole concept that it is not acceptable to be using bugs or chemicals maliciously, that that can become pervasive.

An example. I spent a year of my graduate research in a lab in South Africa. Got there, and my professor started showing me how to do a technique, and he was mouth pipetting. You just think, wow, that is something that is so pervasive through all of my training, it is laughable. I have never seen it, it is a joke. You need to make the concept that you can use biological agents that ingrained in our students.

Literally, when all of a sudden when someone approaches them with an ideological pitch, saying we have to bring down the infidels or we have to bring down those people who don't agree with us domestically, then they have to be able to say, you are kidding, that goes against the fiber of how I was brought into this community. I think it has to be that pervasive.

DR. GORDON: We have DHS and FBI and NIH and CDC. How well are we working together? How well are we sharing information, that you all see?

MS. LORENZI: I'll go ahead and start since I'm probably still on the mike. I know that FBI has put a lot of effort into improving its interagency work, and we are not known for being team players historically. But we do a huge amount of joint FBI-CDC training in order to prepare at the state and local level our agents to work with public health responders in an emergency, to conduct joint interviews and be able to keep their investigations going in parallel. I know that we work constantly with DHS because of our overlapping missions.

I'm not at all convinced that FBI has worked very much with NIH, but I don't think it is personal.

DR. BERKELMAN: NIH wants to respond?

DR. DIXON: I'd just give two examples. I think that NSABB and select agents would be two cases in point where we have good representation across the federal sector. NSABB has expertise from ex officio members from all the relevant agencies, way beyond what we have here, on the select agent drafting process. There were representatives from FBI and Department of Commerce and Transportation and all the biological agencies as well. So I think as we move through the process, we will see that replicated, our recognition of the need to converse across all the relevant parties.

DR. BERKELMAN: It is a pretty important question though, because we have all seen inconsistencies.

DR. LINDEN: Also, the relevant agencies at least are working closely together on the WMD countermeasures working groups, and there are several subcommittees by topic area under those working groups. I know at least HHS, DHS, CDC is on there, FDA is on there. It is medically focused, so the Department of Defense is there, their program, their folks.

So I think there are several fora in which we are

interacting across the government with the right kind of agencies.

DR. LEE: I just wanted to make a comment about dual use research. I know that NSABB has really been pushing for this, and so have all of us involved in this. We are looking for a single policy that can apply across all of the country, and ultimately with international cooperation that we can agree on how to manage these data and this scientific information that might be of dual use. If all agencies have different approaches and different ways to assess risk and benefit in different ways to define DUR, then we are not going to be protected in the way we need to be.

So at the very least from that perspective, in terms of defining both what dual use research is how to look at that risk-benefit ratio, I think there is enormous cooperation around getting a single policy out there that can be useful for all scientists, not just for HHS scientists or a single agency.

DR. BERKELMAN: Dr. Cook-Deegan has been waiting patiently.

DR. DIXON: Could I just follow up on that last

comment?

DR. BERKELMAN: Yes, follow up, and then we will go to you.

DR. DIXON: I think it bears redundancy. That is, if one looks at the mission statement for NSABB, even though it is placed in the NIH operationally, it is the advisory body for all federal agencies that are federally funding life sciences research. So that mandate really does require some level of harmonization across all federal parties.

DR. BERKELMAN: And it is being relatively well received, from what I am hearing as well from the scientific community.

DR. COOK-DEEGAN: I had a question for Drs. Dixon and Lee. Both of the institutions that you work at, you have given us examples of work that is going on that raises dual use concerns. I have two questions for you.

One is, somebody must be already dealing with these issues, and accumulating experience in how the decisions are made. How is it being done in the intramural program at NIH and CDC for experiments? You don't have to apply for grants, but presumably there is some review

process that is happening already that I don't know how it works.

The other is, when it comes time for publication, you gave the example of the -- publication. Presumably that is going through some special set of reviews. How is that working? Who does it and how is it located? How is it working?

DR. LEE: An excellent question. We have been doing -- at CDC we have convened this dual use research of concern working group that has been in existence since mid-last year. Prior to that we have called special meetings. We have an internal process of scientific clearance, and a manuscript or a protocol will go through clearance through a divisional associate director for science and a center director for science, and ultimately to the CDC associate director for science, with research of concern of this nature, or other topics that might be controversial or whatever. They have a special path through which they go to the CDC office of the Chief Science Officer.

Before we had the dual use research working group, we called special meetings of our Chief Science Officer or our director, other scientific experts in the

subject matter, expertise of the particular area of the manuscript.

We have relied, though this is not the mission nor the potential future for NSABB, we have relied on them in the absence of a policy to advise us on particular cases. The two I did today, we actually did have consultation with NSABB, because there was no body for us to turn to.

Our main gist for this working group now is to move these NSABB policies forward so we have a very transparent system through which this goes at this point it is an ad hoc kind of thing. Using our dual use research working group, our Chief Science Officer and our director.

DR. DIXON: Just commenting first on the communications aspect, and I will go back to before 2001 and just put things in the context of what publication required then and still requires. That is, all supervisors need to clear all work that is published. There is a process where we look at that for appropriateness of communication in terms of duty activities, so that is still in place. Now it is being looked at as a good way to get at these same issues.

In terms of scientific review, I can focus my comments on extramural, since that is where I am based. But in the extramural side, there is of course the peer review process. There has always been a biosafety review and appropriateness of research and containment, so that is still a part of the review process. It is getting more and more flags for administrative action. Then the program officers such as myself are called into play to deal with the grantee entity in coming to a resolution.

In some instance it might require additional involvement or oversight to address bio containment concerns. But there is an excellent dialogue that the program officers I supervise have. We often are being contacted by individuals who start to wonder about the direction the research is going. Tell us what we should do, and then we say we want to work with you on what you think we should do, what do you think is the right thing to do. We often consult with a body such as NSABB.

We are anxiously awaiting those tools that will tell us the how. I tried to give you an example of the communication working group's algorithm, where you work through the risk-benefit analysis, and they hope to have a

tool that individuals such as myself can use hopefully on the web to refer the grantee and us to work through together, let's work through this and see what we think about the issue, what should we do together. We can invoke our counsel if we need to when we take them forward for funding.

The intramural side I have less experience with. There is a biodefense working group, but there are annual reviews of the scientific research that goes forward that have to be proposed for commitment of funding. I think it is not dissimilar from what we do on the extramural side.

But we are looking forward to having a consistent document. I know that the communications working group at NSABB has even spawned a federal-wide look at what are the publication rules of dual use and how we keep those as consistent as possible.

DR. GAST: We have been blessed to have such a very educated and scientifically trained group here. A lot of good points were made about how we on the academic side need to improve training of our scientists and awareness of these issues. I think that is very much an important part of the picture.

But on the other hand, I have a question probably mostly for Gretchen in the law enforcement field. My concern is with people like domain officers and others who are not as technically educated, how they will be able to start to learn the scientific side and what to be concerned about it, how to figure out where the areas of concern are. Do you have some thoughts on how we can make it a dialogue and help your folks understand our perspective while we try to get our folks to understand yours?

MS. LORENZI: You have definitely identified the other half of the law enforcement-university partnership problem. That is, getting the law enforcement agencies to understand their half of that. Definitely a lot of the historical damage has come from misunderstanding between those two communities.

It is similar to how it has to be done on the academic side. There is a big training element to that. The idea that you are ever going to get your law enforcement officers to have technical proficiency at a real level is unlikely, but you can provide enough awareness that they can start to be able from a law enforcement perspective recognize the signs that at least

tell them, I need to bring in some technical specialists to this type of area.

As far as our coordinators in the field, each year they get ongoing training in how to better do their field coordination efforts. It hasn't been a strong aspect in the past, but it is something we are trying to push, to increase their understanding of what it means to work with the science community, how that community is different than other ones that they work with.

So we are trying to push a training aspect on the law enforcement side as well. It is a process. One of the hard parts of starting this work is, because I am trying to advocate that both sides go at this at the same time, there is this imbalance, where you get the feeling that you could have a scientist reach out to a law enforcement officer who is not ready, then you have got something that creates 20 years of damage. The damage that happens there doesn't just go away. People harbor that for a long time, and it really stays.

So I am very sensitive to that question. It is one of those things about getting the law enforcement -- our coordinators all will undergo training this summer, and

I think I am on all their training schedules, at least getting awareness level talk to them, if not specifics on the best way to do it.

DR. BURNETT: I am going to paraphrase what I think I heard Dr. Linden say. I think everyone else kind of inferred this. I heard that the regulations on guidelines that exist are probably adequate, NSABB notwithstanding. There are regulations coming forward that strengthen the management oversight, and then increased awareness through codes of conduct, training and things. It seems to be what you all are saying is a workable system.

Can you confirm, or is there something else that you would add to that? I don't hear anybody advocating new regulations or big changes in regulations, but if you could expand on that, I would appreciate that.

DR. LINDEN: I'm not sure I said that this was all adequate. What I was trying to convey was a sense that it is not like there is nothing there. There are a large number of rules and regulations and guidelines and community standards that we already need to comply with.

It is just like many other laws that are on the

books on a day to day basis. There is a question of whether it is enforced or not, or whether you obey it or do it.

I think that much exists out there already that would be very helpful in achieving our goals of minimizing the risks of the hostile use of life sciences research. I don't think there is any magic bullet. I don't think there is any one thing that we are ever going to be able to put in place that will eliminate that risk.

I think the guidelines that come out of the NSABB will be additional and will be very helpful. I think if we start looking at the big picture and looking at how we can use all of these things together to minimize the risk, that that will be very helpful to what we are trying to achieve, which is to minimize these risks as best we can without causing damage to our intellectual and academic and civil freedoms.

DR. DIXON: I can comment on that, too. I would say two points. One, we already have two very powerful laws, two different ways. One is a select agent law, the other is -- I have forgotten the number of the statute, the prosecution of individuals who use biological agents for

inappropriate purposes. No amount of prosecution will prevent people from other nations who are not regulated from acquiring the same information that they need to move forward.

I haven't heard people from listening to the NSABB discussions advocate for regulations. I think they would say, we might come upon something that we find might need to be modified. Let's reserve that as an option. But right now, I think the emphasis is on guidance.

Personally, I think we can gain far more advantage in figuring out the how to move forward, and recognizing things that maybe need to be moved forward, the classification, versus how to responsibly communicate those things that haven't crossed the boundary, so the guidance will be extremely effective to lead everyone to a consistent effort in developing that culture of responsibility.

DR. LEE: I will just conclude with the idea that we do have guidance, we do have regulations. Some of the guidance is under development. I think the biggest task ahead for us is training every single scientist in our country to look at these issues and consider these issues.

But we do have a model for that. We have a model where we train scientists. Certainly at CDC we do this annually, but other places do as well, around ethical research, human subjects issues, animal welfare. There are a lot of things that scientists consider every single day in their research, and we have models that we can use to make sure that these regulations and these rules and these considerations get out there to each scientist doing the work.

So I think that that will be our major push once these guidance documents are available to us.

DR. GANSLER: I would like to thank the panel.

DR. GAST: Do we want to take a five-minute break?

DR. GANSLER: If you promise that you won't go out for more than ten minutes.

(Brief recess.)

Agenda Item: Dual Use Life Sciences Research: Regulation or Self-Governance?

DR. COMPANS: I'd like to welcome everyone to the session this afternoon. I am Dick Compans from Emory University. We have two university based speakers who will

be presenting their perspectives on regulation versus self governance of dual use technologies, Elisa Harris from the University of Maryland and Gigi Gronvall from University of Pittsburgh. Elisa will be our first speaker.

DR. HARRIS: Thank you, Richard. I want to begin by thanking the National Academy and the committee for inviting me to appear today. You have already heard a lot this afternoon about the subject of dual use/sciences research.

As has already been discussed, the concerns about work in this area have been spurred largely by two things, first, advances in the life sciences. I think for many of us, the mouse pox experiment which was published in January 2001 was the wakeup call. This was work done by Australian scientists trying to develop a contraceptive for mice. They inserted the IL-4 gene into the mouse pox virus and in the process ended up creating a highly lethal pathogen that killed even mice that had been vaccinated against this particular virus. The reason people were concerned about that was because it raised the question of whether the insertion of the IL-4 gene into other pox viruses like smallpox would have a similar effect, and that would be

highly consequential.

After mouse pox there was a polio virus experiment you may remember, in which scientists at the State University of New York using mail order DNA and genomic information from the Internet created a virus without any pathogenic material. This raised the question of whether other pathogens could be created in this de novo fashion.

Also, and this is important, there has been a lot of database of the select agent regulation this afternoon, this work also raised serious questions about the effectiveness of the existing controls over access to pathogens that are reflected in the select agent regulations. If you could create a virus without pathogenic material, then the select agent regulations become irrelevant.

And of course, there has already been discussion of the influenza research that has been done here in the U.S., the recreation of a virus which killed between 40 and 50 million people at the turn of the last century.

So that is one set of developments, advances in the life sciences themselves that have raised concerns

about dual use life sciences research. You have also heard some discussion today about bioterrorism. In the aftermath of 9/11 and the anthrax letters, there had been a very real concern that terrorists or other subnational actors might use dual use research to cause harm.

So where these two strands have led us is to a number of developments which the previous panelists have already talked about in some detail, the Fink committee report, the Bush biosecurity initiative, in particular the creation of the NSABB, and the increase in bioterrorism and biodefense research here in the United States.

You have already heard some perspectives on those three issues. I am going to give you a different perspective on those issues, and then I am going to turn to some work we have been doing at the University of Maryland on this issue of life sciences research and how to manage the risks.

If I were to try to summarize in a sentence or two what my message is this afternoon, it would be the following. The choice is not between regulation or self governance, as the title of this panel suggests. Neither one on its own is sufficient to be effective. To develop

an effective response, we need to do both. We need self governance and we need regulation.

Let me just quickly touch on the Fink committee report. You have heard a lot about it. I think it is important to underscore what the committee said about the threat. They stated unequivocally that biotechnology research is dual use and could quote, cause disruption or harm potentially on a catastrophic scale.

Now, this is a National Academy of Sciences committee. They are not inclined to use inflated rhetoric when talking about problems. So they clearly took this issue very, very seriously. As others have discussed, they outlined a number of recommendations for beginning to address the problem here in the United States.

I want to be sure that we are all clear on what they said about oversight of dual use research. What they recommended was a prior review process for experiments in these seven areas on the slides, to determine whether the work should be done, and if so under what conditions.

We have already heard a lot about the NSABB. Indeed, this committee has two members of the NSABB that are part of it. I want to emphasize something that has not

been emphasized yet with respect to the NSABB, and that is that it is an advisory body to the U.S. government. It is to provide advice to U.S. agencies on how to reduce the risk that legitimate research will be misused for hostile purposes. Others have listed things from the charter. This is my attempt to compress what the charter says, but the words are really key here. They talk about guidelines, recommendations, strategies, it is all advisory.

A third development which Carol Linden has talked about a bit, and that is the increase bioterrorism and biodefense research effort. I think there are some important data points that we all ought to think about here, looking at NIH funding in particular. We have seen a huge expansion in dollars for bioterrorism and biodefense related research funded by NIH, from $53 million in fiscal year 2001 to over $1.9 billion requested for fiscal year 2007. NIH is funding a 20-fold increase in BL-4 lab space. Those are the laboratories that can handle the most dangerous pathogens. They are funding nine new regional bio containment labs with BL-2 and BL-3 capabilities, and eight new regional centers of excellence for biodefense and emerging infectious disease research. That is a huge

expansion of our laboratory capability for work with dangerous pathogens.

We also are seeing thousands of new researchers taking advantage of these funding opportunities to begin to work with dangerous pathogens. According to a CDC official speaking earlier this week, some 16,000 researchers have now been approved to work with select agents, 16,000 people across the country. That is a staggering number.

Finally, we have the creation underway of a national biodefense analysis and countermeasure center. This is being established at Fort Dietrich, the home of the former U.S. offensive biological weapons program. This center will be doing research, pathogen research, that falls squarely in the areas that the National Academy of Sciences identified as of concern, susceptibility to therapeutics, host range studies, environmental stability, aerosol dynamics, et cetera.

So we have a huge expansion in the amount of money funding this work, the number of facilities, the number of people doing highly consequential pathogens research.

Let me give you that different perspective on all

three of these developments, on the Fink committee report, on the NSABB and on the expansion of bioterrorism research.

None of these things are bad in and of themselves, but we can't rely upon them on their own to deal with the problem we face as far as dual use life sciences research. Neither the Fink committee recommendations nor the NSABB approach on their own will result in adequate oversight, either over the expanded bioterrorism research effort or over the activities of other legitimate researchers whose work could have destructive applications.

Let me give you three reasons why that is the case. First, both the Fink committee and the NSABB approaches do not include key segments of the life sciences research community. The Fink committee called upon the use of the NIH guidelines, and the guidelines only apply to institutions receiving NIH funding for recombinant DNA research. What this means is that the oversight recommended by the Fink committee would not apply to industry researchers or to the government biodefense program. Big gap; only academic researchers getting funding or others getting NIH funded would be covered by

the guidelines.

The NSABB guidelines are expected to go further, in that they would apply to government labs or government funded research, but there is an explicit exemption in the NSABB charter for classified research. There is also no coverage of industry in the NSABB approach.

So gap number one is that neither the Fink committee approach nor the NSABB covers the entire relevant research community.

The second problem involves binding obligations. The NIH guidelines are exactly that, they are guidelines. We can pretend like they are mandatory, but they are not.

I think it is important to just pause for a moment and consider the results of a survey that was done in 2004 of the institutional biosafety committees that are supposed to be implementing the NIH guidelines. This work that was done by the Sunshine Project found that at the time the survey was done, scores of biotechnology companies, including some three dozen doing biodefense research for the government, had no IBC registered with NIH. A number of government labs, including the Army biodefense lab at Fort Dietrich, also had no IBC registered

with NIH, and many of the university and other IBCs that were registered with NIH either had never met, or had issued blanket approval for projects and not undertaken the individual project review that was required.

So I'm not as confident as other people are that we can rely upon the NIH guidelines in a voluntary approach to deal with the very real risks that we face from dual use life sciences research. We think it needs to be mandatory.

Finally, the third and last weakness in the approach o the Fink committee and the NSABB is neither actually directly explicitly addresses the international dimension of the problem. I hope I will be proven wrong with respect to the NSABB, but at the moment there is not a lot that has been done that suggests that a harmonized international approach is going to be coming forward.

Let me now turn to some of the work that we have been doing in a project that I have been co-directing at CISSM at the University of Maryland. In contrast to the ideas developed in these other bodies, we have very consciously tried to develop an approach that is comprehensive, applies to the entire relevant research community, is mandatory, and is global in scope.

That approach has two key elements. The first is licensing of researchers and facilities engaged in relevant research, and the second is peer review of experiments in advance, consistent with the Fink committee recommendation.

Now, licensing in particular has been very controversial in many quarters. Let me just take a moment to talk about the precedents here. There are precedents for national licensing and vetting. The 2002 bioterrorism bill for example requires background checks as has been discussed, and registration of both people and facilities. FDA licenses facilities that produce pharmaceutical products. Outside of biology we can find other examples in which individuals or facilities that are doing things that can affect large numbers of people are licensed. Labs that work with radioactive materials have to be licensed. Doctors have to be licensed. Pilots have to be licensed. All of us have to be licensed to drive a car.

There are also of course as has already been discussed percents for an independent review process. We have the IBCs, the institutional review boards that look at human subject research, animal care committees. All exist at the local level. Nationally as has been mentioned we

have the RAC, and internationally, which some of you may not know, there is oversight by the World Health Organization for smallpox research in the two designated depositories in the U.S. and Russia.

The approach we have developed at our project builds on these precedents and has the following features. First, it is narrowly focused. The areas of research that we believe ought to be subject to oversight excludes most biomedical research and pathogen research and only again focuses on the most consequential areas of dual use research.

Secondly, it can be readily implemented. The areas of research subject to oversight are clearly defined and presented in a form that researchers can understand.

Third, it is responsive to the threat. We have combined both the pathogen based controls that have been enacted by the United States and the United Kingdom and other countries with the activity based approach that the Fink committee reflected in its seven experiments of concern. We think therefore that our approach is more dynamic as well as more responsive to the threat.

Finally, it has a tiered design. The level of

oversight of particular research activities is linked to the level of risk posed by that work. Local level review bodies are responsible for the vast bulk of the research oversight.

I am going to skip through these slides very quickly. As I mentioned, we have a notion of a tiered design. At the top would be a global implementing body to oversee the most dangerous research as the World Health Organization currently does with smallpox research. After much work with many scientists we have suggested some areas of research that we think ought to be subject to international oversight. We have a national review body that would approve research of moderate concern, and we have a local review body that would oversee research of potential concern.

Our approach covers all these seven areas that have been identified by the Fink committee, but it does so in a much more detailed way.

Let me just say a few words about how this oversight system would work in practice. Any researcher that was interested in doing work that fell within one of those three areas covered by the system would be required

to complete a project questionnaire and submit it to its approval body, review body, for approval. Then that review body would conduct a risk-benefit analysis based on criteria like those listed on this slide.

I should just mention that these risk-benefit assessment criteria came out of a peer review simulation we had in January of 2005, in which we asked five researchers to submit hypothetical projects for peer review. One was a U.S. government scientist, one was a European scientist, the other three were American scientists at different points in their career.

We didn't really set out to try and develop risk-benefit assessment criteria, but we discovered over the course of the day that the same questions and the same issues were coming up again and again. From that, we assembled this proposed list of criteria for assessing the potential benefits as well as the potential risks of proposed projects.

In addition to working on risk-benefit assessment criteria, we have also given some thought to the question of how to handle potentially sensitive information that would result from dual use research, including from

biodefense research. We had a meeting in April of last year in which we brought together scientists from the former U.S. offensive biological weapons program and from the defensive biological weapons program of the U.S. and the U.K. and a few Canadians, and we talked about this issue. I think there was general agreement among the participants that there might be circumstances in which research results needed to be restricted in terms of their dissemination. But there was also agreement that we should do this as infrequently, as rarely, as possible, because of the obvious benefits of sharing information and research.

So what came out of that deliberation was a suggestion that we not reinvent the wheel here, but rather that we draw on criteria that had already been developed by another National Academy of Sciences committee in 1982, that looked at the question of scientific communication and national security. This was the Corson panel. So what we are proposing is an adaptation of the Corson panel's criteria for determining whether and under what circumstances research results might need to be restricted. Those criteria are listed on this slide.

I am happy to talk about any of these things in

more detail.

DR. GANSLER: Is there anything excluded from that second bullet?

DR. HARRIS: Direct military application? There are many things that wouldn't be covered by that.

DR. GANSLER: Or just dual use.

DR. HARRIS: And involves production related technologies. I think it was our sense that that wouldn't cover the entire universe, that that would actually be a pretty defined set of things.

So what would it mean if we actually were to implement a system along the lines of what I have just described? What would be the impact here in the United States to start with? We had that question.

So we commissioned a survey of journal articles published in the United States from 2000 through mid-2005. What we were interested in seeing was if our proposed oversight system were in place, how much of the biotechnology research enterprise here would be affected? We realize that looking at publications is an imperfect measure, but we nevertheless think that the results of this survey are pretty interesting.

What it showed is that less than one percent of U.S. publications involving bacteria, viruses or prions would fall within our system. Overall, slightly over 300 facilities and 2500 researchers were engaged in work, again as reflected in the publication of their results, were engaged in work that would have been subject to oversight under our system. And of these, 53 facilities and 137 researchers would have fallen under jurisdiction at more than one level.

Again, this is an imperfect measure of the impact of an oversight system, but we think it does provide some insight and suggests that our approach would impinge upon only a very narrow swatch of biotechnology research in the U.S., and the impact in other countries would likely be even more limited.

Let me just say a few things in conclusion here. I think that the need to enhance oversight in a meaningful way over dual use life sciences research is greater today than before September 11, before the anthrax letters, but not for the reasons that you might suspect. Personally, I am much less concerned about deliberate misuse of advanced life sciences research by sub-national actors, by

terrorists. I think that work by traditional biological warfare agents is already technically and operationally challenging enough for these particular actors.

The greater threat that we face is the one of inadvertent consequences, one, because of the pace of scientific developments that I talked about as the beginning, as exemplified by mouse pox, polio virus, reconstruction of the 1918 influenza virus, and because of the great increase in work with dangerous pathogens in the biodefense and bioterrorism research programs that have been pursued since 2001.

Some of the self governance ideas suggested by the Fink committee and the NSABB, which the NSABB has been asked to look at, codes of conduct, education and training programs, can absolutely help sensitize science to the risks from dual use research. These ideas for self governance do have value, and they must be part of our approach. They are useful first steps, but they are not enough.

Senator Hart has repeatedly asked throughout the day today for specific suggestions of what to do, so I am going to give you some very specific suggestions that build

on the existing processes that we have talked about, that build on the NIH guidelines, that build on the institution biosafety committees in the following way.

First, add dual use experiments to the NIH guidelines. This can be done. You can use the Fink committee's seven experiments of concern. We have our list of dual use research that we believe ought to be subject to oversight, which as I said is very consistent with the Fink committee approach, but more detailed. Whatever the list of experiments, they should be added to the NIH guidelines. That is point number one.

Point number two. Make the NIH guidelines apply comprehensively to everyone doing consequential research, whether it is an academic laboratory, a government laboratory or an industry lab. It is not sufficient in the world that we live in today to focus only on institutions that are receiving NIH funding for recombinant DNA research. There is a huge gap that needs to be filled.

Third, make NIH guidelines mandatory. This is perhaps the most controversial thing that I am going to say here, apart from the licensing issue. Let me remind everyone that the requirements for oversight of experiments

involving human subjects, a single person, are legally based. The IRB requirements are legally based. We are suggesting that research that could affect potentially a much larger number of people, a much broader swatch of our society, also should be legally based. That will help insure that the financial and the human resources that are needed to make the system work properly are forthcoming.

Finally, we need to begin to work to develop a harmonized international approach. As the Fink committee itself said, if we focus only on the United States, we will not have addressed this problem. The first experiment that called our attention to the dual use problem was in Australia. Work with great consequences is happening in labs throughout the world.

We ultimately need a harmonized international approach. One way perhaps of doing that is by building upon the work that the World Health Organization has done to develop biosafety guidelines and have them work to develop biosecurity guidelines for dual use research for adoption by member states. That is one possible avenue to pursue this, but however we do it, we need to be approaching this in an international way. We need to get

internationally compatible common approaches and standards.

Thank you.

I should just mention that we have a lot of publications outlining our ideas, including a very detailed monograph that is on our website. The cover page from that is 100-plus pages, so I couldn't bring copies. We hope that you will download it, read it, e-mail us, give us comments, criticize it.

Thank you.

DR. COMPANS: We have time for one or two burning questions. Otherwise we have ample time at the end.

DR. GANSLER: You flipped through that one chart you had on the global organization. Could you amplify a little bit about what you are specifically recommending in terms of what organizations it would take the lead on and how you would get it set up?

I think most of us agree that particularly in this area it is going to require international cooperation and agreements. Who takes the lead, and how does that get done?

DR. HARRIS: There is no body that exists today that can do this. The World Health Organization could take

on part of this mission, but it would require real resources, a clear mandate from member states. We don't see that happening in the near term. This is an ultimate vision of how we would suggest one approach it.

But in the nearer term, one could imagine the World Health Organization developing as I said guidelines for oversight, for national implementation, that would address a large part of the problem. There is very little research at least in our approach that would be subject to oversight at the global level.

You have a body now within the World Health Organization that oversees smallpox research. It could be given some of this additional responsibility, but it would require more resources and more support from member states to do that job.

DR. COMPANS: Thank you. Gigi?

DR. GRONVALL: Thank you. Thank you very much for giving me the opportunity to speak today.

Just as a way of background, I come from the University of Pittsburgh, sort of. I actually come from the Center for Biosecurity, which is an independent section of the University of Pittsburgh Medical Center, which is

located in Baltimore. Our genesis came from Johns Hopkins. We used to be the Johns Hopkins Center for Civilian Biodefense Strategies, and when we left Johns Hopkins we moved across the street. So we really have not moved to Pittsburgh, but we are at the Center for Biosecurity of the UPMC.

We are a collection of people from a variety of different professions. My own background is in laboratory science. My Ph.D is in immunology. I work with physicians and medical anthropologists and public health experts as well.

I disagree with Elisa on a couple of issues, but one of the major ones is that the power of science and what it is possible to do with technically challenging or not challenging a biological weapons is. I think it is much less challenging than Elisa suggests. The growing power of biological science will increase the destructive potential of a biological attack or a laboratory accident. I think that is a problem for legitimate science and legitimate scientists.

I think that a thinking enemy can outdo what nature has come up with by genetically manipulating things

that have not been in contact with each other before. New pathogens can be created, antibiotic resistance can be generated faster and more easily than just waiting for natural selection to take its course. And of course, dissemination is a lot easier or can be more deadly with a thinking enemy versus a natural case.

It is considerably easier to create a natural pathogen than to create new countermeasures. In the very simplest of cases, antibiotic resistance, an antibiotic can according to some studies take eight to ten years to create and $800 million. I think most microbiologists, most scientists, can create an antibiotic resistant strain of most pathogens or most bacterial pathogens in a couple of days. So I think the problem is very great.

The real problem is that biology is not yet powerful enough. As powerful as these techniques are, we are not able to take this situation, a new disease, and go to a new vaccine or a therapy as quickly as we would like. That really is the challenge for science, to be able to get to that point in a reasonable amount of time that you can save lives. That is the goal of all legitimate scientists, to get to that point.

How do you deal with the dual use problem? A web of approaches are clearly needed to do what is possible to constrain the development, the misuse of biological science for harm. But we have to be prepared for its use.

Some people have approached this problem by wanting to put a command and control structure onto biological science similar to other technologies that have been controlled. However, this is inappropriate for biological science.

I don't think so many people have discussed this today, but it is worth repeating the differences between biology and other technologies. Biologists need to know what is allowed, what is not allowed, and any discussion of dual use issues is much more grave than that. Dangerous research just from the length of time that the NSABB has spent trying to define dual use research is indicative of how difficult it is to be able to clearly say what it is to other scientists.

Dual use research is ambiguous, it is large scale. It is not just a handful of papers. It is practiced all over the world. It will evolve with the pace of science. It is contextual. By that, I mean the mouse

pox example that Elisa just spoke of, but interleukin-4 put into some mouse pox in that particular spot caused that virus to become much more deadly. Interleukin-4 in a different virus might make a good vaccine. So the same thing in a different situation will cause different results, so it is not as easy to put into boxes.

And of course, a lot of the work is meant to be and is ultimately beneficial as well, as it gives us understanding of biological systems and hopefully gives us increased power to be able to create therapies and vaccines in the future.

Biology is extremely global. I was just talking before, I was just visiting Singapore a few weeks ago, and their beautiful laboratories and extremely dedicated scientists that are so energetic and so interested in pursuing biology. It is very diverse. There is no one scientific community. We keep talking about things that the scientific community should do. I never really referred to the scientific community until I, according to many of my scientific friends that are still at the bench, left it. It is really a bunch of groups of people who are all working very hard in their own corners of the field.

Because of the constantly evolving nature of biological science, to say that one thing is incorrect or one thing can't be done may be putting too much effort on one thing, and there are many different scientific ways to get around doing it. So it risks being irrelevant.

I would maintain that the pace of research requires that scientists have an idea of what could potentially be dangerous and what could potentially be misused, and to have an awareness of that as they are doing the research, so they are aware of when their work could be misused. So regardless of how this structure of scientists is organized, there must be an element of self governance. Whether or not you think scientists have a moral obligation to participate in making sure that their research is not misused, they are certainly in the best position to understand the potential for misuse. They will be, if there is a natural epidemic or a biological attack, the key people who will have to be working on doing something about it, and there is a longstanding ethics framework within science and what is good science. Really, I think the challenge is to put security into that.

But I don't think awareness is really good

enough. I think it would be great if scientists were aware that their work could be misused. I don't know if that is really going to carry you through. There needs to be some thought on how that should influence biodefense strategy and biodefense funding, because prevention will only take you as far as when it doesn't work anymore. Then you are going to need to have scientists that are working on countermeasures.

One of the ways that we have -- at the center we have had a few meetings, we have brought people together, scientists, national security experts, to discuss specific papers that are dual use and what they would do with this information, and how they would react to it, and whether or not they would control the information.

When you look at real examples of dual use research, it is very hard to know what can be done about it, except to maybe think a little bit more about how you would coordinate a biodefense strategy.

I'll give one example. We have a whole bunch of these if you would like to know a lot more dual use examples, but this one is five years old, but it is still a good one. It is a paper about a powdered measles vaccine.

Now, measles causes disease still, maybe not so often in the United States anymore, thank goodness, but it is still a worldwide problem.

One of the problems with measles vaccine is that it is a live vaccine, it is a live virus. One of the problems with this live virus vaccine is that it has to be kept in cold storage. Or even if it is powdered you have to add some liquid to it and then once you add the liquid to be able to give it to somebody, then it will go bad and you will need to get a new bottle.

So the idea behind this paper was to come up with a powdered vaccine so people could inhale powder and be vaccinated with this live virus, so you wouldn't have the problems of refrigeration and you wouldn't have the problems of waste.

So this paper was published by a biotech company. It was funded in part by the World Health Organization, and their intent was to keep things open, so they were extremely detailed in what kinds of equipment they would use, what kinds of filters, much more detail than typically method sections tend to be in the biological sciences.

People talk about how maybe we should be strict in methods

sections, and some people would argue that they are already pretty restricted, so that it is very difficult to actually reproduce an experiment from the method section.

But this is extremely detailed, the whole paper. The details were seen to be necessary for the public health aim of the paper. So this has clear dual use potential because it is a live virus that was put into a powder, and that could be any live virus, and you would only have to make a few modifications.

When we put this to our panel of people who have thought about this issue a lot, we couldn't get agreement, although most people thought it was a good thing that this was out in the world, because many people dying of measles was seen as a severe public health threat for which this was supposed to address. But nonetheless, there was disagreement.

I don't know if you are going to get so many clear-cut answers in an institutional biosafety committee or whatever organization within a university that is tasked to handle these problems. It is much easier to think about the dual use problem if you think about, this person made this virus so it infects all kinds of animals, not just

guinea pigs, and it has no public health benefit whatsoever, we will classify it. When you look at most examples of dual use research, they have lots of shades of gray that are not going to be -- and this is going to come up down the road.

So in the end, I would recommend that we have to accept some level of risk from dual use research. Scientists need to recognize that their work could be misused, and there need to be mechanisms to make sure that they do the work safely and smartly. But on the other hand, and this is more addressing a code of conduct discussion, but I don't think that scientists can promise to do no harm. They can promise to intend to do no harm, but what they uncover is very often by serendipity and there should be some mechanism to deal with the consequences of an experiment, as well as just the intent.

When you look at some of the criteria that people will ask themselves if their proposed experiment could come up with, whether it might do this or might do that, that doesn't really work so well with a lot of biological research. When I was working in the laboratory, I was hoping that every day was going to be the day that I was

going to cure cancer, but that did not actually happen any of the times that I was going into the laboratory. So I think it is important to also deal with what the reality is in the laboratory.

So what is at stake if we don't accept some of this risk and push forward? We will harm research that needs to be done in a time of crisis. Which brings me to the scientific response to SARS. Three years ago SARS was causing an epidemic. It caused 800 deaths, it had huge economic impacts, and it was eventually stamped out through public health measures. It was not stamped out with a vaccine. If it appeared today, three years ago, we would still not have a vaccine. There would be no drugs. There wouldn't even be validated clinical models with which to approach SARS, because a lot of the research was not done in a way that was translated between institutions.

So there were problems in the response, and there is a problem with our response to these diseases in general. We have to get better at being able to counter these new threats, whether they come from nature or from a deliberate attack.

In conclusion, I would recommend three things,

that we promote self governance and we promote self awareness as scientists as best we can to make sure that work is done safety and is done as fast as possible in the public interest; that the information that is uncovered that is dual use be used to inform strategy. For example, the mouse pox experiment demonstrated that perhaps a vaccine could be evaded. This was something that bioengineers in the Soviet Union had carefully considered long before, but this was big news for the legitimate scientists who thought that they were done with smallpox, and maybe we need to rethink some other strategies to be able to deal with smallpox.

Third, we need to get better at response in general, because eventually prevention efforts are going to fail for a deliberate attack, and it is certain, certain, certain that we are going to have another natural epidemic of a new disease that we don't know how to deal with.

Thank you very much.

DR. COMPANS: I would like to open up the floor for discussion and perhaps comments first from the panel.

DR. GANSLER: Something that has been bothering me as we have been going through the day is the database of

risk-benefit analysis of each of the speakers, but the emphasis has all been on the risk side. The issue of how to do the benefit side, obviously each of these dual use examples that have been used are going to have some risk associated with them, whether it is one percent or .01 percent or ten percent. The benefit side might be solving cancer, as an extreme example obviously.

It has not been clear, and I would be interested in the panel's discussion about how they are approaching the benefit side to balance out the risk side in the solutions that you have each given.

DR. HARRIS: The slide that I showed that included the risk-benefit assessment issue only had a subset of the details that we have developed in this area, but we very consciously are looking both at potential risks and potential benefits, for example, whether the research will advance our understanding of the disease causing properties of existing biological agent threats.

So the longer version of our risk-benefit assessment criteria is in our monograph. There are many questions that as part of the peer review process the review body would ask the researcher to try and get a

detailed understanding of the potential benefits as well as a detailed understanding of potential risks.

We absolutely agree, one can't look just at risks. You have got to balance those risks against what you may get in terms of public health, in terms of biodefense, et cetera.

DR. GRONVALL: I don't know how to quite answer. Most things that would be published usually have some benefit to either advance science, is considered novel, it is demonstrating a point or proof of concept that is considered valuable. You go up the chain of journals, and eventually when you get to the top it is a lot more flash. But it already is going through a review of whether it is good science.

So I think if it is good science, it is hard to think of too many examples that are good science and yet are of no value.

DR. COMPANS: I think a good example of high benefits is the powdered measles vaccine that you mentioned in your slide. Half a million children die each year from measles, despite the presence of an effective vaccine. But it can't be delivered effectively in less developed

countries, so there is a very high benefit in that particular instance.

DR. GANSLER: But the people that are reviewing it may be risk minimizers, as was pointed out with the response. The first person said, this is a risk, which it is. What I was trying to get at is, yes, you can list some benefits and yes, you can list some risks. Are we risk minimizers or benefits maximizers? Are we making those trades?

I had the same concern when I heard the government perspectives, which struck me as being much more in the risk minimization side. That is why I was trying to raise it. I think one can easily list benefits. Clearly the measles case is an example of that. One can also list risks. Then the question of, if we put a regulatory body in it, that is going to be a really tough thing then, because there will be risks present even if the benefits are significant.

DR. HARRIS: We are doing this when it comes to human subject research. There is a requirement for an institutional review board to weigh in a very specific way benefits and risks, and there are specific questions even

in the regulations, and issues areas, that that body has to consciously consider.

What we are suggesting is, we ought to be doing the same thing for biosecurity risks. This will put a high premium not only on the development of the right questions and the right issue areas, but also the composition of the review bodies. You need an interdisciplinary group that includes scientists and security experts and ethicists and, dare I say, lawyers. You need to bring all these different communities into that process.

Today, what we do is, we have a process that assesses biosafety risks, but doesn't look at security risks.

PARTICIPANT: The NSABB does have legal representation, ethical representation for that very purpose. I believe there are tools that could be developed with the risk-benefit analyses just as were being described that would be effected at the local level by some appropriately constituted body.

So I don't know that you differ from what I have heard discussed thus far at the open sessions of NSABB in that regard. I do understand your point that this has the

limitation of the effect of federal funding. What I have heard as a counter to that is that industry is exempt from the RAC, yet I think there are numerous examples, if not the majority, of the industrial sector that have adopted this, having the effect of being mandatory. That is what they require in their programs. It might be useful to get an official NSABB consult on that, since I am just a messenger here.

Along with that, I would like to follow up with a couple of comments for Elisa. I think your first recommendation about adding dual use research to the NIH guidelines, how do you see that that differs from the NSABB guidance that would come out that is specifically tasked to dual use?

DR. HARRIS: I think we are talking about the same thing here, that it needs to be added to the guidelines. But if we leave the guidelines as they are now, let's not minimize the point about comprehensive application and mandatory compliance.

We don't have a system that applies comprehensively across the relevant research community, and that is a very significant gap. We don't have a system

that is mandatory. You may think that industry is complying with the NIH guidelines, but I am aware of no empirical evidence that that is the case. There is anecdotal information.

The only survey that we have that tells us anything about the extent of compliance with the NIH guidelines in fact raises very serious questions, not only about industry compliance with the guidelines, but also about academic institutions and government labs. If there is a survey that NIH has done, which would be wonderful, that can give us more empirical evidence about this, then we obviously all need to see that.

PARTICIPANT: I can certainly take that recommendation back to my colleagues at OBA. But I haven't seen such a review, so I can't comment on that.

A point on the periphery. I may be taking out of context one of your earlier statements, but I think it was dealing with creation of select agents without pathogenic material in hand using gene synthesis or some other such method. It would be that the select agent regulation would be irrelevant. Once such an entity is created, it is still within the purview of the select agent rule. That

individual would be in violation of the law, because they would then be in possession of that material.

So I think that it is no more vulnerable there than we are vulnerable for someone going to an endemic site and naturally isolating a naturally occurring agent. The regulation doesn't prevent someone from acquiring it by that means.

DR. HARRIS: I think you just put your finger on another reason why there is limited utility to the select agent rules, because there are now multiple ways of circumventing those rules in terms of getting access to it.

PARTICIPANT: But I can't think of a good way of preventing someone from going to the San Joaquin Valley and grabbing sand and culturing coccidioides ematus to it. I just can't think of a good way to regulate that possibility.

DR. HARRIS: That is why we need to look not only at who has access to pathogens, but what they are doing with them. That is why we are proposing the things that we are here today.

DR. LEE: A couple of comments. One about this risk-benefit ratio. One is the assumption that we all have

that public health scientists are doing work because it is valuable and good and for improvement of health. So I don't think that we would get too far off the ground with research that wasn't inherently good, so there has got to be some benefit or it wouldn't get very far.

The other thing is, we can't always recognize when we have a finding because science is an iterative process. This is the whole reason you do peer review and you have a body of literature; you never know what is going to tip off the next brilliant scientist to figure out from your seed what came to be the cure for something horrible.

Then the risk side of that, one of the things we are struggling with in terms of this risk-benefit ratio is that it is not just about what is the risk of this particular paper or this particular product. It is about how does that fit in the context of what is already out there; is this particular bit of information going to tip the scale, and all of a sudden someone is going to be able to do something terrible because they have this one last piece, or is this a piece that is going to be helpful, but other pieces just like it are already out there and this isn't going to add to -- by itself it might be risky, but

it isn't going to add to the risk that is already out there.

So there are a lot of things to consider in terms of the context of risk.

Then I have a question actually for Elisa about the proposal that you put forth. What are your thoughts about how other forms of doing this research would be managed in this system, things that aren't biologic, things like chemical modeling, nanotechnology? How would that fit into what you have presented?

DR. HARRIS: That is a really good question. We spend a lot of time in our project talking about beyond pathogens. We recognize that there are other, as you say, dual use risks. But it strikes us -- struck the Fink committee -- that the most immediate risk really is from life sciences research. There are clearly identifiable things we can do now to begin to address that.

The process that we are suggesting is one that ought to be able to be adapted to new threats as they evolve, starting with pathogens, but adapting it over time as the threat environment changes. I think that is one of the real values. It is not just saying these experiments

that should be subject to independent peer review using risk-benefit assessment criteria, but you have a process that can then be built upon to address other threats.

The Fink committee said much the same thing. They said their seven experiments of concern were a starting point. They recognized that the things we would be concerned about a decade from now were likely to be rather different than today. The process itself ought to be able to be adapted to reflect those changes in science and technology.

Let me just make one other point that might not have been clear from my presentation, but I want to emphasize. We are not talking about prohibiting dual use research. On the contrary, what we are proposing is that we put in place a system that allows it to proceed in a safer way, in an environment in which the potential risks have been identified to the extent possible in advance, and having people that aren't themselves intimately invested in that work is important to have that independent assessment, and in which the risk is mitigated.

In our peer review simulation, what was interesting was that in the dialogue between the PIs and

the reviewers, in every case there emerged suggestions for slight tweaks to the projects to mitigate risks, but allow the work to proceed. That is exactly what we envision happening in this sort of system.

I imagine that is what the NSABB envisions, and the Fink committee, including us. We are not talking about prohibiting research. We are trying to create an environment in which the risks of misuse are minimized.

DR. LEE: I agree with that, and I think that is the general flavor. I guess my comment about the model is, there are other very real risks, things like research into personal protective equipment, what protects people, building safety, those kinds of things that are real right now.

I guess my point was just that with the numbers you showed about who would be affected by a body like this, the proportions are quite small, et cetera, less than one percent of research. If we add in all those other things, that is going to be gigantic.

So we can make that percent very small if we restrict enough about what we are talking about, but we do have all these other areas that would increase the effect,

not that that is a bad thing. I am just stating that if we consider other kinds of research, the reach of a proposal like this would be much greater. That was my point.

DR. TILDEN: My name is Sam Tilden. I am from the University of Alabama-Birmingham. My question was, the dissemination of the information, you talk a lot about the self regulation and governance. Have you given any thought to what role publications might play in this process as well? And do they have any responsibility in addition or integral to this process?

DR. GRONVALL: Actually, before the Fink committee came out there was a National Academy -- sponsored by the National Academy, right?

DR. HARRIS: Jointly with the CSIS.

DR. GRONVALL: -- meeting of journal editors, and they came up with some guidelines on how they would review their journals. We also have a review for our journal of biosecurity and bioterrorism.

ASM, the American Society for Microbiology, they have -- I think they said they had two papers that warranted extra consideration and review in the last several years. So one wonders how narrow or how great

one's definition of dual use is, depending on your seat. But there is a review that a lot of journals, including Science and Nature, General Virology, et cetera, have agreed to.

DR. HARRIS: Can I just add to that? In our dialogue with scientists -- and I should say, our project has involved predominantly scientists, many of whom came into the exercise very skeptical, but in our deliberations and in all the interactions we have had with other scientific groups, it has become clear that scientists don't want to be told at the publication stage, you can't publish this, or we need to place some restrictions on this work. They want to know as early as possible.

So part of what we are suggesting is that as part of the risk-benefit assessment process, as part of the review process, potential dissemination restrictions be considered up front at the beginning, before the work is done. We think that is really important. If you wait until a journal article has been submitted to a journal, it is too late. Those scientists have already been to meetings, they have done posters, they have published abstracts, they have talked to their colleagues, the

information is out.

So relying upon the publication stage is too late. It is not what scientists as we understand it want.

I am a little less confident that the publisher statement that Gigi referred to is really a very effective mechanism. What the publishers agreed to do was to not publish information that would be damaging to the national security. But there were no guidelines developed by the publishers for determining when that might be the case. There were no criteria that were agreed for use by all these different scientific publishers in assessing manuscripts.

So there is a statement that they won't do harm, in effect, but there was nothing developed and nothing since then to guide the review of those manuscripts. That is probably the reason why so few have even been flagged, and none as I understand it, at least as far as the ASM journals, no journal article has been denied publication because of security concerns.

DR. GRONVALL: Although from what I understand, a couple of sentences have been removed that were not considered germane to the actual article or the scientific

point of the article.

DR. IMPERIALE: If the concern is about something inadvertent coming out of the research, I don't see how you can anticipate how the information is going to be disseminated. So in other words, if you are going into this thinking that it is going to be a fertility drug, I don't see how you can decide up front, if it turns out to be a way to evade the smallpox vaccine, this is how we are going to approach publication.

So I'm not sure that part of your system works that well.

DR. HARRIS: I think our sense is that if you have a true independent peer review process in which there really is a serious consideration of potential benefits and potential risks, the latter, the risks, many of them will be identified. There may be changes made to the research protocol as a consequence, and therefore, the concerns about the work at its subsequent publication may no longer be an issue, because you have addressed it up front at the beginning of the process.

DR. IMPERIALE: I guess what I'm saying is, with that mouse pox experiment, no one would have anticipated

that outcome. So you would have never addressed that up front. So I think there has to be a way to deal with publication. I don't think you can always deal with the publication issue up front. I think that is something that has to occur later on when you know the result.

DR. GRONVALL: That raises a very interesting quality. With the mouse pox experiment, a few months after that a group in the same research facility on the same floor, but down the hall, published a paper basically saying it could have been predicted, and these are stupid colleagues that didn't work anything out there, either.

It brings a couple of points up. One is, the researchers that did the work, they clearly did not anticipate that result, whether or not they should have. Two, the incremental nature of the work was such that you could look at the pieces of it and say they should have known because IL-4 in this situation did this, and they could have done this. So it is really hard to know exactly what about that paper is so damaging, and is it really new, is it really novel. I can't think of a dual use example that doesn't have all that gray.

DR. LEE: I just wanted to make a comment about

your comment, Elisa, about moving this to the project stage, to the protocol stage, and not waiting until publication.

Part of what we are struggling with is, if we know this research needs to be done because we the good guys need this information but it is not publishable because it is too dangerous, how do we get scientists to get excited to work on those things when we say you can't advance your career and you can't publish, but please do this very good work for us. This is something we have struggled with.

DR. HARRIS: We are doing that now. There is $1.9 billion in NIAID funding. I don't know whether Carol gave us actual numbers for DoD or for DHS. It is very hard to track these numbers. But there is a huge amount of money available to researchers. As the 16,000 people registered to work with select agents demonstrates, there is no shortage of people interested in doing this work.

Let me just say though, on the issue of dissemination restrictions, trying to respond more clearly to Jack's question earlier, you asked about the second criteria in our list of criteria that ought to be

considered in deciding whether there needed to be some sort of restriction based on research.

All these criteria fit together. Something has to meet all of them, not just one of them. That is why I was trying to suggest that we think the number of projects that would fall under all of these would be fairly limited. So we recognize that there may be situations in which even after a very thoughtful and careful peer review process, you have research results that need to be withheld.

We ought to have clear criteria for determining when that should be the case, and we should think creatively about different mechanisms for restricting the release of research results. The choice isn't just between classification and publication. In industry, as others have heard me say, scientists do research and they don't publish that research until they get a patent. Once they have a patent, they publish. So there is a delayed publication option. We ought to think about that in the dual use area as well, obviously for national security reasons as opposed to commercial reasons.

DR. COMPANS: So if someone were not able to publish something, would they be able to use it in the

competitive renewal application as a progress report?

DR. HARRIS: Sure, that is another area where we would have to think more creatively about how to make it possible for people to continue to get grants. It is a different world today, and we need to think about different approaches that enable us to protect, I still agree, that narrow subset of things around which we need to build some high fences.

But withholding that information need not be an indefinite thing. Once you have developed a countermeasure, for example, then there isn't any reason to continue to refrain from allowing the publication of those research results.

DR. IMPERIALE: I think you need to check your numbers on how many people are registered to use select agents. My understanding is, it is 300 and something. When you think about it, I'm not sure there are 16,000 members of ASM. So it would be one out of every three members of ASM.

DR. HARRIS: I'll give you my source on this. Mark Hemphill from CDC at a meeting last Wednesday and Thursday in Washington said that there were 16,000 people

registered. Previously the number was 11,000. That was already a lot, but he updated that number to 16,000.

DR. DIXON: A facility has to register, but there are individuals with access, so we are mixing apples and oranges there.

If I could just pick up on the comment about publication, we have heard many agree that when you get to the point of publishing a paper, it is too late to have thought through the issues. Most of the time, there will be those examples that Michael pointed out, where it was an unforeseen consequence that one couldn't have thought about.

That is why I think the tools that we are seeing in draft form from NSABB are interchangeable, they are interdependent. The criteria that people go through in determining whether research will go forward or not are totally divorced from those criteria that you look at for how to communicate them.

In the graduate arena, I was given the adage of, you see the experiment once, you do it once, then you teach it. I think we are now at risk of trying to teach something when we haven't seen the curriculum, when we are

trying to develop the curriculum.

I come back to the RAC. We look at the guidance, we look at the tiers, it all makes good sense. But I was in graduate school when the Silimar was taking place, and I know the concern and the confusion in the community at that point, not dissimilar to what we are looking at right now. I am convinced we will get there. I am convinced we will have some tense moments as we work through it. But I am fully convinced that the scientific community will finally come together on what gives us that curriculum, that is, what are the work tools that we all can look to, and then they would be built into the curriculum and the fabric of science across the U.S. and adopted throughout the world, where we have the work tools, and here are the curricula that your experiments will have to go through before you propose them, here are the criteria people will look at on responsible reporting of them.

That will be part of the training as we go forward, and we won't be caught in those moments, how are we going to communicate this, we should have thought about this before we started the work. That won't occur as often.

I have seen in a number of the background documents that have been published on how the rest of the world is anxiously watching the U.S. They are often applauding the approach that the U.S. is taking in not having censored or limited the flow of information. I know that while we don't regulate the rest of the world, we will set an example that others will watch. There are a number of publications that are looking at that as we show the way forward.

The NSABB also has the international working group. I think that their approach is to be good emissaries of, here is how we are approaching this, how does this work with you and how are you doing this in your country, so the dialogue can evolve. So it is a grass roots effort rather than a top-down kind of approach. But I think your points about, think of it before you bring it to submission for publication is part of that discussion.

DR. KRAEMER: It seems like people are dealing with, either you publish it or you don't publish it. Is there any happy middle ground? Is anybody talking about some sort of scientific escrow or something along those lines, that you could limit access until you have a

security assessment done or something like that? That still allows for publication without much information that allows the academic to get credit for that, get their competitive renewals and get the publications that are necessary, but limits the access to the information.

DR. GRONVALL: Who would have access? I think it would be great to have some alternative, but who would have access to it? If the information has public health value, how can you ethically withhold it? If it could advance science in some other way, how practical would that be?

If it is valuable research it is valuable research. I just don't know what -- I would like to see what category of research you could put into that. If you were going to wait for a countermeasure as was discussed earlier, that could be eight to ten years in the future.

DR. KRAEMER: So let's talk about the publication of the 1983 virus. That was a big controversy, and it was published in its entirety. If there were concerns about something similar to that, maybe not publish the sequence in entirety, but publish parts of the information sufficient to say, we have done it, it is now being held by some government agency. If you require this information,

please apply to have access.

That way it would be for people who have legitimate reason to have access to that information for scientific purposes to have access, but you get the credit and you get the information out there. That is absolutely critical information when it comes to immunology, for instance, but now there is this other thing about, we shouldn't have published it at all. Well, that seems like we can't have it both ways.

DR. GRONVALL: But that was done in Australia. That was actually considered by the Australian government and they decided it was okay to publish it. The 1918 flu virus, there wasn't so much of an outcry about that as I was expecting about the dual use issues. I was expecting more press coverage of the danger than I saw, I think because many people realized that that research did shed light on a current situation with avian flu and how viruses go from being a seasonable problem to going pandemic. I think that it is so contextual.

There was another experiment. When WHO and people at CDC were trying to mix up H5N1 and see if they could create a pandemic strain, if it was likely to go

pandemic, just for purposes to see if this was likely to happen naturally. You could think of some very good reasons for why you would do it. The result has big consequences and would have to be disseminated in order to fuel a research program to defeat your conclusion.

So it is really hard to say that people shouldn't benefit from the scientific details, because the scientific population is global.

DR. HARRIS: There is a precedent for what you are describing, a sort of limited access approach. That was the approach taken by the National Academy of Sciences a few years back in response to concerns by the U.S. government over a study that had been done on agricultural bioterrorism.

The Academy as I understand it was set to publish this report. Some parts of the government had concerns about some of the information in the report, and in the end, one annex was removed from the publicly available document, and researchers, individuals interested in having access to that information had to apply to the Academy and make a case as to why they had a need to know, why they should be given this information.

So there are various possibilities for how to handle sensitive information. It is unlikely that the entirety of a manuscript is going to be sensitive, but maybe some part of it, the sensitive part, as was done in this case, could be withheld and made available on a need to know access to legitimate researchers. One way of determining who should get access is through a licensing process in which people have undertaken certain obligations, have agreed to follow certain requirements, and have determined to be following those requirements, and therefore can appropriately be given access to information.

DR. COMPANS: One last comment, Michael.

DR. IMPERIALE: I think as Dennis pointed out, the tool that NSABB is working on for publication is not black or white. You may remember the one slide he showed with all the checkmarks. As soon as you start withholding information, or saying only certain people can have access, you run the risk that someone who might otherwise have access might come up with something important.

So for example, in that 1918 flu paper there is this issue about whether or not you need trypsin to cleave the glycoprotein. A colleague of mine in Michigan saw

that, he works on proteases, and he was able to come up with some interesting ideas on how one might be able to then deal with that.

Now, if that key point were left out of the paper, that this is one of the key determinants of pathogenicity of that virus, someone like my colleague would never even have the chance to be thinking about ways to come up with countermeasures.

So it is a very tricky line to walk, to start withholding information selectively, because you never know which piece of information is the critical piece that is going lead to advances as opposed to misuse.

DR. KRAEMER: I agree with that. I think that instead of absolutely restricting publication altogether, that would be an alternative. It seems like if you were going to say that doesn't get published at all versus published with restrictions, I would say publish with restriction for communication purposes.

DR. COMPANS: I'd like to thank all the panelists.

(Whereupon, the meeting was adjourned at 4:45 p.m.)