

NATIONAL ACADEMY OF SCIENCES

COMMITTEE ON A NEW GOVERNMENT-UNIVERSITY
PARTNERSHIP FOR SCIENCE AND SECURITY

SOUTHEAST REGIONAL MEETING

June 6, 2006

Georgia Institute of Technology
Atlanta, Georgia

Proceedings By:

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P R O C E E D I N G S

[9:05 a.m.]

Agenda Item: Welcome - Dr. Gast

DR. GAST: Good morning, I'd like to welcome you, I'm Alice Gast, the co-chair of the committee from the National Academies that's hosting this event and I'm pleased to welcome you to the second day of this interesting and exciting conference, we're looking forward to another day of fruitful discussions and I'm joined with Jack Gansler in adding my welcome to this meeting and thank you for coming.

I'd like to thank Georgia Tech and Emory University and the Southeast Regional Center of Excellence for Biodefense and Emerging Infections for hosting us here today. And I'd also like to thank the Academy staff for all their work in hosting this meeting.

We've been delighted by the range of speakers and the participants and we are strongly encouraging you to freely participate in the discussion and we'll try to keep to our schedule and leave as much time for discussion as we can today.

So we're here under the auspices of a National

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Research Council committee called the Committee for a New Government-University Partnership for Science and Security. We've been charged by our sponsors, the NSF and NIH, and also by OSTP, to identify and host a broad and open discussion of the key issues at the heart of the balance between science and security, and to offer them a range of policy options for their consideration.

In carrying out this charge we're holding three regional meetings at university campuses, this is of course the second meeting, the first was in MIT in mid-May, and we will hold a third and final regional meeting September 27th and 28th at Stanford, University, in California. Then we will culminate this activity with a convocation early in 2007 in Washington, D.C. So these regional meetings are an essential part of the committee's activities to collect input for its report, therefore we would like to encourage open and fruitful discussion from the speakers and the attendees and fellow committee members.

It's important to understand that the committee has not yet drawn any conclusions and thus we greatly value the input from our participants so as our speakers frame

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some of the challenges we face in science and security we welcome your thoughts and particularly your potential solutions and suggestions.

I'd like to remind you that we are in open session on both days and we welcome the public and so there could be press present although I haven't seen any, but an unedited transcript of the meeting will be posted on the Academy's website in a few weeks if you'd like to look back at the discussion.

I have another little bit of a disclaimer that sometimes committee members will make comments to provoke further discussion and they shouldn't be interpreted as final conclusions or viewpoints, they do not represent the views of the National Research Council or the committee, and sometimes our probing questions are really just a line for the purpose of gaining insight and provoking further discussion.

The committee will deliberate thoroughly before writing its draft report and once it is written it will go through a rigorous Academy's review process, so there will be ample time for thought and revision and input. And to

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that end I ask that anyone who has further thoughts and would like to contact us to email Jack or me with further items of interest or news items you might want to contribute.

So before getting started I'd like to introduce our committee members to you for those of you who weren't here yesterday, Jack Gansler of course is the co-chair, we have Louann Burnett, she's the biosafety officer at Vanderbilt University, Gary Hart, former U.S. Senator and now at the University of Colorado, Michael Imperiale, professor of microbiology and immunology at University of Michigan, Julie Norris, director emeritus of the Office of Sponsored Programs at MIT and now a consultant, and General John Gordon, retired from the U.S. Air Force although he doesn't seem to be retiring or retired.

Unfortunately several of our members could not make it, Arthur Bienenstock from Stanford, Karen Cook from Stanford, Richard Meserve from the Carnegie Institute of Washington, and Elizabeth Rindskopf Parker from University of the Pacific.

I'd like to especially make note and thank Julie

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Garton and Michelle Green from Georgia Tech for their help in having us here and hosting this meeting as well as Ruth Berkelman of Emory University, so thank you very much for your hospitality.

So with that I'd like to turn it over to Paul Gilman, the director of the Oakridge Center for Advanced Studies.

Agenda Item: Concerns of the Academic Community

DR. GILMAN: Thank you. I'll remind our panelists that we really do want to stick to the time limitations of about 15 minutes each so we have ample time for discussion, that's really important for the committee. My own observations on this, yesterday we heard a lot of talk of peer review as a process, institutional review boards as mechanisms for wending our way through the security and research issues. In my time at the EPA I heard more criticism of those processes and those institutions as mechanisms to safeguard then I did sort of have them held up as the solution so I put that out for the committee remembering that especially as it relates to industrial participation in those things there are a lot of

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folks who would ask you to justify the use of those mechanisms.

Introductions, Bob Cook-Deegan is the director of the Center for Genome Ethics, Law and Policy at Duke's Institute for Genome Sciences and Policy, and is also a research professor of public policy at the university and at the medical school, he's going to speak to us on ethics and law in this matter.

Gary Miller is an associate professor of environment and occupational health at the Rollins School of Public Health, also part of the Center for Neurodegenerative Diseases at Emory. And he's going to speak to us from the perspective of the chair of the institutional health and biosafety committee there, he also served while he was on the faculty at the University of Texas on an institutional biosafety committee.

Bill Wepfer is vice provost at Georgia Tech for distance learning and professional education, he's going to be speaking to us on the implications of all this for distance learning and professional education. I noted in his bio he said as Georgia Tech moves towards a more

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globalized university, my center ran a session on export control and the globalization of universities and we actually used Georgia Tech as a poster child who gave a presentation on that just a few months ago.

Gary Bertsch is the university professor of public and international affairs, he's also the director for the International Trade and Security Center at the University of Georgia, he does research on trade, technology and strategic issues and he's going to put this in a framework of export controls for us.

So those are our panelists, Bob, do you want to lead off?

**Agenda Item: Concerns of the Academic Community
- Biodefense-Policy, Ethics, and Law**

DR. COOK-DEEGAN: So thank you, I'm from Duke but I'm representing the sixth university consortium that is part of the Southeast Regional Center of Excellence for Biodefense and Emerging Infections. Several other of the members of this committee are in the audience but the people who deserve special recognition are Meghan Davidson who's in the beautiful turquoise shirt and Nicki Vonness(?)

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who's right next to her.

And one of the features that I'm going to be talking about is an education module that was actually done by somebody here at Emory, he's not here today but Ruth who was our connection to him is. And then each of the universities has a member, at least one member that is part of a committee that is overseeing the set of activities that I'm going to be talking about and I list them here. Ray's in the back, Sam, where are you, Sam Tilden(?) was here, there he is, and who else, who am I missing, Stuart Finder(?), and I don't think I've missed anybody else. So if you have questions about it you can ask any of us, we actually do talk to each other.

So about three years ago the nation started this huge investment that we've heard about in increasing the level of research going into biodefense and one of the ways that that was done was through the National Institute on Allergy and Infectious Diseases at NIH that decided to spend large amounts of this money through regional consortia, they mapped to the federal regions, there are now ten of these centers. We are one of them, as far as I

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know we're the only one that has a policy, ethics, and law corps and I thought it would be worth talking a little bit about what we have done in that corps because I think it might help you in the task that's facing your committee in thinking about the policy issues.

Policy is the first word in this corps activity and there was a pretty good reason for that, we didn't know exactly what we were going to be doing when this all started so we decided the first thing we should do is go talk to the people who were doing the science because we were very clearly a corps of a grant. Now corps are things that other parts of the grants are supposed to take advantage of and use to make their work easier and better and more effective and we thought that what we should do is actually ask the users what might be most effective for them, what issues were facing them, so we did.

Each of our members at our respective universities went out and talked with folks at their universities and in the process of doing that we set an agenda, we began to do commissioned white papers. I won't go into the topics of those white papers, the most

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important thing on this slide is the URL to go to the website. We have several white papers, the author of one of them, GiGi(?), is here, and there are several other white papers that have come up. Those were to educate ourselves on the Pell(?) Corps first, then the investigators who are part of SERCEB, but these are actually documents that we think are of general interest, several of them have been published in journals for general readership.

But I wanted to talk in particular about three of our activities that grew out of trying to figure out how we could be useful. One was something that all of us have talked about and it's the first thing that anyone comes to when they think about what are they going to change the culture, change the norms, and make scientists aware of the consequences of creating results that might be misused, that's a new game that many biologists are not used to. The first step is obviously to educate people and the way that we went about doing this, we did not want to preach, what we wanted to do was come up with a tool that would allow people to engage the issues but without speaking down

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to them, and so this was where the magic of Verizon helped and we designed an education module that is intended, our primary audience for the module was the people doing research in our regional center, now its turned out to be useful to other groups.

And I won't say anything more about it except please go take it. It does not use a select agent, it uses a non-select agent, but it goes through the issue of what happens if you're doing research, you submit a paper, and somebody comes back and says well you didn't think about how somebody misuse this information so we're going to review, we're going to do a special review of your publication and we go through the lab dynamics and how to think about those issues. So that was an education tool first for ourselves, then for investigators, and now more generally.

The next thing that we bumped into was these regional centers have resources that they can spend on pilot projects and there's an application process, so it's like applying for a grant except it's an internal application process. Our steering committee that makes the

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funding decisions for those grants, or for those funding streams, turned to us and said well you know there are a few of these that kind of caught our attention and we think that they might raise issues of dual use. That immediately got us in the game of dual use review. Now we weren't put in place for that purpose but since we were there our steering committee turned to us, we are advisory to the steering committee, we didn't make any decisions about funding, what we said is here are some questions that you might ask the investigators.

So for example one of the first protocols that we looked at that kind of made us stay up at night was a proposal to take one of the hemorrhagic fever viruses, break it into pieces, mutate one of the proteins that is involved in infectivity and pathogenicity and the intention here was to attenuate the virus so that you could develop a vaccine, everybody would agree that's a wonderful thing. But there's a possibility of course that in the process of doing random mutations you're going to change the host range or you're going to change the infectivity in the direction of increasing it, so we just asked the question

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well what are you going to do if that happens, are you going to publish it, are the grad students and postdocs who are doing this work going to talk to everybody, what are we going to do with this information, what are you going to do with the materials. What we quickly discovered is all we did was ask the questions, it was left to the investigators to figure out what the answers should be and the investigators in answering those questions have almost no guidance.

And that's where we are, three years later that is still where we are. If this comes up in your lab you can turn to places for advice, our policy right now is please turn to the steering committee for advice and we're going to figure out something sensible to do. But we do not have any particular guidelines for what should be done and I don't think we will until we've accumulated enough cases like this that the rules that we're beginning to apply in making sensible decisions begin to codify what it is that makes sense in a different context, then we'll have some criteria, then we'll have some experience, and then we will kind of begin to know what to do when these things

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happen.

Next step after having done some dual use review, and we've done that now in two rounds and there was at least one protocol in each round that raised some concerns among us that were reflected back on the investigators. The next thing we did is we're trying to follow the bouncing ball in Washington, the same group of activities that you all are trying to contend with as you're writing your report, which is what are the rules going to be, what are the criteria going to be, and we kind of thought we could see the direction things were going, the Fink(?) Report of course recommended basically that the infrastructure that's been set up to do recombinant DNA review be retooled, because it exists that infrastructure could be used to do this dual use review.

So we thought well okay, well then that means that institutional biosafety committees are going to be the ones that are in the crosshairs, maybe we should talk to them. So we got Gary and his colleagues from the other five institutions that are part of our consortium, we got them together and said well what's happening at your level,

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are you expecting to do this. And what we learned of course is that some of our institutions are going ahead, they're going to do dual use, Duke for example has decided we're going to do dual use review for our institution and our institutional biosafety committee has said we want the resources to teach our people what they need to know in order to do a good job of this. Some of the other IBCs are waiting more or less for the NSABB to make a decision in Washington and they're waiting more for direction from the top. And I think that's probably what you would find if you did a national sample right now is different groups are approaching this in different ways.

So that's my plug for what we've done with the Pell Corps. I also after yesterday's talks, I learned a lot yesterday but I thought it would be useful to use a model, a historical model, I tend to do history of technology, and I want to march, I'm going to go through about six slides in a row here very quickly and I'm going to only make one very major point which is that we're fighting the old war, we do this over and over and over again, but I'm going to show you some numbers about funding

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of research and biomedical research.

This is a slide of all major, all the seven major accounts that fund R&D in the United States over a three decade period starting in the '70s going through to 2000 and the only thing you really need to notice, these are all inflation adjusted, and what I've done here is I've stitched together a bunch of disparate funding accounts and the only one that you need to pay attention to is this huge wedge in the back, that's biomedical research, basically what is now the NIH, and the thing to notice is that it's a whole lot bigger than it used to be.

This is the part of R&D that has grown a lot and the United States is unusual in that it spends a higher fraction of its R&D on life sciences than our OECD country, peer countries, and as a fraction of GDP, U.S. is the red thing on the left here, as a fraction of GDP our expenditures on life sciences are higher than any other country that I know of of these that are accounted. And in fact when the Global Forum for Health Research took a look and they added up the government and non-profit funding for health research all over the world their first cut at this

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in 1998, they did this actually in 2000 but the numbers were from 1998, they thought the U.S. accounted for 57 percent of the world total.

Now that's probably down from what was probably two thirds sometime in the late '70s and it's probably going to continue to go down. And actually when they redid these numbers just last year it turns out that that number should have been 49 percent but it's still a very, very high fraction of the total funding for R&D.

Now that's government and non-profit and that's a rough equivalent to this red line here which is the, this is budget function 550, this is a number that Paul knows quite well from his work at OMB, it's roughly, NIH is about 85 percent of this but the thing to notice here is the private R&D, this is just the members of the Pharmaceutical Research and Manufacturers Association, since the 1980s when the arms race for R&D and pharmaceuticals began it has exceeded the rate of increase in the public sector.

And now I'm going to shift gears to one particularly salient technology at its peak, this is the year 2000 when the genome project was the thing. And we

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did a little snapshot of who's funding that research and we found that government and non-profit, we had 70 funders that we kept track of and they accounted for about a billion and a half dollars. If you took only publicly traded companies, of which there are about 70 some in the year 2000, they accounted for about two billion dollars. And then if you took the big pharmaceutical firms and established biotech firms that's about another billion. So if you add it up it's about two to one private dollars to public dollars.

Now why do I mention that? Well, these dollars do not cleanly conform to national boundaries, they don't behave by the rules of government funding and they are not constrained by national rules or many of the policies that we were talking about yesterday, it's a complicated game.

Now I'm going to now, the numbers that you've seen before are overall health R&D, these are the genome funding figures and of course the U.S. was spending the most on genome research in the year 2000 compared to any other country. But here's the magic of actually taking figures and making them, normalizing them according to size

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of the economy, suddenly the U.S. drops from being number one to being kind of in the middle of the pack here. This was an anomalous year, the country of Estonia has a low GDP and decided to plow all of its health research into a massive effort to study its population using high tech whiz bang genomics, so it's a really funny outlier here. But the point is that Canada, the UK, Sweden, Netherlands and Japan and Germany were all spending a higher fraction of their GDP on genomics which is the hottest science of that day. So these are countries that have deliberately targeted genomics and in fact what I think we've probably seen since, we're redoing this right now, I don't know what the numbers are going to be, it would not surprise me to see that the Asian countries are probably now spending a higher fraction of GDP on genomics than the United States is.

Now what does that tell you? That tells you that other countries are being strategic about how they think about life sciences and a lot of the talk that we were going through yesterday is not terribly relevant to that kind of a game. If these countries are targeting their

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investments and we are not it suggests that the premise that we have something that's really valuable and we have to guard it is probably not the exact framework that you want to be applying to your policy because we're part of a much more complicated world.

Here are some hot areas right now where I presume that the same thing is probably going on, stem cells and certainly synthetic biology and nanotechnology are highly relevant to our discussions today and other countries are certainly paying attention to what's going on in those fields, at least as much as we are.

So what are we going to do about it? Well, I think I've heard several historical models for how we should think about this problem, the two that I think came back and forth were invoked several times yesterday were institutional review boards and the recombinant DNA review process. IRBs grew out, the way they happen in the United States and here I'm focusing on the U.S. model, basically IRBs as we know them grew out of the intramural research program at NIH, that was beginning to develop in the 1960s. Then there were a bunch of scandals including Tuskegee but

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not restricted to Tuskegee in the early '70s, and an apparatus was put in place and it was put in place under threat of legislation, in fact Senator Kennedy basically told NIH get your regulations in place or we're going to pass a law.

So the regulations, the 45 C.F.R. 46 and the equivalent for the FDA were put in place very quickly by NIH in response to threat of legislation and the thing to notice about that, one of the issues that Lisa raised yesterday was that industry is not covered for recombinant DNA. Well, it is covered for human subject protections to the extent that any product or service is going to be regulated by FDA conforms to the common rule for IRBs through the FDA regulations and that's a mechanism that could be used for any procedure that you put in place for dual use review.

The other model is recombinant DNA which grew out of the moratorium in the mid-'70s and led to guidelines that were developed in 1977. Again there were 16 bills on the floor of the U.S. Congress in March of 1977 and none of them passed, and the reason they didn't pass, probably two

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reasons, one is that that's the year that we cloned insulin and it began to look like recombinant DNA was going to be really useful for medical purposes, took a little bit of the heat off because all the discussion up to that point had been about the dangers of recombinant DNA and suddenly there was a retooling, a reframing of the questions in terms of benefits of recombinant DNA.

And also the scientific community stepped forward and basically put in place a credible set of guidelines that are admittedly voluntary for industry but they've been in place for a good long time. This structure has been retooled once already, the recombinant DNA review process was mainly about biohazard from 1977 to roughly 1990. Starting in the mid-1980s it began to retool to become the process for reviewing gene transfer protocols for clinical research in human beings, that is inserting recombinant DNA into human beings, and it became a second level of review over IRBs and IBCs at the federal level. So that required the federal committee to retool itself and reeducate itself about clinical research.

The proposal that the Fink Committee put on the

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table was to retool it again and use it for dual use review. Could it do that? Of course it could. But would it take some tweaking? Yes, it probably would and it would take some attention to covering industry in particular.

Finally just a mention, nobody has talked about it yet I don't think, there's a very active discussion right now in synthetic biology and nanotech and those two overlap quite a bit. A lot of it is focusing on one key technology which is how do you make DNA in large quantities and controllable structures. There are proposals on the table that have actually been proposed by the scientists themselves, George Church in particular, to screen any requests to make a big segment of DNA and also to keep track of who's manufacturing these machines because right now there aren't a large number of people who make these machines, is it possible to keep control of this particular seminal and key technology for synthetic biology. I don't know what the answer is and that's an active debate and it's something that I'm sure that you all are paying attention to but I think it might be worth, if you haven't already, you may have already done this, it would be worth,

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okay.

And finally, this will be the last thing that I say, it seems to me that the real questions facing you are how do you make decisions in such a way that you begin to accumulate a feedback mechanism that allows you to make better decisions the next time around so you're capturing the experience and turning it into something that can be improving over time. One thing that we kind of screwed up in the '60s when we were thinking about IRB review was they didn't come up with a procedure for appeals so IRBs, a lot of the pathologies of the IRB process are attributable to the fact that each institution gets to make decisions but there's no way that when an IRB makes a bad decision it has to take account of other IRBs in other places and there's really no federal court system or court of appeals to rationalize those decisions. So as you're thinking about it it would be a good idea to pay some attention to that feedback mechanism that comes from having an appeals process.

I'll just say orally what I said on the slide, one of the discussions yesterday was about there's really

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two frameworks going on simultaneously that we're talking about as we're thinking about allocating resources. One framework is we've got something where we want to think about how do we control access to information, materials, and dissemination of information that might be misused, that's a framework for kind of regulation and oversight. And you can spend resources in doing that to try to achieve the end of reducing the risk.

GiGi's point yesterday was there's another way to allocate resources which is to kind of assume that sometimes bad things are going to happen, some of those may be by deliberate use or they may be from emerging infections that happen anyway, and another way to spend some of the same resources might be to have a system that acts faster and better and more efficiently when something bad happens. And there's a tradeoff going on here, these are not incompatible systems and in fact you're probably going to have to do both, but they are two very, very different ways and I think you do need to have a way of deciding what level of resources to pursue through which channel because you can spend a lot of money on regulation

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and still bad things are going to happen, and I think that was GiGi's main point yesterday and I'll finish with that.

Thank you.

-- [Applause.] --

Agenda Item: Concerns of the Academic Community
- Challenges for Institutional Biosafety Committee

DR. MILLER: Okay, so I'm going to be giving you the perspective of the IBCs, very much focusing on this academic perspective.

As all of you know IBCs are based upon the NIH guidelines for recombinant DNA but many, including Emory, also oversee infectious agents, biological toxins, hazardous chemicals, that Emory just thought made sense because these are concerns on campus from a health and biosafety standpoint, and we are also now dealing with dual use, primarily based on the recommendations of the Think Report and their recent initial draft they put out of some questions that where it's incorporating those things right into our application process. So we haven't really seen a lot of it yet but it will be able to give you some feedback on that in a few months after we've seen more proposals

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that way.

The other aspect of this was that at this point the IBCs are probably the closest thing to the science and security entity that exists on campuses right now. Now whether this will end up being the arm of recommendations that are given or just a model, maybe there will be a new biosecurity committee that's developed, or it might just serve as a sieve that we might identify things that need to go to this new committee. It clearly has many of the make-up of what you'll see in a committee that we'll be dealing with, the concerns that will come out of this committee ultimately.

You don't really have to worry about reading these details, this just gives an example of what a typical day in the life of an IBC member is, and what you should note is that there's a lot of things going on and the investigators are worried about their grants and their teaching and all their other concerns, and they try to fit in this committee work in there but there's not a lot of extra time to pursue all sorts of other endeavors. So the members tend to be faculty, they're over extended, and

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there's very little time to develop new policies or forms relating to biosafety, not to mention biosecurity, like how do you come up with all these new forms and every university is doing all these things, all these different places. So you go and hire an individual to handle all these issues and hire a biosecurity person, you may need to have some of that support but the idea is to engage the individuals on the campus that are doing the research, so you really want to have the committee, you want to have the faculty heavily engaged in this where they rotate through these committees and more people understand why they're doing it, and it will make it much more successful, so you still need to focus on this committee structure.

So what I actually just took over as chair of the IBC about six months ago and as I learn more and more about it, I've been on the committee for a while, I came across this mantra of the community, that if you've seen one IBC you've seen one IBC. And this, it's somewhat comical, I find this to be very unfortunate because while you'll expect to have some variation across campuses because you'll have a private medical institution or a state

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university that has a lot of ag programs, it would seem that if some program has developed a very good way of doing it that you'd be emulated by others. There's no reason for every university to keep reinventing the wheel over and over and over.

And for biosecurity I think this is even a greater issue in that you have to have consistency and compliance across campuses, if you have 75 percent of university having great biosecurity programs and the other 25 percent don't, that's a failure, you can't have that many people not working with that. And so what I'm going to try to talk about now is really the how that was talked about yesterday, how can we actually get the university campuses to be successful in implementing some of these things. So again, to me one of the biggest challenges is how to implement these plans at the individual universities and I believe that investment in this information dissemination on the front end will greatly improve the compliance and consistency across university campuses, so again how would we actually do this.

So it's by providing useful guidance, if you have

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guidance for these things that include things like chapter five, section B, article three, line four, you've failed. Professors don't want to read all the legalese stuff, they just don't want to see that. But if you had an easy to follow guide book that had advice, training materials and sample forms, so rather than having to reinvent these things they could just say oh, I can just download that, put the Emory header on top, make these modifications for my university, you'll really take out all that extra work that there's really no time to do, but you also have this basic standard that will meet the expectations of the committee. And I think this would be very well received by the academic community because I think that on these committees we're not as concerned about like this issue of an unfunded mandate, it's more of the uninformed mandate, we don't know what to do, it's not that there's not the resources, we just, we're flying blind on these things and it's a big challenge.

So what I would propose when like the Fink Report when you come out with the Alice and Jack report or whatever it would be called, that it's followed up with a

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recommendation or commission of this book, Science and Security and Academia, which will be the guidelines for these programs to be implemented in academic settings, like a how to guide to actually make these things work. So what you'd have with this, you'd have, for example you would have some background on what it means for science and security on the university campuses.

I think it would be really good to establish like a biosecurity assessment team on each campus, this would be a high level thing, vice presidents of research, deans, department chairs, biosafety people, IOCOOC(?) officials, and they would assess what that university needs. And then from that you would build your institutional biosecurity team. So again there will be differences across campuses but if you start with this basic guideline about how to do these things everybody will be starting from the same level and then they'll be able to adapt it to their program.

And then the idea of developing these policies and procedures manuals, again, this could be something that could be templated out for them and then they could add in as they identify if they have issues of the classified

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research or it's all mainly medical school based or if it's agricultural, they can adapt these things right to their policies from that.

And then the appendices could actually have these templated forms, the policies and procedures, the educational materials. And this is a very important part of this, for example Bob mentioned Oreicins(?) educational module for dual use. Well, this was a very well done website and I was able to have all my IBC committee members go and take, go through and take that training and get them up to speed very quickly on these dual issues. But if it hadn't been done in a professional high level thoughtful manner it wouldn't have been very useful.

And then also the educational materials you would need for the university personnel. Training IBC members or committee members is different than a general university population, you need different tools, different handouts, different types of web materials, and I think the suggestions will make these things work.

And again something like developing a web based program, so an example of this, I'm going to pick on Emory

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some here, this is a website from Emory's IOCOOC website and it has new IOCOOC policies have been posted and the date is 2002, and the chair listed was gone two years ago and it's very hard to follow, there's no rhyme or reason to it, and so if an investigator goes to this website or actually at the time, the same thing we have for IBC, it's very, it's not useful, and so the investigators don't see that as a place to go.

But then I went to UCSF's website for their IOCOOC and they have a very nice layout that has all the proper links and everything you want to know is on that initial face page, it can link you to what you need to have. And so the same thing, if you're going to set up these security issues you want to do it at a high level because academicians can be very peculiar this way, that they go to some place and it doesn't work or it's not updated, they just dismiss it forever on. And so if you can put something up there that impresses them they'll be more engaged with it and actually use that.

So some final thoughts, when developing these guidelines remember the people, like me, who will be

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implementing these plans. If you want these academicians to comply we have to arm them with the tools that are necessary for their success. And if you don't want to do that you can go to something a bit more dramatic, and I'll end with this, I'll just let you read that and you can see the surgery this individual had.

-- [Laughter.] --

-- [Applause.] --

Agenda Item: Concerns of the Academic Community

- Implications for Distance Learning and Professional Education

DR. WEPFER: While we deal with the technology I can start and put a couple things in context, and then we'll bring the slides right up. I am really happy to be here and we're really happy as a representative of Georgia Tech to have this group here, this is really exciting and important work.

I sometimes call myself the cats and dogs vice provost because I do things that are either not strictly research, not strictly education, kind of the things that sort of fall in between. And of the two things that fall

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in between that are of relevance today are both in the area of distance learning as well as continuing education. In any event, that's what happens when you're the boss, you have people far smarter than you on the technology.

Let me also kind of put a couple of things in perspective. At Georgia Tech I sometimes, we're a public institution, we're not a land grant but in some ways we're a near land grant, and we're also one of these hybrids that sort of we're somewhat private like, somewhat public like. And so the reason I comment about that is most of what I do is in the education field and if you go back to the Moral Act or wherever before one of the fundamental values that's in our genes, it's our legacy, is the sense of openness and transparency. And I think at Georgia Tech we've developed relationships over the years primarily based on our defense work where I think we've adapted a healthy attitude and relationship to be able to have that balance between both the openness aspect as well as the national security aspects.

So in any event I think we're a pretty good case study of how we can do things and I think, I sort of like

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the spirit that during all those very intense Cold War negotiations with the Russians the idea of trust but verify, I think we've got a spirit like that on our campus that so far has served us very well.

I also want to make the comment that in the area of distance learning we have nine engineering degrees, they're all physical science based, we do have engineering programs and biomedical engineering but none of the health or biologically related stuff is delivered either as a part of any of our continuing education programs or as a part of our distance education programs. And what's kind of important about that is the fact that the masters degree in the hard core engineering areas has a lot of professional value. Some of the science based programs, the masters degree can sometimes be viewed as a consolation prize for those people who don't go on to the Ph.D. but in the engineering world it's a very valuable and important credential.

The other comment I want to make before I move forward is distance learning is a real moving target. I have a colleague of mine who is just retired and he worked,

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had a career doing some fairly interesting signal processing work, he spent the last three or four years of his career working on developing these techniques for teaching technologies and his definition of a distance learner is anybody beyond the first row. And so I think that gives you some context for just how sort of the education dissemination of information has become so pervasive, it's a real moving target.

Let me go through and just put some standard items up here. When we do a distance learning program, when we do a continuing education program, we have to ask ourselves what's the objective and does it make sense, and I've got educationally and financially but I think we've gotten pretty good at Georgia Tech at asking are there any national security implications to these programs. If you're going to partner it is absolutely critical that you ask some very, very serious questions about the partner.

We have a lot of faculty that have for example collaborations with China and I'm sure like many folks you go over and you come back and you're really excited but then you've got to kind of decompress and ask yourself some

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important questions about who's getting what, what are the benefits, what are the risks. Definitions and language are critical because sometimes what we mean is not what either a customer means or what our partnering entity means.

Within the State of Georgia and Georgia Tech we're pretty firm in insisting on using State of Georgia laws which will help us a lot. Sometimes there are issues and our counsel is here to make sure I don't say anything wrong but I think that's been a very important thing for us.

And then a key issue is curriculum content, we're not going to compromise on curricular content, our faculty hold that authority. But now curricular content in a day and age of distance learning gets to be very interesting and I've kind of intentionally put curricular content right in front of import/export. In this day and age what do you do about laboratories? In the old days people in our distance programs would actually come to campus and do laboratories but now you can do virtual laboratories, you can do simulations, very sophisticated software. We talk a lot about dual use but I almost view some of these

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simulation packages as being sort of a multi-tiered use. And so the separation at the graduate level between educational content and research is a very grey area. I mean I'm a faculty member too and you can have a syllabus, you can plan ahead of time, but you're in the fifth week of class and you're doing some stuff in the research lab, you're teaching this high level graduate course and you get an idea and you say well I want to do this in my class and so it's really critical that for faculty members working in sensitive areas we provide some education and awareness for them so they have a sense of how far they can go and when they can pull back.

The other area of the computer technology is do you have the right safeguards in terms of protecting your systems and not allowing the software or your networks to be abused. And with the advent of very low cost high bandwidth videoconferencing you can have seminars now with participants from several locations in the world, how do you manage the content, how do you make sure you protect whatever information that you need to protect.

The import/export, deemed export concerns,

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certainly most of what we do is either public domain, graduate level material or fundamental research, but again when you get into interactive global situations how do we know that that student in our Shanghai Jiao(?) Kong(?) dual degree program does not work for the Chinese equivalent of the CIA, I mean I do worry about that at times. We worry a little bit about some of our programs in the sense that we have an aerospace program that we provide domestically, it's open record, educational graduate level stuff. We have not taken that overseas because its in some circles considered to be a pretty sensitive technology and yet we provide our electrical engineering globally and there's some pretty sophisticated courses in electrical engineering, they're part of the traditional or the emerging curriculum in the country, and yet it's sometimes hard for me to explain to our faculty in aerospace engineering the concern about that content as opposed to the concern about what we're already doing in mechanical or electrical engineering.

So those are some concerns that we have, I'm not sure we have any easy way around them, we handle things

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case by case right now.

Another issue that I think we have to deal with that is sort of interrelated to some of these is the copyright issue and Congress passed the TEACH Act in 2002, the intent of that was to begin to deal with what you might call digital rights management and it puts some, it enhanced some of the definitions, added some clarity on the limits of the use and the dissemination. From a provider standpoint we try to rigorously adhere to the limitations imposed by that legislation, but we also have to be careful about again technology access, licensing, and issues like that.

We also understand that the copyright laws are going to continue to evolve just because of the technology. Certainly there are IP licensing royalty trademark issues that are very, very important, again our open nature, we tend to want to give stuff away, and if it's intellectual property one of the challenges that I have is to explain to our faculty that yes, you might want to give it away but wait, there may be some value to this that you could benefit from, the university could benefit from, the state

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or the nation could benefit from.

Accreditation issues, we have had some exploratory discussions to work in some way shape or form in India. For the last four or five years we've had about a half a dozen students at the GE research lab in India. The arrangement we have with GE is we work everything through GE in the U.S. so all the money flows, they pay me real U.S. dollars, I maintain tuition integrity, the students are admitted, they access stuff through our servers, it's a really nice situation and its worked well.

Interesting, when we were in India a couple months ago we had discussions with a variety of people and there was a real mixed reaction in the sense that are we subject to the accreditation policies in India and we've taken the position no because we deliver everything from the U.S. but we did have some discussions and somebody printed out the Indian educational stuff and that may be one where we're going to have to beg for forgiveness rather than ask for permission. But you run into all of those kinds of issues educationally when you go overseas or have an international partner. And certainly there are HR

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regulations, even student discipline situations, that you get so American centric about dealing with the advanced state of our labor laws and human relations issues that they're different in different parts of the world.

The last point I wanted to put here is another item that I sometimes worry about and that is our faculty consulting. We have a policy like every university where we try to have clear policies and faculty try to go through and ask for permission, it's within certain guidelines and protocols. But our faculty and entrepreneurial and it's not sometimes that they don't want to pay attention, sometimes they forget, they don't know, and oftentimes there's a fine line between what they're doing for the university and what they're doing on the consulting side, and although at the end of the day the faculty member themselves have some liability if they don't follow the protocols you really don't want to get into that situation, you'd prefer to avoid it.

This is not so much dealing with the national security issue but I think we in the universities in spite of our legacy and tradition of wanting to evangelize

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knowledge to the state, to the nation, to the world, we also live in a financial world and we've got to ask some very tough questions and I sometimes think we maybe aren't rigorous enough in asking the fundamental dollar questions, I mean I've just put down a number of different items there and then at the bottom when we do these activities how do we know we're successful, I think that's something we really have to think about.

And then finally, the advantage of being here on the second day is I think Senator Hart asked the question yesterday, how can this committee help us, well let me just say what do we do. Well in my shop, working with our legal staff and Jilda's(?) office, we do have a protocol that we've established where we ask all of our faculty involved in distance ed and continuing education on a yearly basis to go through and file sort of self reporting process for export control as well as copyright. And we review them, I've got a couple people in my shop, we work closely with Jilda's office, legal and research security, to make sure that our ongoing programs are in some level of compliance. And then we also have a similar review that we've

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instituted for any new programs that people wish to start or create and certainly we'd be happy to share that with anybody here who might be interested.

And what do we want? Well, I think two real things and when I say clarity I'm not looking for exactitude because obviously it's a moving target, I don't think you can have black and white rules, but some additional clarity on the deemed export issue, I think that would be helpful to us. And then certainly some clarity and guidance with respect to the various overlapping and at times conflicting federal regulations. I know that's kind of like asking for the impossible but again we want to comply, we want to do the right thing, and so anything you can do to bring that clarity and give us some guidance would be appreciated.

Thank you.

-- [Applause.] --

Agenda Item: Concerns of the Academic Community

- Export Controls

MR. BERTSCH: Good morning. I want to thank the National Academy, our committee and our sponsors for

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organizing these meetings, I found them useful and I hope that you have as well. I'm asked to address the concern in the Academy related to export controls.

I went around my university, I've gone around some others, and asked about concerns on export controls and most of the faculty said what are they. Not only faculty but about 30 years ago I went to a fellow professor at the University of Georgia, former Secretary of State Dean Rusk(?), we both came as new faculty to the university in 1969 and about ten years later we were in a discussion about export controls and he said you know during my eight years of service to Presidents Kennedy and Johnson I really never figured out what these were and how important they were, whether we were doing the right thing.

And I thought well that probably requires some research and attention and we put together over the last 20 years a program at the University of Georgia Center for International Trade and Security where we've given a lot of attention to export controls. I started by going to Washington and talking with people in our Congress and executive branch about what we were doing, I got involved

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in the renewal of the 1979 Export Administration Act, one of our last real in depth renewals of this legislation. More recently we've been working primarily on international export controls, places like Russia, China, India, need a lot of help and we're involved in that work. But I also think giving considerable attention to how we handle our export controls in this country are critically important to science and security.

Well we know that export controls are laws intended to restrain the transfer of technology, technical information to proscribed nations and users, we certainly don't want to get some of the things that are being researched on university campuses to get in the hands of terrorist groups and other proscribed nations. During the Cold War when export controls were really developed as we know them today we were concerned about nuclear weapons design getting into the hands of the Soviet Union, it was primarily business, the national labs that were most concerned about export controls, but today there are many things going on in university campuses that can be significant to national security. And so we see export

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controls becoming more widely discussed on university campuses and there are concerns.

These concerns relate primarily to foreign scholars, foreign students who are involved in research and can transfer this technology and know how to their home countries and to undesirable users. This is all complicated by the concept of deemed exports and I'm delighted we have our Undersecretary of Commerce David McCormick here to tell us more about thinking in the U.S. government today.

Just briefly deemed exports are those transfers that are deemed to be of national security significance, this is troubling for universities because of the presence of large numbers of foreign scholars and foreign researchers in our universities, in the Academy, and the many ways by which technology can be transferred, through distance learning as we've learned, through involvement of foreign researchers, foreign students in the research process within our countries. Touring labs, emails, private discussions, these are all part of this deemed export concern.

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Well, although the percentage of controlled research on our campuses is small it is significant, particularly in places like Georgia Tech, MIT, Stanford and others. I think most faculty and most administrators are not well informed about what is expected, what is possible and how to go about it, I find considerable confusion about what is to be controlled, a lack of understanding about the exclusions, fundamental research, so forth. Universities do have an important role to play but I think they need much more guidance. There are key people that need to be educated in universities and they should be aware and they can be more useful and becoming more self regulating and self governing if we reach out.

My assessment is that those who are aware of export controls and deemed exports are concerned about how we're going to manage this in the Academy. Those who are unaware or poorly informed are going to be part of the problem for us and so education and outreach is very, very important and the U.S. government I think has an important responsibility to helping with this.

The government and the scientific community

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academy should be working much, much more closely together and this isn't happening and I think part of the problem is that there is confusion in the U.S. government about what we really want to do, need to be doing. There is no overarching strategy and resulting policies governing export controls for the 21st century in this country. The U.S. Congress has tried repeatedly to update or to really pass a new central piece of legislation, the Export Administration Act, which expired over ten years ago. There are many reasons for this pitting of national security concerns against free trade pro trade concerns, but this is a national tragedy for a country who really was a leader during the Cold War in export control policy, has really lost that leadership because we don't have a clear vision about what we want to do and we need that very much.

With all due respect to Undersecretary McCormick and to our U.S. government, they're trying to do the best they can, but there is a lot of muddling through on this problem and that is not serving us well. I think it's possible to design a new export control system. I would be delighted if someone provided just a bit of funding to the

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University of Georgia in our center, I think we could do it, but we're busy with other things like every one else is and I don't think there's anyone in this country who has really taken a responsibility, time and effort to try and do it.

I think that it can be done, we had some meetings on our campus last week where we hosted the first group of people who we've asked to join what's called the International Export Control Association. We put together universities, non-governmental organizations, think tanks around the world to work on some of these issues. And I believe there are growing international norms about how to handle this in the world but we need leadership in the United States and we need to try to work to create a new export control strategy that can be shared with others around the world and organize our own system.

Well, I'm going to make just one recommendation today and it really goes beyond the work of this committee but I think it's important in this field of science and security and that is that we make a call for a commitment to developing better policies in the area of science and

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security and one example is that of export controls. We indicate to everyone the importance of U.S. leadership in this field, it's critical, I have studied export controls and my center has worked on these issues in 40 different countries, field research on the ground, and while these countries are prepared to try to follow they're not going to take the lead so U.S. leadership in this area is critical.

And I think that this new system should be based upon much more of a partnership between the U.S. government, between the Academy, and between business. These three groups are critical players in the field and in the past it was sort of a top down model where the U.S. government would tell business and universities, the Academy, what needs to be done. I think this idea of informing and involving and engaging the Academy and the business community is critical and they can become more self regulated, more responsible for helping out, because this issue of deemed exports and export controls is too big for the government to manage, it requires close good partnership.

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So in closing, going back to our opening keynote address by Frank Gaffney yesterday I disagree, I think we know what the challenge is, I think we have a good understanding of what needs to be done, I don't think however that we've taken the time and put together the kind of brain power and people who can really devise a strategy of dealing with it. Everybody is busy doing their own things and no one is really coming up with a good policy, a better way of doing things, and I think that that's a national challenge that I hope the committee will address.

Thank you very much.

-- [Applause.] --

Agenda Item: Discussion

DR. GILMAN: Okay, we're open for discussion, why don't we start with committee members.

GENERAL GORDON: Gary, on your last set of remarks and you talked about calling for a kind of broad review of policy, could you give just a minute or two of sort of the key features that you would think would be in that, or the key functions, we're not going to pay you for the university go salvage the whole policy but what would

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be the three or four things or two or three things that are most important to address.

MR. BERTSCH: Well I think the point that President Cluff(?) opened with yesterday about very high fences around very well defined technologies of national security concern, I continue to think that in the area of export controls we may be trying to control too much and not focusing on really what is important, we need to think carefully about what are the critical things to be controlled because in this day and age control is so difficult so let's make sure we're focusing on the right things. And that requires I think closer collaboration between researchers, scientists, people in the business community who are generating this new technology along with government.

I know the Department of Commerce and other government agencies are trying to do this, I think we need more of it, and I think that a group like the National Academy of Sciences should speak loudly and clearly.

Finally I would say it's not just a U.S. challenge, it's a global challenge and unless we work these

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issues multilaterally with our friends and allies around the world and emerging suppliers like India and China we're not really going to solve the problem. We can work as hard as we want in this country but we have to recognize that the technology is getting out there and if it's not transferred from the United States it can be transferred from other countries. And so fortress American will not work, this is something that requires a national leadership in this country but within a multilateral international context.

I think we can build upon the old system but we need to think anew about what kind of century we'll be living in.

SENATOR HART: To follow on that question then for the entire panel if as a number of people here and elsewhere have indicated to us scientific knowledge is becoming increasingly international aren't we really dealing with an interim problem, that is all of this discussion supposes American superiority in science and technology. If in fact other nations are on crash programs in a whole variety of areas aren't we really talking about

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a problem that exists for the next five to 25 years where all inventions are not occurring in the United States and increasingly fewer and fewer are, sadly.

MR. BERTSCH: Well I couldn't agree more but I'll let other panelists talk about in their fields what this means.

DR. GILMAN: I think the focus for the future will be on the areas of innovation as opposed to an existing body of knowledge.

DR. COOK-DEEGAN: One of the things that your committee is obviously facing big time is that biology is not physics and biological and toxin weapons are not going to be in the same framework as controlling fissile materials, and so we've got a Cold War framework for thinking about things that's dealing with an organism that is entirely different. Universities are a much bigger deal in the life sciences than they ever were in the physical sciences and particularly in the applied domain because there's really nothing related to the biology that isn't both fundamental and applied and that's the nature of the beast. And universities have been a really, really

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integral part, everybody who does anything in it is trained in those places, information exchange is happening there, and the fact is yes, the U.S. for two decades has been, it was really dominant in the '70s in the era of recombinant DNA, when that was discovered most of the science was going on in the U.S. or Europe and ever since then other countries have been catching up and now they're growing faster than we are, so that's going to be a feature of the future so you've got to features of this organism that are very different from the old model and I think you just have to contend with that.

The framework of trying to identify I don't think, one other thing you can generalize about biology is that generally it's full of surprises and it's not nearly as controllable or predictable as the physical sciences and in fact that's going to be true of the ideas that are seeping out of this. Look, the Jackson experiment, they didn't do that because they wanted to create a super bug, they wanted to contracept it, all right, in rabbits, excuse me, in mice, for a problem that plagues Australia. This wasn't a designed experiment and it wouldn't have triggered

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any of our review mechanisms.

So that's going to happen in biology and we just have to live with that, that's GiGi's point that she made at the end of her talk yesterday I think is really, really important, we need a structure that detects bad things happening quickly and acting quickly as much as we need to try to prevent bad things from happening.

DR. WEPFER: For somebody who last took a biology class I think in about 1967 I'm not qualified to comment on any of the life science thing but I have this sort of naïve belief that having been to China, they're pouring money into their universities like they build expressways, it's very command and control and there was an interesting article in a Chronicle of Higher Education about a month or so ago about some of the problems at the top Chinese universities with regard to intellectual property and whatnot and I have this innate naïve belief that they will always be a brilliant people but at the end of the day we can really be of service to the entire world community by the whole issue of openness, transparency, I think that's definitely got to be the way to go, we have to be careful

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as we do it and I don't mean to be a unilateralist or play to American exceptionalism here but I really think that value of openness in education and research is going to be critical for the world to overcome some of the issues we're dealing with now.

DR. MILLER: I think that over the next 20 years we will see the volume of research catching up from other places but I still think the quality, and the reason so many people come to the United States is that our model of science is superior and I think that you'll still get these major breakthroughs that will come from the United States. And so while the volume of concern may not be as much there's still going to be these instances where the U.S. will take the lead on things that we do want to have control over.

SENATOR HART: We only take the lead if we increase our investment, which had been declining.

DR. MILLER: I support increased investment in the sciences.

DR. IMPERIALE: I have a comment and a question and let me preface the comment by saying I don't speak for

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this committee and I also don't speak for the NSABB, but NSABB is acutely aware of the need to provide not just guidance but education so that there hopefully will be some sort of standardization and as chair of an IBC, another thing I don't speak for, I've been pushing hard on NSABB to make sure that there is going to be education along side of everything so I think that is going to be one of the next big steps that NSABB is taking.

And then my question is for Bob, with respect to this educational module that you guys have come up with, so have you been sharing with the other RCEs, you were talking about this unevenness and so I'm wondering whether you're taking the bull by the horns here and doing that.

DR. COOK-DEEGAN: Sharing in a passive sense, I mean it's openly available on the web, we'd love, we have been trying to roll it out and get people interested in it, we would love other people to do it, the Federation of American Scientists, I don't know if their modules are up but they should be soon if they aren't already. There are other materials that are being developed so I think there's probably, certainly this module is out there, it's ready to

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use and we would love to have anybody use it. We haven't, I don't think we could say that we've been really aggressive in trying to make everybody aware that it exists except that we have done it through the inside game, the folks at NSABB certainly know about it and folks at our universities do.

DR. GAST: I really applaud both Bob and Gary's proposals, using the IBC there is a sieve or a body and the mechanisms for education and really bringing this up to the level where each scientists will be thinking about it every time they're pursuing a research project. Given this discussion on international aspects though I'm wondering how we can bring that at the early stages into an international forum and really provide some leadership because so many of our projects are international collaborations and it seems like having the ability to have this review, have our colleagues in other countries following similar practices would be important fairly early in the process.

DR. MILLER: It seemed good to start with at least some partner countries where you have those

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collaborations and to give them again like these templates, here's how we're doing it, we'd really like you to participate in the same thing and if you could start getting several countries to do that then you might have a way of getting it to spread out.

DR. GAST: [Question off microphone.]

DR. MILLER: We haven't had that much international things that have come through on our side at Emory but it's something definitely to keep in mind.

DR. COOK-DEEGAN: I think on the publication side that's kind of got a natural venue for that to happen at the level of the editorial review. The institutional level review I actually don't know what's going on in other places, I haven't had any discussions, anybody else, I don't know, I simply don't know.

DR. GAST: [Comment off microphone.] -- similar counterparts in other countries, universities.

DR. GANSLER: A sort of a follow-up to Gary's issue but I'd be interested in other parts of the panel, and that is when we talk about export controls throughout the two sessions now that we've had at MIT and here there's

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an ambiguity about whether we're talking about it really for just security or also for economic nationalism if you will. And then there's this ambiguity about whether we're talking about it for terrorism or for the "Chinese threat" that we heard about. And I think as we intermix these two concepts, the economic and the security one what is it we're really trying to control against issue that we lose sight of what might be, and I agree strongly Gary about the need for this new direction in export controls, in the 21st century these issues are going to be intermixed quite a bit, I'd be interested in the panel's comments in this direction.

MR. BERTSCH: Well historically the United States has been accused of using export controls not just for reasons of national security but also for reasons of economic advantage. I don't think that's the case, we have used export controls over decades primarily for national security and sometimes for foreign policy reasons. During the Cold War we often controlled things from countries like Cuba, China, Russia, because we didn't like their ideology, their foreign policy, they were not of national security

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significance. But what we're talking about here, and I think what we're talking about in the 21st century, is national security, it is a concern, a real concern that the U.S. government should have that we have to keep certain things out of the hands of people who would use them in destructive ways. But we should do that clearly so that the world doesn't think that we're pursuing economic nationalism and controlling these things to keep them more backward.

Also the way in which we implement export controls I think have implications for our economic security. If we implement them poorly and constrain scientific research and constrain the economic opportunities of our high tech companies we will undermine our national security because we will be undermining the economic and technological leadership of this country. So this is a big challenge, an important challenge to get it right in our country.

I believe in all due respect to Frank Gaffney who spoke yesterday that if we implement export controls the way I think he would like to implement them, that we will

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undermine our foreign policy leadership, our credibility as a responsible player in the international system, our economic competitiveness, and our national security. Because the rest of the world will not go along with controlling things to the extent that he would like and that means that we would isolate ourselves economically and scientifically at great cost I believe to the real national interests of this country.

DR. COOK-DEEGAN: We're trying to follow the histories of a bunch of seminal technologies that are important and this question of, the framework of export control seems to work in my mind only if a technology is uniquely American, and of the technologies in the life sciences that I think are really important like micro arrays or whatever I cannot think of a single one that isn't either an idea that could be picked up anywhere in the world or where there is a company somewhere, the U.S. may be the leader in many areas but I can't think of any of those technologies where there isn't another alternative to a U.S. source for any of the seminal technologies. So it seems to me in that framework export control is not the

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most powerful tool in the toolbox and so you better be thinking about something else.

MS. BURNETT: I have two questions, the first is for Bob and for Gary and the second is for the whole panel. From where you Bob and Gary sit what do you perceive are the current tools to get the attention of the researchers and maybe more importantly the upper level administration to embrace some of the things that you've suggested even in the current structure, and if we do go forward with implementing some of the recommendations, the educational module on a more broad base and certainly the template approach that you've suggested, Gary, do you recommend a different mechanism for getting an appropriate level of support and visibility both from the institutional level and from a national level?

And then my second question, I'm sorry, I'll repeat it again if we need to, but as we've talked the last couple days just almost very intensively about education, we saw a very compelling slide from Dr. Miller about his day, and we also know that there are, this is only a very small subset of the things that researchers need to be

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educated on, there are certainly people in the room that would say that there is grants and contracts issues, there is other environmental health and safety issues, how do you propose, how do we create the time for this kind of thoughtful and actual retention of some of these issues that create the kind of thoughtful careful researchers we're after?

DR. MILLER: When I've talked to the administration at Emory and remarked about some of the troubles in investigators getting their science done, a lot of these regulations and compliance issues, and have ideas on how to solve them, they were very supportive because they hear these things all the time. And so I think it's very much this consumer friendly and consumer oriented approach to saying how can we help the investigators and I think that for example, the example of the website, you have something that's useful to an investigator, that can solve their problems, they're going to be much more amenable to being told that they have to do it that way. If you say, the administration just says we have this new policy, all investigators have to go through this checklist

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on this website to determine if they have dual use issues, if they have infectious agents, and it's done in a professional way that I think you'll get better buy in when it's done in that fashion. And it's actually something we're now trying to develop at Emory as a way to capture those things, a lot of people slip through the cracks because they may not apply for an IBC approval or something else and how can we get all the labs to at least go through some level of registration to identify what the potential concerns are.

MS. BURNETT: Do you feel that the researchers are advocating putting the staff in place in the university setting to provide that support? Because that takes, a website doesn't just automatically appear --

DR. MILLER: Right, again it seemed that in talking to the investigators at Emory they all said there's a need for this and all the investigators seemed to think that's part of what those indirect and FAA costs are for, they're to support the research and so they tell the deans and chairs this is something we need and so far they've been responding at Emory. Now I don't know how other

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places will be but that's certainly been the situation.

DR. COOK-DEEGAN: I guess my sense is that education and codes of conduct in the kind of first level, those are always necessary but never sufficient, so they're really important so I don't mean to downplay that at all so that's where the attention has gone first. It seems to me this is an area where we're kind of trying to decide how high to escalate it, so we could go all the way up to regulations and certification, accreditation is an intermediate step, I think we're trying to figure out how far on the oversight and real oversight to go. It seems to me the place where the action is right now is when you're asking for money to do research you have to jump through certain hoops and those hoops are the places that we're really configuring those hoops and asking investigators to make sure that they've thought about certain features of their research that they might not have thought about before, that is how it might be misused, that is going to be part of the process of applying for resources to do what they want to do. And that's kind of where we are right now, we could go up another level if it becomes important

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enough.

DR. MILLER: What we're trying to do is we're trying to add new hoops at Emory but at the same time making it easier to navigate all the existing ones and consolidate them, so in kind of adding more effort but then trying to make it easier for the investigator so they say this seems like a better system.

DR. GILMAN: On a historical note I'd just remind us of a little more than a decade ago as we went through the process of discussion on scientific conduct or misconduct and the discussion of the need for coursework in the universities and the like and training, pretty much that discussion, pretty much that infrastructure disappeared when Congressman Dingle stopped writing letters to the Academy. Your notion of how far do you crank it up, how useful do you make it to make it have the inertia to keep going, is an important one I think.

DR. COOK-DEEGAN: One other comment on that, there is one option that I just don't know how powerful it is and it's the one that the genome project chose which was to indulge in a massive experiment in the Matthew effect,

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that is to provide a stream of funding for paying attention to what was going on in the science and the application of the science as it was going on, I personally believe that that actually changed the direction that things went because there were people out there who were being paid to think about issues that were about policy, ethics and law in addition to the science. I think that probably changed the outcomes but I cannot prove that. That is a, that's a policy option that's available, it has been tried but I don't know how you know how powerful that mechanism is.

MR. FISHER: This is a couple of comments and then a question to Gary and the other panelists, I'm Don Fisher and I head up our export control practice at Price Waterhouse Coopers out of San Francisco and we've been asked by several clients in the biosciences pharma area, biotechnology, to try to correlate some of the dual use applications that we talked about yesterday to the existing ECCN, export control commodity number system on the commerce side. And Bob, to your point, what we are finding is that the way that the ECCN is currently structured is really about tangible items that we already know about and

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that the concerns on the part of this industry group really speak to evolving applications and experiments, and quite clearly those which are going to be collaborative internationally, there's no question about it. And so to the comment that as we go forward we might ask the question how does the existing CCL or commerce control list get reframed to take into account these evolving applications on the dual use science side.

Likewise in terms of foreign availability, we have historically defined that really from a licensing standpoint whereas to say if there is some foreign availability to an item or a technology we will take that into account or the government will take that into account in terms of whether to grant a license to export a controlled item. And now I think what we're saying is that this foreign availability issue goes way beyond the licensing permission context and it really speaks to the definition of what's controlled and not controlled at the threshold let alone whether or not the government would actually grant a license for something.

So my question first to Gary is has the center

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looked at making this correlation between the dual use biosciences side that we've spoken of and the existing ECCN? And secondly, has it focused or attempted to quantify foreign availability of some of the dual use sciences for purposes of this export control framework?

MR. BERTSCH: These are important issues that you've identified and no, we haven't, I think that they require attention, I think they've gotten the most attention in the U.S. government and perhaps the Undersecretary can refer to this in his remarks. But these are the kinds of things that need to be known and factored in and addressed in a policy for the 21st century.

DR. GARTON: I would be remiss as a university official who signs the indirect cost proposal if I didn't follow up on the questions, the comments, and really remind the committee that these costs in general fall under the capped component of the indirect cost rate. These are new requirements for the institution, as we've noted a couple of times here the pie isn't getting any bigger, the direct cost pie on which that indirect cost is calculated isn't getting a lot bigger nationwide, and so as we seek to do

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these educational programs which I agree are the core of what we have to do, and invent systems and put out websites and come up with the control mechanisms that ensure compliance at universities with all of these various regulations, we're doing it with no additional funding and in order to do them we have to take funding away from something else that's important to do, or we have to come up with a different way to pay for these programs. And I do like the suggestion that we follow the genomics model and look at a body of research in the law and societal implications of what we're doing as we create these programs.

DR. GILMAN: Any other questions from the committee? From the audience? Any closing comments from the panel? Okay, thank you.

-- [Applause.] --

DR. GANSLER: We're going to take a 15 minute break, we'll be back at 11:00 please.

[Brief break.]

DR. GANSLER: Okay, we're really very pleased to have the Honorable David McCormick here, Dave as you all

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know is the Undersecretary of Commerce for Industry and Security and he's been in that job for only eight months and I'm not ashamed to say this in front of Dave, I think he's been a really terrific person in coming into a new position with a highly controversial activity having already preceded him with a lot of the draft deemed export control documents coming out from both Commerce and DOD, and he's gone way out of his way to in that short time period to ask for inputs from universities and elsewhere, and then besides even listening to them which has certainly impressed many of us in terms of the impact that he has had in a very short time period in terms of responding to these discussions that he has requested and been very open in listening to.

I think it's important to actually read you the description of what his office is doing, this is the Bureau of Industry and Security, its charter says advancing U.S. national security, foreign policy and economic objectives by ensuring an effective export control and treaty compliance system, and promoting continued U.S. strategic technology leadership, so it's very encompassing and I

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might say very challenging. And then the question is how does the government in toto help and support such an organization and that's one of the challenges I think that Dave has.

Normally we don't read the resumes but I think it's important to have a little bit of a feeling for his background coming into this position, he was president and CEO of two publicly traded software and services companies, so he's got industrial experience. He also was an officer in the U.S. Army and a veteran of the first Gulf War, and from a university perspective he has an undergraduate from the military academy West Point and then also a masters and Ph.D. from the Woodrow Wilson School of Public International Affairs at Princeton, so he's got significant academic exposure as well. And that combination of the industry, academic and government is what all of us have been talking about in terms of this need for dialogue in the changed 21st century environment.

So with that, Dave, you're on.

Agenda Item: Deemed Exports and Academic

Research

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DR. MCCORMICK: Well I am happy to be here today, thank you all for the invitation and thank you for making time, I guess I'm the last speaker which isn't always the most enviable position but I hope I can make it worth your while.

As I was listening to some of the comments and concerns that were raised here I was thinking to myself I wonder what the Undersecretary is going to say as well and I really came to talk primarily about deemed exports because I know that's an issue that's of great interest to this group, but maybe I could comment a little bit on export controls more broadly. And I should probably start by just thanking and congratulating this committee for the role that you're playing in bringing groups like this together and talking about these issues and thinking through the balance and the tradeoffs involved with national security and science and economic interests more broadly. You don't have to read too much in the newspapers these days to come across issues like Dubai Ports and the question of foreign direct investment, the civil nuclear deal that's been proposed with India, high technology

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trades with China, and of course deemed exports to realize that this question of how economic interests and national security interests come together is really one of the most pronounced and important issues that we're dealing with as a country right now and deemed exports is certainly a critical part of that discussion and so often when you read about this it's presented as either/or, it's presented as a zero sum game, you can have one at the expense of the other, and sometimes that's the case but I think rarely the case and I certainly don't think it's the case with export controls.

I was nominated in the summer of last year and was living in Pittsburgh, one of my board members on my company was a fellow named Jerry Cohen who is also the president of CMU and we were having a great lunch and went through sort of all the different topics on our agenda and I was getting ready to move to Washington and I was just getting ready to leave he said oh one thing I want to mention, it's this issue of deemed exports. And I said I've never heard of this, what is this deemed export thing. And he described to me in some details some of the concerns

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that the university community had and I thought about it for a minute and I remember thinking to myself, I didn't say this to Jerry but I remember thinking to myself that really doesn't seem that complicated, it seems pretty straightforward, and I was hoping to be confirmed in October which I eventually was and I thought hopefully we can get that behind us by the end of the year and then we'll be able to move on with more significant and more challenging issues.

Well, as I think with most people coming from the private sector to government I soon learned that this was much more complicated than I had once thought, and I think much more important and really a significant question, not only for the academic community for the research community but also from a national security perspective. I spent a lot of time between October and December, January, February timeframe talking with some of the people in this room about the issue, just listening, trying to understand, trying to learn about the various facets of this question. And I came away with a set of observations, which I call observations of a newcomer.

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The first observation with regard to deemed exports was that this is really a legitimate issue where people regardless of what side they come down on this recognize it's really important and something that they want to invest time and energy in getting right, which is encouraging.

The second observation was that this is a very contentious issue and I think fortunately not partisan, this isn't a political issue, it is an ideological issue in many ways for many people but as I sort of jumped into the middle of deemed export question it really felt very quickly like we had lost, we I mean all of us had lost in some ways the forest through the trees. And there were volleys of letters going back between various constituencies on the definitions of the regulations and the interpretation and and versus or sorts of questions, all very important from a regulatory standpoint but I think begged some very basic questions about our policy objectives, what are we trying to accomplish, how should we be thinking about accomplishing that and then how do regulations change, be altered to reflect those policy

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objectives. And so we had lost sight of that I think in a very real way.

And part of the challenge around the debate was that there's really some widely held misperceptions, in part because this is a really hard thing to communicate, it's very new to most people in academia, to most people in industry, there hadn't been a lot of dialogue, there certainly hadn't been a structured dialogue in terms of making sure there was great communication. And as I hope you'll leave this discussion with I think there was a sense this was zero sum when I don't think it needs to be.

Finally there was I think a recognition, everybody said collaboration between the different constituencies, academia, industry and the government was really critical to getting this right but I think if you were very objective about it there wasn't a whole lot of collaboration.

And so that was where things were January, February of 2005 and when we stepped back and tried to look at the forest there was really a fundamental policy question, and the policy question is given that there is a

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national security issue here, given that there is, and I hope I can make this case to you, a reason to really focus on this issue and have concern about some very real risk from a national security standpoint, how do we address those risks from a policy standpoint, from a regulatory standpoint eventually, in a way that doesn't jeopardize what has made our country the leader in technology, the leader in research, in the leader in the finest universities in the world, the leader in the finest most innovative companies in the world. And how does one advance both interests without jeopardizing one at the expense of the other.

And I'm happy to say I think that this is not a question that's unique to the United States, it's a very real question that is at the forefront of people who have these same sorts of responsibility in lots of other places. I was in Japan last week and had a very interesting discussion to my surprise on deemed exports with the Japanese. This is a major issue in Taiwan, this is a major issue in Australia, major issue in New Zealand, there's been some press recently in both of those places. So this

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is something that many people, many countries, many policy makers, are struggling with. And the reason they're struggling with it as I said is because of the significance of the issue, the threat is real in many cases, and the risk or implications of getting it wrong are very, very significant.

Let me talk a little bit about the threat because when I meet with many of you and your colleagues there's a lot of push on is there a real threat, tell us about it, quantify it. For those of you that have spent time around intelligence in your careers that's inevitably a tough thing to do because intelligence is never as clear cut as you want it to be but I did prepare a presentation for the Higher Education National Security Advisory Committee that the FBI has launched with a number of academic leaders that have intelligence clearances and so I was able to share with them in some detail some of the intelligence around the deemed export issue. I won't obviously be able to do that today but I can just share a couple high level statistics which I think are interesting.

This question of technology transfer, and I'm

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speaking now particularly about for national security reasons, not from an economic espionage standpoint, but this issue really has become an area of focus over the last four or five years, and if you look at the FBI caseload, for example, that caseload in this area has gone up very dramatically. In our particular part of the Commerce Department we have agents that work with the FBI, work with the university community in this particular area and there's also real growth again in large part due to the focus in the number of deemed export cases that are under investigation. And there's some high profile cases which some of you are probably aware of where there's been issues of technology transfer or deemed export violations within industry but also in the academic environment.

With all that said there's not, and finally, probably something that I should note, is that there's been Congressional testimony, unclassified Congressional testimony by a number of intelligence executives in the intelligence community that have noted very systematic programmatic efforts by certain countries to use researchers, visiting business people, visiting students,

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postdoc students, to ascertain or eventually repatriate elicited technology. So there's a body of evidence. Is that evidence ironclad? Is it widespread? The answer is certainly no but I think there's enough evidence here to suggest that we need to be thinking about this in a very focused way and working together collaboratively to address whatever national security threats there are. And this is obviously a priority from a national security perspective, if you think about it from an academic leadership standpoint, from a research leadership standpoint, there's reliability associated with getting this wrong.

Now of course the other side of this and something that was captured in great volume but the response to the IG report were the concerns of the academic community particularly industry but primarily the academic community around some of the suggestions and possible changes on the deemed export policy. And in particular the academic community, or the research community I should say, focused in on three main policy concerns. The first was that any of the changes that were being recommended would ultimately impede innovation, it would impede research, it

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would place restrictions on activities in the future that aren't restricted today and in doing so undermine the research enterprise.

The second piece of concern or second critique was that this would be costly, be very expensive, I heard some of that today already that rolling out incremental compliance programs and everything associated with deemed exports would just place a burden on our universities which would be too much given the relative benefit, incremental benefit we'd get in national security from some of the measures that were being considered.

And the final concern and I think this one is something we all feel right now as Americans is the concern that the messages we've been sending or could send through some of these changes would ultimately serve as a deterrent to foreign nationals who are coming to the United States and are really in many ways the lifeblood of our leading edge research, the numbers are staggering as all of you know in terms of the dependence we have on being the magnet for some of the world's best brains to come to our great universities and our companies to do their research.

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So this is the backdrop for that along with some of the feedback that I've received for our decisions in terms of the road ahead. And quite simply there were four or five things that became obvious priorities for the administration and for those of us that are involved in this particular issue.

The first was to really create a very open dialogue and I've probably spearheaded that as much as anyone but just reaching out to leaders across the research community in a variety of capacities, roundtable sessions like this, numerous meetings with the National Academies, numerous meetings with AAU, numerous meetings with a variety of individuals and groups that have an interest in this issue and begin a dialogue. And that's really based on the belief that any answer we ultimately to get to from a policy standpoint is going to need leadership from this community to make it work, and buy-in from this community to make it work, so we've really done a lot of outreach. We've actually had about 100 if you can believe it, this is completely separate from me, 100 outreach events in the last 12 months where we've had people from the Department

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of Commerce go out and try to meet with individuals or groups in the research community, either on industry side or the academic side, there's actually one happening this week at RIT.

The second thing we've done is try to invest in this question of deemed exports so one of the things, there was an IG report which I haven't spent time talking about and I won't get into here, other than to say the IG report recommended a number of regulatory changes in this area, and that was sort of what got this ball rolling, but it also recommended investment and focus from the U.S. government on this issue. And so we've invested, we actually have a line item in our budget where we've invested in outreach, invested in working with the FBI and the Higher Education National Security Committee to talk about these issues and try to create a better level of understanding between these various communities.

The third thing we did was we decided to put a hold, it's not even really the right way to say it, we decided not to implement the IG's recommendations which had a series of regulatory changes that were recommended. And

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the primary reason for that was because the conclusion that we had drawn was that whether those specific regulatory changes were wise or not wise they sort of missed the broader question, and this broader question really needed to be thought through in a very different way than we've been thinking about it in the past. And ultimately that may result in some regulatory changes but let's not put the cart before the horse, let's step back and ask some more fundamental policy questions before we go forward with any sorts of regulatory changes.

Which brings me to my fourth point which is that we decided to create a vehicle, a group, a body, outside the U.S. government to advise us on this policy, not advise on the recommendations but advise on this policy. And so we announced last week or the week before, they've all sort of started to run together, that we've created a federal advisory committee. And for those of you that have been around government research this is probably not unfamiliar to you, it's something that is ultimately launched by the Secretary of Commerce with White House approval that will be 12 we think and believe very distinguished individuals

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that will be selected to participate in this group.

We would hope and expect that there will be representation from the academic community and we said that explicitly in the notice. We would hope and expect there will be representation from industry and given some of the interest that's been expressed already I think both of those communities will be very well represented. And we also hope to have representatives from the intelligence community, representatives from those that have worked in the Department of Defense and sort of understand that aspect of this issue. And also we hope people who are very knowledgeable about or at least have worked in or have real insight into our national labs which is another dimension of this issue.

So the idea is to bring together not 12 like minded people but 12 very thoughtful, very credible, very distinguished individuals that will have had together a combination of experiences that will really inform this question. And we'll have credentials that not only satisfy those of you in this room as very credible people, scientists, individuals that understand the research

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enterprise, but also as individuals that understand the national security dimension of this.

That group will have a 12 month time period to come back to the Secretary of Commerce and to come to me with a set of recommendations and what we've asked in that initial mandate that we've defined, again this group is in the process of being selected, the final submissions have to be closed by July 21st, the mandate is to really come back to the Secretary of Commerce with recommendations on deemed export policy, not deemed export regulations. They may include regulatory recommendations but it's deemed export policy and I'm often pushed on this well what does that mean exactly. And this group really has the mandate to ask more fundamental questions, to get back to first principles, so some of those, let me just throw out what some of those questions might be and again this committee will be outside the government so they'll have the mandate to do as they wish but these are three things that just off the top of my head seemed to me to be logical questions.

The first question is how does this integrate with other processes in the United States government, the

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visa process, other regulatory processes that affect research. It seems to me that whatever our deemed export policy should be it should be integrated and thought through within the context of those others.

The second question that one might think is worth getting into is around the risk posed by foreign nationals and how does that compare to the risk posed by non-foreign nationals, and is that really the right slice on this national security dimension to be thinking about, I think that's a reasonable question and one that there's probably some data that might be looked at to explore.

The third question, one that I think was raised by Gary and some others in their comments, is this the right technology, the commerce control list is a fairly long list of technologies, the underlying premise of deemed exports is that if you export a piece of equipment and it's sitting in a factory floor in X, Y, or Z country the risk posed by that sitting on the factory floor in that country is the same as the risk of a foreign national opening up the back of it, of that piece of equipment, to do some sort of maintenance upgrade and then closing the back of it and

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then going back to their research. Oversimplified but there's an underlying assumption that those two situations are fairly consistent from a national security standpoint, it's a reasonable question to ask, is that really the right way to think about it.

So I'm sure there are many other questions that this group will undertake and we hope they will take their mandate as one which really allows them to step back, given their wisdom, given their experience, and come back to the government with a real set of recommendations. The one thing that I think is somewhat unique about this group is that the individuals that will participate will have to have security clearances because I think to really tackle this issue credibly and effectively one has to spend some time with the intelligence and really understand to the extent that the intelligence can tell us this what the risks are and how we might best address them.

I'm excited about this, there is I think, those that have served in Washington before, I'm not one of them but those that have served tell me there's a long tradition of creating committees to get around a hard issue and then

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hopefully those things die on the vine and nothing happens. That's not what this is about, this is really intended and I'm very hopeful that we will be able to come at this issue in a new way and one that really does satisfy national security concerns, which again I think are very legitimate in this issue. But also the very, very real need to make sure that whatever actions we take they're not standing in the way of our innovation, our invention, our creation in our research universities and our universities more broadly and in industry. So I'm hopeful that this will be the right, this will lay the groundwork for us to be able to do that.

Let me stop there and I'm happy to answer any questions you might have about deemed exports, about export controls in general, I've only taken a small slice of some of the things we're working on today but it's the slice that I thought was probably most relevant to this group.

-- [applause.] --

Agenda Item: Discussion

DR. GANSLER: To stay consistent with what we've been doing let me ask the committee first if they have any

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questions for Dave and then we'll throw it open to the rest of the group. Let me start, one of the things that we've heard, Dave, both here, in fact you heard it with Gary's talk at the end and we heard it also at MIT, that in order to address the deemed export issue we need to put it into the context of an overall export control policy that would recognize the really dramatic differences in the 21st century environment, the distribution of technology around the world, the life science issues and so forth. And so it's going to be hard for this committee to address the subset without addressing the set and is there someplace that people are in fact going to be addressing from the government perspective the overall next generation in export control policies?

DR. MCCORMICK: Thanks for the question. Well, I'm not sure I agree with you on that, it's hard to cut this piece out. I actually think that if there's any aspect of export controls more broadly that lends itself to be able to talk, to be able to be thinking about it distinct from our overall export control system I would argue this is the place because it really is a fairly

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unique dimension of our export control policy. There's a very conscious effort on my part here where you could try to create a mechanism to solve export controls more broadly or even export controls across the entire government, not just dual use but ITAR and really address a whole broad set of issues. It felt to me like that had a lot of risk associated with it in terms of not getting anything done where this was a big enough issue that my sense is we've got, its got people's attention at the highest levels, certainly at the highest levels of the U.S. government, in Congress, at the highest levels of the research environment, this is on everybody's radar. So it's big, it's important, if we get it wrong we really screw things up. Therefore if we come out of this with a group that's made credible recommendations, that can speak with great integrity and credibility on what they think we should do, and we can actually make something happen, that I hope begins to lay the groundwork for a set of more fundamental questions.

Just going back to some of Gary's comments, the way I think about this is there's a whole regulatory,

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there's a whole set of statutory issues, there's a whole set of political issues and Congressional issues in terms of changing export controls, I look at this, the metaphor I use is this is a car, I've inherited a used car, it's in many ways broken down, it's designed for the highway, we're taking it off-road, this is an imperfect car. However it's the car that I've been asked to drive and so I think our mandate is to try to drive that car very intelligently and make whatever adjustments we can within the framework we have, that's one responsibility.

The other responsibility is to step back and say what should the new car look like, and so I don't want fixing the car we have as best as we can given the constraints we have to stand in the way of designing the new car or vice versa. Now I do think, and I'm hopeful there's the beginning of some interesting things happening on the broader export control reform front. I am in conversations about this regularly and you have some major industry groups that are very interested in this, this community is very interested in this, you have a set of Congressional dynamics which I think potentially bring this

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more to the forefront, and you have a Presidential campaign in the not so distant future all of which could be a confluence of events that might lay the groundwork for something more substantive, but I don't want that to stand in the way of trying to improve what we have.

And I'm also concerned that if we fix everything right away then Gary and his center are not going to have anything to write about and we want to make sure that we don't take away that opportunity.

DR. GANSLER: I wasn't viewing it as an either/or but making sure that that bigger, address the next generation of cars.

DR. GAST: David, thank you again very much for coming today and also for all your efforts and all your discussions with many of us in the academic community. I don't want to ask a question that tries to presuppose what the committee will find but of course we are very interested in these questions, I think you've posed three very excellent questions. And I just wanted to get your perspective on your first question about how export, deemed export policy integrates with other processes, e.g., visas,

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etc., and clearly that's something for the committee to address carefully but I guess I'd like from the Department of Commerce perspective to understand how you view the integration in relationships between the other agencies that are responsible for things like visas. And as you know the academic community has often said things like we want, if a student has a valid visa, they're in the country legally, they should have open access to all our open and unclassified work and we don't want to be putting up secondary barriers and restrictions, so one can push it off to the visa decision but it strikes me that there has to be mutual trust then between the State Department, the Department of Homeland Security, the Department of Commerce, the Department of Defense, and we as a community really want to understand and know that these agencies and departments are able to work together towards some sort of common --

DR. MCCORMICK: I think it's a great question, I would differentiate for the sake of this discussion sort of a spirit of collaboration of working together from processes that are integrated, and let me try to tease that

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out a bit. The Commerce Department informs the visa mantis program, there's a lot of sharing of information and data on that, there's absolutely left hand talking to the right hand in a very coherent way. There's no formal integration of a deemed export licensing process for a foreign national in a lab at MIT that's in any way linked to my knowledge with a visa approval process.

Now part of the reason for that as I understand it is that there's an inability in some cases, in some instances, to be able to be specific. As you know deemed export equipment is technology specific and so when someone applies for a visa just from a process standpoint there's not necessarily the clarity of I would need these three deemed export licenses to be able to conduct the work that I'll be doing 12 months from now. So there's a very real question of timing and the way the processes and systems are set up today it's in sequence, you get the visa approval and then six months later someone says oh they need deemed export license to be able to do this.

The reason I raise the question is it seems to me that for many of these people there is clarity on what

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they're going to be doing, certainly for industry hires, someone that's coming for industry, an industry visa who knows exactly the position and what lab, the whole set, the portfolio, they're hired in many cases a specific portfolio, and I would suspect in academia as well there is more clarity.

And so it just begs the question if we're going to go through that process is there a way to do those together and is there a mechanism by which we might be able to establish that and in doing so I think there's not only the benefit of just streamlining but there's a real perceptual benefit, impact benefit, on our foreign nationals that sort of feel like they've just gone through one hoop after another to participate in very legitimate research all of which gets approved at the end of the day in many cases so how do we minimize that burden on them as well.

DR. GAST: So let me be a little more pointed and these views are not part of the National Research Council's views, I'm not representing anybody but to say that some perceptions that are out there, that some of the concerns

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and activity on export controls were driven by a mistrust of the visa process, that the visa process was letting some of the bad guys or wrong people in, the visa mantis process was like Swiss cheese, things like that you hear in the street. And I guess I just, there seems to be the need for collaboration and cooperation but also mutual respect and trust of the processes and them serving their roles so that it doesn't have to be a secondary mechanism to try to do something to make for a deficiency on this.

DR. MCCORMICK: I don't think that's true, and I'm new to this, but let me tell you the history of this as I understand it, it's very interesting bureaucratic history of how this issue became as prominent as it is, I think it's actually positive that it's as prominent as it is, I think it's unfortunately the way it came to this position of prominence. But there's an ongoing requirement that was passed by Congress in 1998 that every single year the Department of Commerce, Department of State, Defense of Defense, have an IG study of export controls and so we're six or seven years into that eight year commitment and the topic that was selected in 2004 was deemed exports. And it

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wasn't based on any, it's based on the fact that they've explored just about every other dimension of our organization, this was one of them that they hadn't. And the IG report elevated this issue by saying, and I think appropriately, that there was a really significant disconnect in terms of how industry was interpreting the regulations, how academia was interpreting the regulations, and how the U.S. government was enforcing and communicating, so it really highlight the issue and they made a series of recommendations. And I actually for the most part think that that was a fairly narrowly conceived set of recommendations and based on the fact that a group of IG investigators came out and did their report I don't think there's any linkage.

Now I think there should be linkage in some of the more constructive ways that I talked about, I think we should at least explore whether there's linkage. But I certainly know from my eight months here that there's never been, we're doing any of this because we don't trust an existing process, it's all we're now sort of trying to dig our way out of an IG report that was thrown out there and

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we're trying to respond in a way that's constructive to the recommendations.

DR. GANSLER: Actually two IG reports. My comment on where the DOD stands relative to the activity that you've initiated, is that going to be part of this committee?

DR. MCCORMICK: It's closely coordinated, it's not part of this committee although the committee will have the opportunity to call upon various parts of the U.S. government to comment on their processes and some of the things associated with that. I don't want to comment on what DOD is going to do, I was at a meeting that the National Academies hosted recently where the DOD talked about a draft rule that was currently being reviewed by various people in the academic community and in industry, so that's the state of it as far as I know but I don't think its been published.

DR. IMPERIALE: I think that a few times now we've gotten a sense on this committee from things we've heard that people are looking at national security and economic security as not necessarily overlapping and the

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examples you gave of the increase in threats, you specifically said those were to national security, not economic security. And so the question is how are you really thinking about these things and aren't the two really intertwined and is that going to be incorporated into how this advisory panel works?

DR. MCCORMICK: Well, here's the way I would represent it, certainly the export controls we have today are oriented for national security purposes as Gary said, there's not, we don't put controls on things to protect them from other countries gaining a competitive advantage. In fact quite the converse, the conversation I have nine times out of ten with industry is that our export controls are making them uncompetitive relative to others in the industry because they view us as more restrictive than other countries. So the focus of our efforts with export controls is very much around the national security dimension.

Now I think there's, to be thoughtful and appropriately balanced in how we execute those national security export controls we need to recognize that if we're

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overly restrictive we ultimately undermine our competitiveness, we undermine research and innovation, we undermine all the things that give us economic security in the long run. So while our export controls aren't seeking to give us economic security if we're not appropriately focused and targeted with those national security controls we'll ultimately undermine our competitiveness and our economic security and that's the balance that we're seeking to strike. And there have been examples of cases where our export controls have been overly restrictive relative to the mass market for national security reasons and ultimately we've lost a competitive position, in industry we've lost share, market share, we put less money in R&D from a U.S. industry standpoint, and so it has undermined our economic security in the longer run.

DR. GANSLER: The infrared example that you've used periodically is one of those.

DR. MCCORMICK: Yeah, that's right.

DR. GANSLER: Any other members of the committee, John?

GENERAL GORDON: David, one of the problems other

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boards like this have had of sort of getting a broad representation, both an ideology and politics, do you have any new assurances that we're actually going to be able to do that? They tend sometimes in all administrations to get a bit skewed --

DR. MCCORMICK: In terms of the members of this committee, yeah, the way the process works is that individuals submit their interest and we are early in that process of that submission so it's a 60 day period that is open for people to submit and then based on the group of individuals that submit their interest then we're able to actively consider their application. I think it's early so we've had some applications, not many, I would have to say that just given the breadth of the conversations I've had on this issue and given the profile of the people that have expressed an interest in the issue, not necessarily the committee because I'm not able to talk explicitly about the committee, but given, I actively encouraged them to apply to the committee, I have limitations on what I can say on that, but given the level of interest on a variety of sides of this issue I think we're going to have a very, very

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important group of people, experienced group of people that will participate, and I think it will represent all sides of it. But the people that have been most vocal and the most interested in this frankly are the people in this room and people in industry who are most concerned about it, the under representation is from the folks that are more on the security side of it, not to present it quite like that but clearly its been industry and academia that have been most interested in participated. If there's any weakness in our representation potentially in the future I think it's going to be people that say boy, the national security risks here are more severe then perhaps some are giving credit to. So we need to actively encourage people to participate with those perspectives as well. It won't be helpful if we're in violent agreement, if the group's in violent agreement from the first day.

MS. NORRIS: On a separate but related topic, when the Commerce Department withdrew the proposed regulations that came out of the IG report there was some comment in that withdrawal about the role and the importance or lack thereof of NSDD-189 and the fact that

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you haven't mentioned NSDD-189 at all poses a question and that is is that a topic of interest or concern about whether it should or would be revisited.

DR. MCCORMICK: Well, I was hoping we could get through this without talking about that. I think that will be something for the committee to consider, I think there are a variety of interpretations of that, I know this group probably has a pretty uniform interpretation but I think it's worthy of consideration for this group and I think it's worthy, this group I would hope would be very hard nosed about not taking anything for granted and sort of starting with first principles, what's the policy objective, what are we trying to accomplish, and how do we do that in a way that protects national security and doesn't undermine innovation. So from my standpoint, and again this committee will ultimately do as it chooses to do because that's the nature of these, but I would hope that nothing starts, I would hope it starts with nothing as sort of a prerequisite and ask some fundamental questions about every aspect of this. That's not meant to prejudge it, that's not meant to say I have any particular views on

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that, but I just think it's important from an integrity of the process to start with that basic premise.

DR. GANSLER: Okay, let me throw it open to the floor now.

DR. FISHER: It strikes me that when we on the industry side apply for licenses, for example for the transmission of hardware technical data to China and India, naturally Commerce and Defense are concerned about the recipients and the downstream recipients and there's a fair amount of intelligence on their part that goes into that wall between a commercial application in those countries and a potential military application. And it strikes me that from the academic perspective given the future of international collaboration in the dual use biosciences, which I think is of critical concern to the academic community, it will require an extraordinary level of government intelligence by the United States about how the dual use collaborative information is received and managed from the international side. So for example if there's collaboration in China and collaboration in India who are the scientists and physicians in those countries that would

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be a party to this collaborative work.

And then if I think about how critical it would be to know that in order for the research to occur it starts, it speaks to the definition of what our national security will look like from a bioscience standpoint. So my question is do you foresee from the government standpoint a stepped up level of intelligence as to the science side of those governments because to say that China is the bad guy, or India is the bad guy which we hear all the time from DOD, and not really understand what the academic communities in those countries are doing seems to me to defeat the purpose.

DR. MCCORMICK: Well first of all I don't think the Administration has said India is the bad guy, in fact quite to the contrary I think the Administration has said India is a country that we're developing a strategic partnership with and that the data on technology sharing and collaboration would support that, so I don't know where the India thing is coming from.

With regard to China I think the DOD report is very clear, that China is not the bad guy, China is not an

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adversary, China is a great opportunity and we are working with China to try to encourage China to address some of the concerns we have, namely around the lack of transparency of its military and the build up of its military. But we tried to say that we want to do that in a way that strengthens the ties and strengthens high tech trade between our two countries, and again the numbers would suggest that high tech trade has grown by 50 percent in the last three years with China.

So I think that these two approaches, these two countries and the way we're approaching them are miscast in the press sometimes unfortunately. In both cases I think and in all cases we want better intelligence and so there's a very active effort, part of being refined and targeted with our export controls is understanding to whom the technology is going and ultimately if you want to stop sort of making blunt assessments of this country gets this or that country gets that, then you're going to have to be more refined and refinement requires confidence that the end users you're sending things to are ultimately, one, they're going to use it for civilian purposes and not

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transfer it to third parties or use it for military reasons.

And so intelligence is a key part of that, there's also innovative things that we can do to try to build that transparency and confidence so for example we have an end use visit understanding with China where we ultimately work with the Chinese to go inspect technology that's been transferred to make sure it's being used for the purposes that were agreed upon. And I was in China two weeks ago and I visited a super computer from IBM that was being used for meteorological purposes, very legitimate use of that computer and that's the kind of thing we want to encourage. So yes on more refined intelligence, yes on a more focused approach to who gets what, and no to China or India being the bad guy, I don't think that's an accurate representation.

DR. WEPFER: David, can you share with us the opportunities that you might see about more self regulation on export controls, both within the business and academic communities. I know government will always have an important role in this but can you conceive of more being

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done at the lower levels?

DR. MCCORMICK: Yeah, thanks for that question. I can conceive of it and in fact I think of both industry and the academic world as being sort of the front line of defense and the front line of any export control system that we're going to have, and I think creating the right collaborative relationship with those constituencies and having them assume a greater level of responsibility is better, more effective, ultimately I'm skeptical of the ability of the government to regulate everything and I'm fearful if we try to regulate everything we'll ultimately regulate nothing so that's the philosophical disposition that I have.

And I have to say just in the spirit of candor this is typically a one way discussion with academia and with industry. The discussion starts with export controls are stupid and make no sense and how do we figure out how to get rid of them and that's the same way with industry, there's always the question of how do we liberalize rather than what I think would be a much more constructive and valuable contribution which would be listen, we recognize

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that there may be national security issues at stake here, here are a set of recommendations that both advance the national security aspect of this and reduce the burden on industry, eliminate the burden on industry, allow us to be more competitive. And those recommendations grounded in data are very rare and that's why I'm so encouraged by this group because I think this group could be a group that makes recommendations that are based in fact and based on an appreciate for the national security dimension as well as the science and innovation dimension. But in terms of cooperation, cooperation is a two way street and it requires objectively on both sides of it and that's what I'm trying to do is create a mechanism by which we get that.

DR. GANSLER: One of the questions that has come up a number of times is the point of where within the government does this balance get addressed, and when we talked you asked the question was there anyone in the Defense Department who cared about economic security and when we go to the other extreme we find even today that the FBI is trying to press and many of the universities are now

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finding much more pressure coming from the FBI side in terms of foreign students, foreign scholars, without seeing the balance there because their job is basically enforcement and not to look at the bigger picture. Do you see the need for or is anything happening on this general question of the federal government perspective needing to change again in view of the way the world is today?

DR. MCCORMICK: Well, there's different aspects of this question of how security and economic interests come together, I think the presence of the American Competitiveness Initiative is an acknowledgement that our competitiveness is dependent on things like foreign nationals playing a very crucial role in innovation, critical foreign direct investment and continued flow of capital ways is an important part of that. So I do think that there's clearly recognition from a leadership standpoint, it kind of goes back to the back that Alice made before where it's tough to wave a magic wand and have all of this bureaucratically, you know given your service, John knows, to be integrated where there's one place in the U.S. government where these things come together.

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In the area of dual use technology I think I'm that place and I take that responsibility very seriously, not only for trying to as I said drive the car as well as possible but really lay the groundwork for a more fundamental rethinking of this and as in most things I think success in that area, which is something I at least have some control over, maybe hopefully lay the groundwork for more fundamental discussions in other areas. The cyphious(?) process as you probably know is something that's being considered by Congress, something that's being considered by the Administration in terms of how can that be appropriately modified to even better address economic security, national security, there's the dual use issue, there's the ITAR systems, so there's these different ecosystems which all cut against this question of how national security interests and economic interests come together and I'm more optimistic probably than some where I think that there's an opportunity to make real progress on it and we're certainly committed to that in our area and I think the American competitiveness initiative sort of gives us the oomph as a presidential priority to really do that

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in an effective way, I'm hopeful.

DR. COOK-DEEGAN: On your list of things that you might think about studying, one of the things that struck me is I don't think probably the open question in the academic community, I think you're right that there is a failure sometimes to appreciate the threat level but I don't think solving that problem is the thing that's most important because I think most folks in the academic community would understand that there is some threat at some level and therefore we have to pay attention to it. Rather the question would be what is the most effective way to reduce that threat and one of the things that is a danger I think in this domain is the structure of the industry, the structure of the players is completely different from computing, from car manufacturing, from all these things that we think of as historical analogies. And there are people who are making investment decisions in these technological spaces and I think involving some of those people who make those investments might be, these are the folks who are seeding companies all over the world --

DR. MCCORMICK: You mean the venture capitalists?

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DR. COOK-DEEGAN: It's a combination of VC and Angel and investment banking, so somebody with that kind of background, that's the intelligence about what's happening on a technological frontier, and they also have to be familiar with what's going on politically and probably that's a constituency you're thinking of but I think studying the industry structure that is different from the historical analogies would also be very useful.

DR. MCCORMICK: I made a note during your presentation of that very point, certainly awareness obviously, the biotechnology area in general is one that we've frankly not been that mature and evolved in terms of how we've thought about export controls, I think deemed exports is another area where it sort of cuts against conventional wisdom of how you manage things so it's a new area, there are a number of areas where we I think have in many ways a Cold War paradigm that we're trying to apply to a whole new set of technologies. Nanotechnology is another area where, which I know means lots of things, where I think we don't have a paradigm in mind, nor perhaps should we. So having that kind of representation on our FACA I

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think is, our federal advisory committee, is an important part of getting it right and thinking about those within the context of the 21st century export control system is really a critical part of this. And I don't mean to suggest in my earlier comments that the academic community is not sensitive to the national security dimension, and I think you're right, it's never eliminated, it's always minimized, I think within the context of the recommendations how do we change it. We also need insight into how we can address that while also not standing in the way of research and most of the feedback we get is how we don't stand in the way of research.

DR. GANSLER: Okay, last question because I did promise Dave we could end by 12:00.

PARTICIPANT: Hopefully the committee is going to address the junk that's been in your trunk that you've been driving around and that is the things on the list that are, that shouldn't be on the list. I've not found in academia any problem with an acceptance of the importance of national security on things that are important but on issues such as needing a license to collaborate with a

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foreign colleague to publish, to prepare an article that's going to be published in a journal in two months and disseminated around the world gives people heartburn because it seems so silly. And for example we no longer supply our offices from the U.S., we have facilities in virtually every civilized country in the world and we have laboratories and all kinds of things, we buy our stuff overseas because half of it has to have an export license and it's stuff that we have in our labs that we got from Switzerland or we got from Germany or we got from Japan and we buy it from those same places overseas and frankly you get it in country every place else yet we'd have to have licenses. The ITAR list which your committee isn't going to address is just as bad with 60 year old military technology that's on there that's readily available also every place around the world. It's those pieces that, the trivial nature of some of this that trivializes the importance of what you're trying to do that I think is the most important thing that needs to be cleaned up and hopefully your committee will address it but the other areas are maybe not going to be address.

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DR. MCCORMICK: It's a great point and I feel like the fact that, I don't think anyone would stand up here in my job and defend everything on the commerce control list, I think there's certainly things on there that are well outdated and my concern is obviously I'm trying to focus on the things that are going to make us most effective in promoting the national security as well as addressing the economic interest, probably a worthwhile case study here is the supercomputer metric which we just, and by the way the President campaigned around higher walls around fewer things specifically in his campaign speeches and trying to actually make that happen with new legislation has been a real challenge as you probably know. But the supercomputer metric is a great example, the Administration said in 1999-2000 when the President campaigned and then early in the Administration that we needed to think about a different way to evaluate supercomputers for export. And it was last month or February that the President sent to Congress the new computer metric and had sort of gone through the process and built the support to actually go do that and that gives

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you some sense of how hard it is to make changes on this thing, taking things off the list are significant and the political challenges here are significant. So to get to the kind of reform that Gary is talking about or others have talked about, it really is going to take not only the right answer analytically and rationally, it's also going to take political will and that political will is not only from the executive branch it's from the Congress and that's not a pass the buck comment, it's just a reality, we need to be working on both sides of this. And part of it, part of that discussion in the 21st century has to start with both for political reasons as well as substantive reasons how do we address the threat but in a way that recognizes how the world has changed. And that's a significant political undertaking, it's one that I think we should have some optimism about for all the reasons that I've mentioned but it's not a small thing. I hope this committee is a starting point for sort of pushing forward on that agenda, I think if we get the right people on it and we get the right output it could be.

DR. GANSLER: Well let me first of all thank you

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very much, Dave, for making the effort to come down here and address the group, and we really do genuinely appreciate it and I'm sure that others here in the audience will if they have additional comments send them to you without hesitation. But we genuinely appreciate it and again, let me thank all of you who came here for this two day session. For the committee's perspective, for Alice and I, we've definitely learned a lot and its been very valuable to us and hopefully all of you have as well and we would come from the committee's perspective additional inputs that any of you might have, not just on the problem but on suggested alternative solutions because that's the direction we need to move in order to be helpful to Dave and others in the Administration.

So again, thank you all very, very much and Dave particularly.

-- [Applause.] --

[Whereupon at 12:03 p.m. the meeting was adjourned.]

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