National Academies
The National Academy of Sciences

Improving the Use of Science in the Administrative Process

A Workshop under the Auspices of
The National Academy of Sciences'
Committee on Science, Technology, and Law
in Collaboration with
The Administrative Conference of the United States

September 10, 2012

The National Academies
Auditorium
2101 Constitution Avenue, Northwest
Washington, D.C.

Proceedings by:

CASET Associates, Ltd.
Fairfax, Virginia 22030
(703) 266-8402

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P R O C E E D I N G S (10:30 a.m.)

Agenda Item: Welcome

DR. KORN: Welcome to the National Academy of Sciences and to our newly renovated building. I am delighted to see so many people, and I am sure that more will continue to come in from across the government, scientific communities and interested stakeholder communities, as well.

My name is David Korn, and with my colleague, Richard Meserve, I have the great pleasure of co-chairing the Academy's Standing Committee on Science, Technology and Law, under who auspices this meeting is being convened. The committee, known to us as the CSTL, was established more than 12 years ago with a broad mission, namely to identify and critically examine issues that lie at the interface of science, technology and law.

Not surprisingly, these issues are typically challenging, and sometimes contentious. I am sure you would all agree that today's topic fits comfortably within this frame. The matter of how the federal agencies use and incorporate science in their decision-making processes is important to our understanding and to our acceptance of government decisions and the actions that flow from them, actions that may have great influence on our economy, our

environment, and indeed, our lives.

Critical to this understanding and acceptance are the transparency of policy formation and decision-making, and the integrity of the processes in which the agencies identify, evaluate and use the scientific information that underlies their decisions into actions. Also critical are the ways in which the agencies disclose and communicate this scientific information to their affected publics.

For many years now, CSTL has explored the numerous ways in which scientific information is used and disseminated by the three branches of our government and the implications of this for the scientific and engineering communities, our research enterprise, and our nation.

We therefore were delighted to have been asked by the Administrative Conference of the United States to provide a venue in which members drawn from the legal, scientific and policy communities could meet to discuss the draft report authored by University of Texas law professor, Wendy Wagoner, and entitled, quote, Science in the Administrative Process: A Study of Agency Decision-Making Approaches.

I would like to thank Chairman Paul Verkuil and attorney advisor Reeve Bull, both of the Administrative Conference, for their efforts in seeking this collaboration

with the National Academies. I would also like to thank the Alfred P. Sloan Foundation – and particularly Paul Joskow and Paula Olsiewski – for providing financial support for this workshop.

We were very fortunate to be able to assemble an outstanding planning committee to organize today's event. I would like to acknowledge these individuals and thank them for their efforts in putting together our agenda. The planning committee was chaired by Jonathan Samet, and included Gretchen Jacobs, Paul Locke, Alan Morrison, Sally Morton, Richard Revesz, Joe Rodricks and Richard Zeckhauser.

CSTL is committed to bringing together the scientific, legal and policy communities for fruitful discussion and debate about important issues of public policy. I am certain that given the importance of the topic, and the diverse range of individuals in the audience, today's discussions will be animated. I am hopeful that they may be successful.

It is my pleasure now to introduce Mr. Paul Verkuil, Chairman of the Administrative Conference of the United States.

DR. VERKUIL: Thank you, Dr. Korn. It is a pleasure for the Administrative Conference to be sharing

this program today. On behalf of the conference, sometimes known as ACUS, I want to thank the National Academies and the Project Steering Committee for their efforts to make today's workshop possible.

I also want to acknowledge senior fellow, Alan Morrison, who is, I know, working on the science NIS side, but also works with us obviously at the conference, and having first proposed the idea. I want to single out Gretchen Jacobs and Reeve Fuller, our staff who worked on the planning committee and have been very active in this project as it's moved forward.

A few words about how we work. As many of you know, the Administrative Conference is an independent agency that provides advice to the government, and brings together senior officials and private citizens with diverse views, to provide non-partisan expert advice to agencies, Congress and the courts in a wide range of administrative issues. In the words of President Obama, who stood this organization back up in 2010 when I had the privilege of being confirmed as the 10th chairman, ACUS is a, quote, public-private partnership designed to make the government work better.

I get a lot of laughs when I say that, what do I do, and that is what I say. Everyone says, make the

government work better? My gosh, how could you possibly think you'd ever get that done? I do feel that we not only can get it done, we are actively getting it done. We do have to be very careful about the directions we go, since we have limited resources, and there are many more problems to solve presumably than there are people to solve them at this point.

One direction we get, however, is from our statute, which in 2004 was amended as part of a reauthorization act to provide specifically that we should look into ways to improve the use of science by agencies. We have taken that Congressional brief on in this project. The conference itself is 101 voting members. I am the one, there are 10 council members and there are 90 conference members, 50 of whom are senior government officials and 40 of whom are public citizens, so-called public members, from a variety of disciplines and from various professional careers, including in the Academy and practice, and public interest organizations.

Every recommendation the conference issues goes through an elaborate process which I think it's wise to explain. We issue recommendations, which are our equivalent of rules. As many of you are familiar with agencies issuing rules, we started an early process

preparing our thoughts, having decided on a topic. The first step we take is to engage an consultant here. Of course, Wendy Waggoner, who is an expert in her field, and who came to our awareness largely because of her fine work in this science law field policy and science before we engaged her.

She prepares a report, which is how consultants operate. Then, when it gets through to the conference, we give it out to a committee, and this is a very early stage really. The committee itself is composed of various segments, there are six committees in the conference of the membership, including those who don't vote but have strong expertise in the field.

Now, that committee is a FACA committee, as you are familiar with. That means that, under the Federal Advisory Committee Act, its deliberations are open, everything is posted, including obviously the consultant's report, and any work of the committee. It is public and it is viewed. You can look it up and watch videos, so you can see it in later date if you want, and participate.

Once it hits that stage, it is out there. Yet, it is up to the committee really, with the help and direction of the staff, to formulate the recommendations. You have before you a recommendation that is still in the

process of emerging. It was the first attenuated draft that we worked on, and then we said to ourselves, well, sometimes there are so many questions that we ought to let's throw it open again and make sure we have the best possible advice. That is what we did by convening with the National Academies, this important program today.

We stayed the process, we have the draft recommendation, we stayed the process. The recommendation doesn't track, I should emphasize, necessarily the consultant's report. It is not meant to. The consultant is a starting point obviously, and then we end up with our own focus. We may narrow it, as we have in this case, to the agency use of science, and that is how we have proceeded.

Now, the committee will be working after we are through here in this fall, and several meetings have already been set up, and we will take the advice and counsel we have received, and incorporate that into the committee meeting. The chairman of the committee, Will Russell who is not here today, will be then in a position to help direct our processes.

Today's workshop is really seeking the input on your part concerning what I think are best practices. That is really where the conference does the best work it does,

by highlighting good examples used in agencies, and generalizing them across the agencies in government, that we provide a function that doesn't exist otherwise, which is for all agencies to come together as they do in one place and work on a process. That is our process. I think it is going to be well informed by the work today, and I appreciate all of the help that you will undoubtedly provide.

Now, let me take a moment just to introduce our next speaker, Richard Zeckhauser. He is our first speaker today, and is the Frank P. Ramsey Professor of Political Economy at the Harvard Kennedy School of Government. Professor Zeckhauser will offer an overview concerning the Agency's use of science, which will help set the stage for the panel discussions and deal with more specific aspects of regulatory science. Professor Zeckhauser?

Agenda Item: Enhancing the Scientific Basis of Agency Decision-Making, Richard J. Zeckhauser, Harvard Kennedy School

DR. ZECKHAUSER: I received this assignment because I wrote a memo shortly after we got the agenda, saying I think this is a wonderful agenda, but I think that we should start off by saying what is it that we're really after. I thought a little bit about what we are really

after. Particularly, I wanted to talk to you about what I would call the enshrinement of transparency in the recommendations that are before us.

On his second day of office, President Obama said government should be transparent, and republicans applauded. That sufficiently unusual event that you might wonder what is going on. Since many of us here are lawyers, not me, probably you are all familiar with probably one of the most famous statements ever made by a Supreme Court Justice, which is Justice Brandeis' comment that sunlight is the best disinfectant. That is a really great line. It is very memorable and I have used it in many of my papers, and I am sure many of the rest of you have used it at various times.

It turns out that that is very selectively true. For example, if you have murky water, adding a little bit of salt will help the disinfectant process. If you just leave a glass of water out in the sun, it will get disinfected. But if you put in lime juice, it will move six times faster. I think what we need to do is we have to figure out what is the salt and what is the lime juice. By the way, if you are getting rid of microorganisms in the house, sunlight will eventually do it, but I urge you to use Clorox.

Now, people long before Brandeis, long before President Obama, though about the virtues and liabilities of openness in government. Indeed, these were issues that were discussed at length by people at Plato to Madison. I want to make a few comments about that, since transparency gets so much support in the recommendations. I want to just raise a couple of questions about that.

First, the disclosure of everything tends to be the disclosure of nothing. I presume some of you are familiar with the very well-intentioned proposition 65 in California, which says that you have to reveal all of the carcinogens that are present. This passed just a few years ago and that has resulted in an incredible laundry list, and nobody knows what carcinogens are available. By the way, don't do woodworking because wood dust is one of them.

I am an economist. I worry about the financial meltdown. The problem with the financial meltdown was not that there wasn't tons of data available. It was that people didn't really have the ability, and including regulatory agencies, to sift through the vast mounds of data that they have to deal with. The SEC today is so burdened that it is very unlikely to find the next creative Bernie Madoff. We will continue to pile more requirements

on them and have them check forms, and go to every individual agency, but not be able to see the big picture.

I also want to suggest that what we have now, if we invoke the recommendations on transparency that are made here, could have an unfortunate evolution. I like to think of these as the ABCD evolution of what would happen under transparency. First, under A, you would advocacy. People who are interested in various outcomes would lobby to have certain elements of science included or not including, including people within the agencies.

Second is the problem of bias. I have written a lot about cost benefit analysis, and it is frequently asserted that what is easily quantified gets excess attention. The same thing is true on transparency. If we have transparency on science, and no transparency on cost, you can be sure that cost will be neglected. Now, I think in the political process, cost will actually be taken into account. What we will end up with is very cost ineffective regulations where we are saving lives or health or well-being over here at great expense, and neglecting to do it over there at much lesser expense for the same amount of effort.

Cynicism will be bred, cynicism by both the public and by personnel in the agencies. I had the

opportunity in the Kennedy and Johnson administrations to work in agencies that were supposed to deal with evaluation and systems analysis. At that point, the government passed legislation saying that all social programs had to have an evaluation done of them so that we could significantly improve outcomes.

What actually happened in many agencies, including some in which my family members and I worked, was the reports would be issued, they would come in, they would immediately be filed and nobody would look at them. Everybody would sort of laugh about the process, so I would worry about that.

And D, after advocacy, bias, cynicism is distortion. Let me just mention one example from the FDA. The FDA, a number of years back, published the mechanisms by which they figured out how much tar and nicotine was contained in cigarettes. Cigarette companies, now having understood how the FDA did it, sort of taught to the test. They figured out ways to deliver more tar and nicotine to your lungs without raising the amounts that were indicated on the test.

I think that there are some things that we have to worry about. The Administrative Conference talks about what we are trying to do is assure basic accountability of

government agencies. I would say, as an economist, that we should take cost and science into effect. We also may want to have accounting for political values, which after all, as Professor Wagner discusses, do go into regulatory decisions.

The last point that I want to make is cost doesn't get much attention in the recommendations before us. Indeed, cost doesn't get any attention. I don't just mean the cost of the citizens in the society. I mean the cost of the agencies. Agencies are supposed to, among other things, identify the scientific evidence that they didn't consider. My guess is that for many important studies, if you started the agencies working today to identify the science they didn't consider, for any single regulation, it would take them at least until this time next year to be able to do that.

There is an incredible amount of science out there, and even a well cited study may have 20 cites, 30 cites, 50 cites, 100 cites. There are 10,000 studies, I don't know how we would bother to count them. Plus, the fact that the agencies, just as I suggested, were somewhat overburdened. As any of us who have watched the budget non-compromise in the United States, we know that transparency is the enemy of compromise.

Elective transparency is the enemy of balance. Though, I think that we should evaluate these recommendations, as the administrative conference says that we should, to see basically, or at least the way I would view it, to see how well regulatory policy meets the interest of the citizens of the United States. It is not clear to me that transparency is the way to do that. Thank you.

Agenda Item: Session 1 - Use of Science in the Administrative Process: A Study of Federal Agency Decision-Making Approaches, Paul Locke, Johns Hopkins Bloomberg School of Public Health, Moderator

DR. LOCKE: Good morning. My name is Paul Locke. I am an associate professor at Johns Hopkins Bloomberg School of Public Health. It is my pleasure to kick off the first panel today. Our first speaker is Professor Wendy Wagner. I am not going to go into her very extensive CV. We have reprinted that in our program, and in fact, I want to let you know I am not going to do that for any of the panelists here, which is because we really want to try to save time, to encourage the audience to participate after the talks.

Professor Wagner is going to spend some time giving an overview of her paper, and at the end of her

talk, we are going to have two commenters on the paper, Dr. Granger Morgan and Dean Lynn Goldman. Let me, without further ado, turn the panel over to Professor Wagner. I will come back after the commenters, and moderate the question and answer and comment session.

PROF. WAGNER: Thanks to the Academy and ACUS, and Anne-Marie in particular and the planning committee for putting this together. It is a lot of bright lights talking about these issues, so I am sure we will come out with some interesting things at the end of the day.

A lot of these problems are obviously very important to policies, and a range of policies, including health and environmental policies. Certainly, as I understood and appreciated, as I did this study, a lot of these are not well understood. We really don't know a lot about how the agencies are using science. This is sort of the tip of the iceberg, in terms of the possibilities.

My assignment right now is just to summarize the report for you. Chairman Verkuil has indicated how that report sort of fits into the ACUS process. It is not an official report, the one that I wrote. It is not published, it simply informs the committee's deliberations. I want to be clear from the outset, because this is very important, particularly since we have so much sort of

science policy talent in the room, that the report is taking a very narrow slice of the larger science policy pie.

In a way, I view the report and the recommendations sort of as the excuse for the party we are having today. I hope that the report doesn't limit the conversations and the focus of the report. When I describe to you what the report does, there are a lot of things it doesn't do. It doesn't go into science advisory boards, it doesn't talk about the role of privately produced scientified information, primarily by regulated parties in the regulated process.

A lot of issues that I care a lot about were put off the table, in order to come up with a narrow report that could lead to concrete, practical recommendations. Even those recommendations are extremely soft. I just want to be clear and, again, hope that we can open the conversation well beyond the relatively narrow bounds of this report.

Because Chairman Verkuil did such a great job describing ACUS, I am going to jump right in, tell you the topic of the report, exactly what it is trying to do, briefly the methods, and then go through some of what I

would call hotter findings and recommendations, at least the ones I am most excited to hear your views on.

Starting with the topic itself, how do you get a handle on the regulatory process in nine months, at least with regard to science, and have some recommendations at the end of it. This was the source of considerable flip-flopping, and the committee helped a lot. Actually, I like a lot where we came out, in terms of what this particular project does. All it does is study flowcharts essentially.

The decision-making process the agencies use for integrating science through that process. How do they integrate science, what steps do they go through, how do they find the relevant literature? How do they put that into a model, how do they explain it to non-scientists? What are the roles of political management in the agency, what are the roles of career management, what are the roles of interagency review? What are the different pieces of the decision-making process?

Now, this seemed like a really potentially good way to look at agencies' use of science for a variety of reasons. First of all, in the philosophy of science, the process is a really central feature of rigorous science. How does the scientists explain their hypothesis, test it, explain their method, show their work, peer review.

Process really, in a way, defines robust scientific knowledge. Now, we wouldn't expect regulatory processes to map exactly against natural science processes. Yet, the idea of process of going through the exercise is important, is one that seemed was worth bringing out, and looking at.

Another reason I think this turned out to be a really neat focus is because there is very little known about the agencies' flowcharts. When you actually look at Carnegie Commission reports or even Academy reports, they focus on a part of the process, but we don't get that overall sort of picture of how the science is integrated. Obviously, since I am a lawyer, looking at the regulatory process was a much better focus for me. I wouldn't get into substantive details about how different agencies were waiting studies and so forth. Process focusing, like a natural fit, and it was an exploratory study. What are the processes, and from studying those processes, is there anything we can learn.

Well, luckily for me, I believe, it turned out that this is like a goldmine of things that are going on, that are interesting to talk about, that may lead to some interesting ideas. Whereas some exploratory studies, you know, you explore it and there is really nothing to say, I think that we have something here in looking at decision-

making processes. Again, I think the study is just a tiny little beginning of looking at processes and flowcharts as a way to understand administrative governance. That is what the report does. That means it is not looking at science advisory boards, not looking at a lot of other things.

Now, in terms of the methods, again, this was sort of a short study. It is the first step in decision-making processes, and so I wanted to look at different agencies that seem to be dramatically different in what they were doing. I started with five agencies, and through the process of research, whittled it down to three, simply because of the lack of time and resources.

The three agencies I ended up with were EPA, for its public health and environment protection, Fish and Wildlife Service, for its natural resource protection, and where the research looks very different, and finally, the NRC, the Nuclear Regulatory Commission, and they are great because obviously they are looking at nuclear plants licensing a variety of different kinds of integration of science.

At the same time, from an administrative law standpoint, they are independent agencies, so they are not governed by presidential review. These three agencies seem

to be good ones to pick for starters. Let me say we are groping in the dark here. We don't know much about agency decision-making processes, so where I pick is obviously highly contestable. Only through time are we going to learn a bunch more. It seemed like good places to pick.

Now, in the case of NRC, it seemed that actually the approaches they take are relatively generic to integrating science. Their flowcharts, in other words, look roughly the same from what we could tell, regardless of what particular program we were talking about. EPA, by contrast, is highly siloed. When you look at the programs in EPA, they could vary quite dramatically from one another in the flowchart of how to use science, so I had to break EPA into programs. There, I looked actually at a range of programs with regard essentially to sort of the outside buzz about those programs.

I started with a National Ambient Air Quality Standards Program at EPA, because that is considered, in the literature and from interviewees, the gold star. It is really an exceptional program and I think my report reinforces a lot of admiration for that program.

Really, on the flip side, EPA's IRIS program, which doesn't result in final rules, has received a lot of criticism and heat over time. It didn't seem like you

could do a credible report on EPA's use of science without looking at IRIS and trying to figure out what the flowchart is there and how it compares.

In the middle was EPA's licensing of conventional pesticides. It is an area that is not very studied. We don't even see much about it in the news, so it seemed like a nice middle ground. Those were the areas that I looked.

In the Fish and Wildlife Service, I looked exclusively at Fish and Wildlife Service's listing of endangered species and habitat designations, simply because that seemed to be an area that receives a lot of attention. I can't tell whether that is representative of how they use science more generally, but it seemed to resonate, at least.

I told you what the project is about, just a narrow slice, a narrow inquiry, and also the methods for trying to gather this information. What did I find? I am going to give you three sets of recommendations and findings, and I will break them into three sets. The first set is, I think, very uninteresting to most people, but to me, it is by far the most important.

When I studied these programs, I expected to see very different kinds of science used under very different statuary circumstances by the agencies. I knew that I

picked them for that reason. What I didn't expect to see was extraordinary variation in the agencies' flowcharts. But even for exercises that seem to be somewhat similar, for example, EPA setting of ambient air quality standards, Fish and Wildlife Services' listing of endangered species. In some ways, you would think that the process of integrating science would look somewhat similar, at least that is what I would have expected. They were dramatically different, just with respect to this checklist.

It also was clear from the study, and I guess I hadn't expected it to this extent, that figuring out what the agencies' flowcharts actually were is really difficult. There are box diagrams in some cases, but they don't begin to explain actually how the science is integrated, the role of political management, all of these very important details are not specified. It was only through extensive interviews that I could extract sort of the flowchart from this area of practice.

The first recommendation is simply that the agency should explain how they integrate science over the process. Again, sort of a yawn, however, I think this could be extremely illuminating, both for the public, the world and the agency itself. I think there is not a lot of self-awareness of the processes the agencies use. I don't

think that is also terribly time-consuming for the agencies to explicate essentially what they are already doing.

Along this first set of big picture recommendations was also an awareness. As I looked at the flowcharts, that the agencies, some in particular, had some very fascinating innovations, very creative ways to innovate science or deal with certain issues. Yet, no one else knew this was going on. Again, looking at EPA's NAAS program, and I will talk in a few minutes about it, there were some really interesting innovations there. They were proud of them, and other interviewees were excited about them. Yet, when I asked other agencies, they had no idea this was going on.

In other words, there are a lot of excellent approaches that are being used understandably, that simply don't make it beyond that big program and the agencies' use of that program. It seems to me it would be much more efficient for government to start to share some of the successes and insight that some agencies develop in narrow areas.

The first set of recommendations is simply, let's talk more about flowcharts, let's make them explicit and let's try to extract from them certain innovations that may be useful to other agencies. The second set of

recommendations then tries to begin that work, and again, that is I think where the focus of the discussions today will be on.

In doing this exploratory search, were there innovations that seem particularly worthy of note that could lead to recommendations that the agency should think about these types of things. In trying to pull out what seem to be the most creative and innovative, I was looking at a couple of things here. One is, and some agency officials repeated this, what they really want to have in their programs is scrutiny of that science as it moves through the process. They want diverse experts kind of looking at it, not only external, but internal. One agency high-level official said, I don't want group think going on in my agency, and yet, I am concerned that will happen.

One virtuous kind of innovation had a way of sort of keeping things mixed up, keeping that scrutiny on the agency's process, whether internal or external. Another virtue is transparency, are they showing their work. This doesn't mean showing every single thing, but just like in science, where we want to know what your methods are. Are they explaining their methods for integrating science? Can we figure out what the heck is going on when we look at that preamble?

Also, are there features of their process that start to map against science. Science places a high role in the responsibility of scientific authors, is that idea something that can map into regulatory science. In doing this, with these sort of general goals in mind, it turned out that the EPA's NAAS process actually had quite a few innovations that met these criteria.

Now, after doing the study, I suppose I could rewrite the whole report to essentially be mostly about what we might learn from EPA's NAAS process. There are other features of the report that find innovations elsewhere. I just wanted to be clear that a lot of what ended up being special things came from that process. Again, that is a wonderful question for today. Maybe that is in fact, a terrible process. All of the literature and all of the interviewees' strong consensus that that is a very, very well-done program post-2006.

In terms of looking at specific best practices, now, because ACUS likes recommendations, these take the reform of recommendations. If you note, they are very soft. It is not agency shall and we will sue if you don't. It is simply that these are concepts or approaches that seem to improve agency decision-making processes that deserve attention across government.

The first, and the one in some ways I find the most brilliant, came out of the NAAS process. This is the conceptual framework they have developed for integrating science into the decision process. The NAAS process takes five years, it is usually expensive. I understand that operationalizing their big approach into very simple quick decisions is not easy. However, what I am talking about is a conceptual approach that easily could be pasted in a single preamble. It is simply a way of thinking about the pieces.

What the NAAS process does is first they say, here is our statutory mandate. In NAAS, EPA has to review every five years ambient air quality standards to figure out whether they need to be revised, based on changes in science. The way they start that process is they say, given our mandate, what might we see in science that we should be considering. What are the policy questions that we are looking to science, to try potentially to answer. This narrow framing exercise was actually seen in a number of agency programs, but in EPA, it is an explicit first step. Let’s frame how we are looking at science and the kind of questions we are hoping it can answer in the get-go.

The second step is doing a literature review. This is a formal process again, goes through peer review, goes through public comment, but every stage does in the NAAS. At this stage, EPA says, okay, here are the questions. What does the literature tell us about this, what are the methodological weaknesses, what are the strengths, what do we have, what do we not have. It is simply a document that does the literature review.

Again, when I pressed other agencies, they seemed to think that this step probably did deserve to be separated out and talked about differently. By doing this, all of a sudden, obviously we are pulling the judgments and the issues just on the literature out separately, before we get into the mess of applying that literature.

In the NAAS process, the third step is integrating, and taking the literature search and figuring out how to make predictive models, what to do with all that. That third step again has a report and peer review again. No other agency could emulate that extensive process, but the conceptual step, nevertheless, seems to me to be the place to pull that out.

The fourth stage of EPA is then explaining to sophisticated non-scientists what all the other stuff is that came before it. What we learned from the literature

review, what are the uncertainties, what do we know, what do we learn from the modeling? This four-step process in the NAAS, again, to me, provides a conceptual step for the agencies. It needn't be extensive, but it is a way to, if anything else, organize the preamble's discussion.

The second innovation in the NAAS process, and this also occurs throughout EPA, is they actually give authorship and attribution rights to the staff scientists that are writing, for example, the literature review or the modeling step. I never expected to see any of this. This one, in particular, it never occurred to me that authorship actually might play a role in regulatory science, in circumstances when it actually can fit.

Now, providing authorship to scientific staff has a lot of virtues. It gives credit to agencies, staff scientists, so it encourages better service. It certainly gives them a stake in the studies. It allows them actually to pull their name off if they dissent, so there is a lot of nice features about having agency staff draft initial reports.

In the recommendations, I think we suggest that agencies should think more about attribution and authorship as a way to ground some of these initial studies. In some cases, it is not practical. I don't know what it would

look like at an operationalized level, but the point is, in our conversation, it is an issue that deserves more attention and though.

A third potential innovation is what I call stopping rules. This is actually drawn from an article that Sheila Jasanoff wrote. She, in turn, pulled it from the decision theory literature. That is simply the idea that if we are working in regulatory science, where the science is dynamic and constantly changing, the agency needs to make a decision at some point. When it works well, the agency is forced to make a decision because the statute gives it a deadline.

In cases where there isn't a statutory deadline in a lawsuit, how does the agency finally come to a close on evidence that is constantly changing. That is where stopping rules come in. Stopping rules simply say, this is where we are going to close the evidence. We are going to close the record. We will visit later, next time we revise a rule. We need a point to stop and this is the explicit point we have chosen.

In the NAAS process, they actually have an explicit stopping rule. At this point, the evidence closes, unless it comes in so significant that we find that we actually need to consider it, because it is so material.

In the Fish and Wildlife Service, in their listing process, they actually have an implicit stopping rule because the poor Fish and Wildlife Service, once they have a petition that asks them to list an endangered species, one year later under judicial review, they have to come out with a decision.

Their implicit stopping rule is simply that they are under such a tight timeframe that there isn't a whole lot of changes in the record, from the beginning to the end. In the case of other agencies, though, it was clear that they grappled with this, and that they never made explicit what they thought their stopping rule is or really dealt with this head-on, so that is another recommendation.

A fourth recommendation, even more preliminary, is the idea of dissent within the agency. This was actually drawn, not from EPA, but from the Nuclear Regulatory Commission. The Nuclear Regulatory Commission, over 20 years, has developed an enormous program to allow and encourage dissent within its staff. To the point where, someone can file essentially a non-concurrence with a decision, and that is adjudicated within the agency. This actually was an issue in Yucca Mountain.

Now, it never occurred to me about the role of dissent in agency regulatory science. Again, the idea is

this encourages vigorous scrutiny, and it gets away from the group think. The recommendations lightly mention the possibility of providing a right to dissent. Now, when I asked other agencies, they said, yes, we have dissent policies, but they are not written down. At the very least, it seems that if there are policies in place, it would be useful to potential dissenters to know what they are.

Let me say this is a loaded issue. It is hard to set up a dissent policy where it isn't abuse, where you don't have whistle blower problems. I am not saying operationalizing the idea of dissent is easy. However, the concept that scientists should have a dissent right seems to be headed on the right track.

Some of the other recommendations, I think, are much more straightforward. We need to have some sort of peer review where possible. We need to do literature searches, and just in response to Dr. Zeckhauser's comment.

Actually, I wasn't recommending in my report that the agencies had to make a record of all of the literature they reviewed, including the literature they didn't review that was actually added by the committee, I think, to the recommendation. I agree with the concern that you raised. A couple of other things are trying to use deliberative

process sparingly and publicize innovations, so some sort of good government apple pie kind of recommendations.

I have given you the first set, the sort of yawn, but important. The second, some of the best practices that hopefully, we will be discussing today. The third set, external constraints on the agency. It could only be me, but when I read President Obama's directive and OSTP's memo and all the literature that came before it, it seems to me an implicit assumption is that whatever might be going wrong in the agencies, with the use of science, can be fixed by the agencies. In other words, this is within the four corners of the agencies. All we have to do is to remind that they need to do a better job.

In this study, what kept coming out was the fact that there are actually some external constraints, mostly legislative, on what the agency can do, that significantly limit the ability to use science with full transparency or integrity, in any way that we might agree needs to be done.

The last set of recommendations says hey, there are a lot of external reasons why these agencies really aren't able to live up to what we might expect of them. Let's at least get those out on the table and talk about them. Now, at the end of the day, it could be that these external constraints are good constraints. Their benefits

outweigh their costs, but at least, let's put it on the table and not expect the agency to be able to use science with integrity and transparency, when in fact it is precluded legally from doing that.

Just as a few illustrations, the Fish and Wildlife Service again. They are given roughly $250,000 to $300,000 in their budget for the listing of a species. That is how much money they have to spend, and they have a year. Now, what they do is miracle work in my view, when I look at the preambles. I don't think that is enough to do a good job, figuring out whether to list a species and designate its habitat, $250,000 from start to finish in one year.

Another example, in the IRIS program, they said they would love to have science advisory boards look at every single IRIS assessment, but a Clinton executive order caps the number of science advisory boards that can be empaneled in an agency. They basically sort of bump up against a wall. Instead, they have to use individual peer reviewers and kind of try to make sense of what those conflicting accounts mean.

Another example in EPA's pesticide program, EPA uses a lot of manufacturer-produced studies, but by law, it cannot share those studies with the public or other

scientists. If you want to see the studies that EPA relies on, and from what I can tell, about 50 to 60 percent of whatever lies on all of these studies, you have to go to EPA's office. You have to certify a bunch of things and you can only do so after the pesticide has, in fact, been approved. Even then, your identity is shared with the manufacturers. It is very difficult to see the studies. EPA has done its best to provide summaries, but that is another limit to transparency that, at least from a scientific vantage point, seems to be problematic.

A second set of external constraints, and the one that is definitely the hot button in this report, I think otherwise most of it is not terribly politically charged, is the recommendations on the Presidential Review, and OIRA, in particular, review of agency rules. When I looked at the flowchart, at the decision-making process, at the very end often, for significant rules, there is a process where it has to be cleared through OMB.

We have a lot of peer review and we have a lot of transparency, but at the very end, at least in theory, in the abstract, that review can take place in ways that lead to changes, to how the agency characterized or used science. In theory, some of those changes can take place without any notice to the public or any transparency.

The report is being heavily revised on this particular recommendation in terms of the facts, and it will be completely revamped. It is not really ripe to talk about the details in the report, but I think the abstract issue is nevertheless a really important one for conversation. The issue is, if we have a flowchart, is it okay to have a step that sort of pulls the needle off of the record. Perhaps it is, at the end of the day. If we are talking about a process, at least that can be recreated by the public and the scientists, it seems to be an issue that is very fundamental to the idea of a flowchart that we need to look at.

In the committee, it seems to me to be the general feeling of the committee that this presidential review issue may be a very important one, but it's left for another report and another day. That is fine, the committee makes those decisions.

At least from the perspective of drafting a report on flowcharts, and looking at each step, I simply can't just leave off that last step, where changes can be made that aren't explained. It seems to me we do have to talk about what that should look like. Again, in the abstract, I would be very curious to hear people's comments on that.

I know I have gone over time and I appreciate Paul for not getting the hook out. I just want to say two things in closing to remind you. First of all, this is a narrow report. A lot of other issues that deserve to be discussed, and I hope they will. ACUS remains very interested in additional recommendations. They don't have to be supported by the report. If there are other innovations or other ways to look at that, those definitely can end up as recommendations.

Also, I wanted to remind you, too, that I think the focus of today is going to be mostly on the recommendations, because that is where the rubber hits the road, and my report is just a consultant report that isn't published. I do want my report to be correct. If there are lots of details in there that aren't material to today's discussion, but you have comments, changes, please get them to me. Email them to me, give them to me in the halls. I very much want the report to be as strong as possible, even on the issues that turn out to really sort of matter, so that I at least get what I did right.

I really look forward to the discussions. I think even if we produce nothing, which I am sure won't be the case, it is cause for celebration just to have us all

here talking about practical reforms to agency processes. Thank you very much.

DR. LOCKE: Thank you very much, Professor Wagner. I would like now to ask Dr. Goldman to come up. She was chosen first because her presentation slides came up first.

DR. GOLDMAN: Thanks very much for inviting me to participate in this very important workshop. I should begin with a caveat that I didn't even know about this workshop until just a few days ago. I am a little bit of a last-minute replacement from the person who they really wanted to have speak to you. Anyway, I will do my best to soldier through, and I hope all of you can tolerate my comments here.

I want to begin by just congratulating Wendy Wagner for a very nice report, and for what I know is a very difficult process, in terms of trying to reason through these flowcharts from the various agencies which, as you say, can be difficult to do. I know that that was a fair amount of effort. I think it has produced quite a bit that is, as you say, meat for discussion about ways that things can be improved.

I believe that my task here actually is just to comment not so much on the recommendations, but more the

kind of the conclusions leading to the recommendations, and that Granger is doing that, as well. In the next session, we are actually getting more into the recommendations themselves. That is, anyway, what I am prepared to do.

I am just going right to the first issue, which is this issue of the availability of the reference list and underlying references that support these agencies' scientific processes. I think that everybody would agree that any kind of agency process that depends on the literature needs to have, at its foundation, a very transparent system for anybody in the public, to be able to see what was the literature that was utilized, and that that literature was successful. Of course, that is very difficult when it comes to literature such as the toxicity tests that are done for pesticides.

Having at one time been the assistant administrator for the office at EPA that regulates pesticides, I understand how these pesticide reviews work very well. It is a standardized set of tests that are performed. Those test guidelines are published, so that is completely transparent, where the data come from and what the study designs are that produce the data. Anybody can see those.

The EPA does publish summaries of each study, and shows the data that they abstracted from those tests. Even though the studies themselves are considered to be propriety information, those who are interested enough to read the test guidelines, to dig into EPA's webpage and find the data reviews, actually can get a lot of the elements that one would wish to have for the sake of transparency.

I would say that there are few people I know who are that deeply interested, and that they have actually been willing to do that. I think that the EPA program is not the only one in the government where there is product licensing based on propriety testing. I do think that this is a best practice to publish the testing guidelines, and to publish the summaries of the data. I happen to think that the pesticide office could use a better method for making those studies available. The website was created probably about 12, 13, maybe 15 years ago, and it doesn't use the most modern tools to allow you to search for things. That is the way life can be in the government, as well.

I would not recommend in this area an approach that is overly prescriptive, and in fact, I think that Wendy Wagner did not, either, in terms of saying that

somebody would tell the agencies exactly how to put these data up. Part of why I wouldn't recommend that is that we are in an era where our informatics tools are rapidly evolving. We should have better and better ways of being able to make this kind of information available to people. We shouldn't constrain the agencies by saying, use this cookbook approach or that approach. Rather, we should try to find ways to incentivize them, to modernize their approaches as much as possible and keep pace, which I don't think they have done.

Staff authorship and attribution, I absolutely agree that this is important. I think it is important for a number of reasons. One of the things that the National Academies has been very concerned about actually is the career paths for scientists in the federal government. An obstacle to that has been the lack of opportunities for publication. I think that this would have a wonderful side benefit, in terms of allowing the scientists to better document what their contributions have been, and be able to take credit for those, have a little more career mobility between agencies, maybe between being in government and the university than they have today.

Certainly to allow agencies, or encourage agencies, to develop better tracts for scientists. A

frustration I had at EPA was many scientists being drawn to a management tract, which would be rewarded more generously than a scientist tract. Finding ways to reward scientists is difficult if you don't have something like the ability to attribute authorship.

In terms of the issue of dissent, here, I have a slight disagreement, not on the basic principle of allowing the provision of dissent, and having more transparency about how that works, but more in the matter of the emphasis that is given on dissent as being almost inevitably leading to withdrawal or leading to the development of if you made a separate opinion. I think that generally the thing that needs to happen with dissent is that there needs to be a culture of science in an agency whereby dissenting views are well discussed and are well understood, and can potentially affect the way that people are evaluating the science. Sometimes dissents are a way of being able to shine a light on a facet of the science that maybe the majority of the members of a review group didn't appreciate. Sometimes dissenters themselves may have a blind spot in some other area of science. Having those discussions and those examinations, I think, helps to shine a better light on the science, and improves the quality of the product. Also, it often helps to shine the

light on uncertainties, and sometimes dissenting views really need to be incorporated into a report, to be able to better communicate the range of uncertainty about our understanding of the science in an area, because where the dissent is really coming from is that there are a range of legitimate interpretations, but that different individuals have different interpretations. Incorporating those views is a way of communicating that to decision makers, without necessitating the provision of a separate opinion or somebody having to take an adversarial stance toward their colleagues, basically.

Encouragement of peer review, I think there is very strong consensus about this. In fact, the National Academies have been in the forefront over many years in encouraging peer review in the agencies. Of course, the devil is in the detail. One area that wasn't really very well explored in the report, but certain highlighted in the report, is that it is not just an issue of whether there is a peer review or not, but the quality of the peer review. Who are the experts who are engaged, and what are really the restrictions.

I think all too often actually the restrictions are restrictions that have to do with the availability of resources. Actually, there are science advisory committees

that can form working groups. I don't think we have to have an indefinite number of FACAs appointed, in order to do peer review.

I think the real issue is that science advisory board type reviews are very expensive. They require the engagement of experts who volunteer, but they have to travel, they have to be served, you have to have staff to take care of them. A really good thing that happens, and you mentioned this in the report, is that they have a chance to deliberate among themselves and do the same thing that I would hope that agency scientists do.

That when you engage experts individually, it may appear that they have differences of view that then provide an unclear path forward for the agency scientists, whereas if you engage them as a group and give them a chance to have discussions, they can often iron out differences and actually produce a much better quality product in terms of peer review. Again, I don't think that you have done this, but I would warn against a very prescriptive regulatory approach to peer review, which I don't think would be very likely to be helpful.

I don't know if this can be read, now looking at it, it looks a little small. In terms of the proposed analytic steps, certainly that the policy questions should

be laid out in advance makes a lot of sense. I think that there is a missing step in what was put forward. I don't know if it is on the flowcharts that you evaluated, Wendy, but it probably should be. I think this was really the basis of the critique of the formaldehyde report. That is that all too often, there really isn't a study design. Those of us who are involved in doing science know that we believe that we should design our study before we carry it out. We should generate hypotheses, we should lay out a priori, how we are going to test those hypotheses.

All too often, it appears that in these reviews, there has been no design ahead of time. If you may, there's room for kind of manipulating the data, manipulating which models you are using, which studies you decide to include and exclude. Laying out ahead of time what the question is going to be, what a priori, what are going to be the criteria for inclusion and exclusion of studies, which models will be used before the data are under analysis.

It is kind of maybe something that doesn't need to be done with a process like a pesticide review, where it is almost always the same set of data following a standard agency process. It is kind of laid out in protocol how that is going to be done. On the other hand, for an IRIS

review, where each chemical may compose a completely unique set of scientific considerations and challenges, it is probably a good idea to have that kind of a practice in place.

In terms of assessment of the evidence, the next step that Wendy laid out, I think that that could be parsed out into separate steps. Again, I think this came up in the formaldehyde review, but first the search of the literature and transparency about how that is done. Second, the decision about which studies are included. Third, the review and assessment of the quality of the studies and transparency about that, which really ought to be again laid out in the study design. Then, fourth, a process to abstract the data from the relevant studies, how the data are abstracted is very important. Selection of the data, whether the data need to be reanalyzed in order to provide data that can be utilized in a review and all of that.

Again, if it is a pesticide registration and it is just data from required toxicity tests, that is pretty straightforward. Usually, that is not going to be the case. Application of the evidence for next step, again, I think that ought to be determined a priori. If it is in an agency standard operating procedure or policy document,

that they are following that, it is fine. But where they are departing from that, that should have been laid out ahead of time.

That is the arena where something like I think a pesticide review has to go to external peer review, either department from an already peer-reviewed practice, utilization of novel models, data, novel data sets. The more that is happening, the more peer review is required in my view. Then, finally, the bridging of the evidence to policy questions and I am about to wrap up here.

Stopping rules, I would agree in principle with this, and certainly, when you have something like a NAC or a pesticide registration, where the law says that that's periodically going to be reviewed, and the resources for doing the review, it is easy to do that. What is really, really difficult is something like an IRIS assessment where there is no schedule mandated. How do you determine when you are going to stop?

I don't think that the answer is well, you stop unless there is something significant that comes along, but significant in whose eyes? How do you determine that something new is significant enough to be significant and to cause another two or three-year delay, which is often what it amounts to in a process?

An idea that I would like to float is that maybe we need to reconsider that these reviews are done, and move away from the idea that we are producing documents, and into an idea that we are doing an assessment process, and that that is a process that could be iterative, and maybe it could be done in a way that would allow for continuously updating these kinds of assessments. I don't think that we are making full use of the tools that we have. I guess I am very inspired, too, by something that the National Toxicology Program is trying to do along these lines, in terms of making the data something that are amenable to reanalysis over time.

Clear explanations, nobody would disagree, I think, with that. I don't think a prescriptive or a regulatory approach might improve the explanations, but I do agree that OSTP could take a role in encouraging the spread of better practices among agencies. I think there is no doubt of that. I think that the last recommendation is spot-on.

In closing, I really do think that this is a ripe area for work across the government. I am really happy that the administrative conference is interested in that. I have been heartened by the fact that the OSTP, as well as OMB, have been working with the agencies in this area. I

do want to caution people, though, especially here in Washington, not to expect too much from this. I think that there are a lot of issues with how the regulatory processes work. There are a lot of issues, a lot of concerns about regulations, especially in the economy that we have right now. It is not clear to me that very much of that at all is embedded in this issue about science and how the science is done. Thank you very much.

DR. MORGAN: While Lynn talked about some specifics in the report, I have been asked to give some more general thoughts on the use of science in the support of regulatory decision-making. The classic model is that one does science, and then that informs the policy process. Actually, back in the mid-60s, Arthur Kantrowitz proposed this notion of science court, ostensively to improve the consensus about the science before it got thrown over the transom to the policy folks.

I think also on the basis of conversations I had with him, as much as motivated by the notion that we needed to protect the purity of science from this messy policy process. I think a rather more realistic model looks like this. It is rare that science directly is in a form that can be used by the policy process. There is this important

intervening step of doing analysis to put the results in a form that is useful for policy-making.

Then, in the 70s, Alvin Weinberg offered this additional elaboration, that is that not all questions that can be posed in the language of science can be answered by science. Alvin called this trans-science, and policy analysis, though it obviously can't answer trans-scientific questions, can often at least put bounds on things. In many cases where the end would have to be millions of rodents or something, and you simply can't get a definitive answer. Policy analysis again can at least bound the results.

Now, when I wrote this editorial in science back in 1978, we had sort of just begun to get serious about quantitative policy analysis. I want to read you one excerpt from this. Good policy analysis recognizes that physical truth may be poorly or incompletely known. Its objective is to evaluate order and structure in complete knowledge, so as to allow decisions to be made with as complete an understanding as possible of the current state of knowledge, its limitations and its implications.

Like good science, good policy analysis does not draw hard conclusions unless they are warranted by unambiguous data or well-founded theoretical insight.

Unlike good science, good policy analysis must deal with opinions, preferences and values, and it does so in ways that are open and explicit, that allow different people with different opinions and values to use the same analysis as an aid in making their own decisions.

Now, that brings us to the subject of decision roles. A standard decision role in science, of course, is avoid false positives. You don't want to get stuff out in the literature that turns out not to be correct, because then it can lead people down long paths that it is a waste of time. In contrast, and quite appropriately, the standard decision rule in public health is when in doubt, act to protect.

Often in public debates, people talk as though they are discussing the science. When in fact, what they are arguing about is the decision role. We need to try to make this more explicit. Unfortunately, this rarely gets pointed out in those debates.

Now, it is fine to argue that we need standard practice. If by standard practice, one means things like adopting peer review, then I have no concerns. However, this constant pressure on agencies to produce and impose detailed guidance, essentially cookbooks on how to do analysis. For many routine, regulatory decisions,

following such guidance will produce reasonable results. Some regulatory decisions that involve issues of science and technology don't lend themselves to analysis by following fixed sets of pre-ordained steps. In those cases, agencies and other scientists and analysts need to have the flexibility to develop and use methods that do make sense. I will say more about this in a moment.

Now, when the stakes are high, it is inevitable, and in a democracy that values free speech, that there will be attempts by interested parties to distort, misrepresent or induce public doubts about the science. In my view, the best ways for regulatory decision makers to deal with this is to have high quality technical experts on their staffs, to use high quality external advisors and reviewers, and to draw upon peer reviewed literature to the full extent possible.

Now, many of the normative judgments that have to be made in regulatory decision making can be politically awkward and controversial. It is not surprising that regulators often try to avoid making explicit decisions by hiding behind the science or treating normative questions as though they were scientific questions. A good example of the latter is this fantasy that somehow the value of life is an empirical quantity. I mean, you can do studies,

but this is ultimately a normative judgment to be made by regulators.

Analysts should have the freedom and the courage to sometimes say, this is nuts, and take a different approach. For example, Executive Order 12866 requires that agencies do a benefit cost analysis of all major rules. I am going to give you three examples where I think agencies should have adopted some other approach.

The first is the regulatory impact analysis for the final mercury and air toxic standards. Now, EPA needed a number. They needed to say, what is the cost of not controlling mercury emissions. They went through this elaborate procedure. They observed that people with slightly lower IQs earned less.

They said, if we exposed kids to mercury and there's an IQ decrement, what is the change in expected earnings over the course of their lifetime. That was the number on which this thing was based. I don't think we are a society that wants to be making this sort of decision about exposing kids to neurotoxins, on the basis of modest changes in their earning potential over their lifetimes.

Another, the Americans with Disability Act, now this is an Act that established a right. I mean, imagine that, for example, that we had 12866 in place back when we

passed the Civil Rights laws. Did we really want to subject them to benefit cost analysis? Yet, rather than pushing back, we went through this elaborate procedure to show that the benefit succeeded the cost for the American with Disabilities Act.

The last is the Integrate Agency Working Group on Social Costs of Carbon. I do analysis for a living, and you have got to admire the elaborate stuff they went through. The bottom line was, we don't know, and so we ought to treat it parametrically. They could have said that up front, and so it really does have to be occasions where an agency says, this is nuts, and goes to OMB and tries to persuade them that they should be allowed to do something differently.

Now, while agencies such as EPA have gotten much better about getting much of their technical work subjected to peer review, at least at EPA, and I suspect elsewhere, the most important products don't always get reviewed by the most scientific competent reviewers. For example, it is my impression that the EPA Science Advisory Board, which I chaired for quite a while, doesn't always get asked to review the agency's most important documents. Indeed, sometimes these get reviewed by ad hoc groups that get assembled by contractors. Agencies would do well to

require that their most important products do get reviewed by their highest quality peer review processes. With that, I will say thank you.

Agenda Item: Discussion with Participants

DR. LOCKE: I would like to thank our speakers, and also at this point, I would like to open the floor for questions and comments. To sort of streamline things, we would like to ask you to keep in mind three ground rules. The first one is when you do approach the microphones to make a statement, please tell us your name and your organization affiliation.

The second is please limit your comments or questions to two to three minutes, so we can have a good flow of discussion. The third is if you have decided to come to the microphone to make a second comment, please yield to someone who has not yet made a comment, if that person is in line with you. There won't be a test on this later, by the way. For those of you who would like to make comments, I see we have one or two people at the microphone. Let me start right here in front of me.

MS. STEINZOR: My name is Rena Steinzor and I am a professor at the University of Maryland, Carey School of Law. I wanted to comment on the issue that Professor Wagner raised, that is kind of the elephant in the room

here. That is the question of OIRA participating in the review of regulatory science. I wanted to articulate, because I think that the ACUS process has really restricted the ability for this point of view to come out very clearly, why some of us are so troubled by OIRA's review of science.

There has been an assumption for many years in this country that these agencies are set up as experts, with people who have a variety of disciplines, not just economics, but a variety of engineering, scientific and managerial disciplines, to make the best regulatory decisions. What has been happening, it has really been happening for quite a long time, but it has come to the fore is that the White House has become much more aggressive about reviewing the rules and changing them. In an empirical study that I did with some colleagues, we found that 84 percent of the rules at EPA were changed. It is very difficult to know what these changes were, because the process is not transparent, and that is step one of Professor Wagner's recommendations.

The reason we are troubled by this is that OIRA has one scientist on its staff, maybe two. The idea that a body that is political advisors to the president, that have very limited expertise in science, would be changing the

science, the findings of agency scientists who are very well equipped to make these decisions, in a way that is not transparent, is deeply disturbing to us. I think I speak for a few people at least in the room. These processes are very time-consuming, and the number of people that share my point of view is funded by foundations is somewhat limited. I would ask that we keep this front and center, because I think it's a very important point. Thank you.

DR. LOCKE: Let me turn to our panel for some comments.

DR. GOLDMAN: I can comment from a couple of perspectives, one being maybe among a few people in this room that has actually probably spent dozens of hours with OIRA staff about rules during the time I was at EPA. At that time, they did not have scientists on the staff, but questions about the science, nonetheless arose. They arose because of the fact that one of the rules that OIRA has is in funneling the comments from all the agencies that are concerned across the government, the interagency review of rules. Sometimes those comments have within them embedded issues that are science issues that the OIRA staff feel that they must transmit to you.

Also, because they do have meetings without outside parties, and sometimes those outside parties bring

issues, often that are identical to the very issues that they brought to the agency prior to the drafting of the proposed rule, often had been reviewed by agency peer review or science boards and all the rest. Nonetheless, the OIRA process is yet one more opportunity for those individuals to hope that maybe this time someone will give them a different hearing. That has been going on since prior to the time that there actually were scientists in OIRA.

If I place myself in the place of being the head of OIRA, I would like to have science staff there for, because otherwise, it is very difficult to even understand these comments. What are these comments? Are they important comments? Are they relevant comments or not? At the very least, from that standpoint, I think it has been a positive thing that there now are a couple of scientists in OIRA.

Are a few scientists enough to review every rule? No. I mean, if you look at the process here at the National Academies, I have chaired committees here that have more staff than the number of staff on OIRA. In addition to that, their number of volunteer members who actually do the work of the committee. You almost never see the same individuals again and again and again, serving

on committees. I certainly have been qualified to be on certain committees, but I would never dream that they would appoint me to a committee to review a technical issue regarding airline engines or you name it, all of the things that OIRA looks at from across all of the regulatory agencies in the federal government. There is no way that there is any small group of scientists who are qualified to look at the science that is involved in all of those issues. It is just not even conceivable.

I think there are people who think that they can, and that is part of what I was trying to imply about the unrealistic expectations that I think people have. I think people that would hope that a small group of scientists like that could second guess all of that science. That is not possible. I don't think it has been clear enough, and here is why I would agree with what you just said, Rena.

I don't think it has been clear enough when regulations have been returned by OMB or when they have been stalled, because there are many that have, despite the 90-day deadline, have stalled. It hasn't been clear enough why, and whether those reasons have to do with the science and the review of the science, or other reasons. I do not think that has been adequately explained.

DR. MORGAN: You need to remember the three-box model rather than the two-box model that I put up. Making judgments on regulatory matters have strong normative components. Somebody has to make calls about how to interpret the science, and how to add the value judgments and how to weigh off various things, or trade off various things.

To go back to the opening remarks from Dick, the problem is that if you have to do all of this in a fish tank, it can be really awkward. Now, I agree, there is a real opportunity for the right or the wrong kind of OMB to fudge things. That is, to really put a heavy thumb on the scale that may be inappropriate. At the same time, though, I don't see any way around having to incorporate a set of value judgments on the basis of by an administrator and by an administration.

Though there may be a case to be made for providing a bit more feedback, in terms of rejecting a particular proposal, at the same time, opening all of that up strikes me as just not likely to produce better decisions, but to simply drive it off into other parts of the process. For example, we all know that all activities of FACA boards have to be conducted in public. Then, of course, you go to dinner and you hold the serious

conversations. You don't want to push OIRA into that kind of situations.

PROF. WAGNER: Just real quickly, obviously this is part of the report that is in process. It was clear in the follow-up interviews I have had with primarily OIRA officials that they feel very strongly about the deliberative process protections for the exchanges that they have, and the need to definitely be able to have those in candor for a whole variety of reasons.

The Executive Order 12866 under Clinton, does simply require that we have a record of the changes that were (off mic). Sort of at the end of the day, not getting into the discussions, just tell us basically what changed from this point to this point. That strikes me, I mean, the Executive Order requires it. That seems to be a good way to kind of get to the win-win, it seems to me. That may be one way to think about it. I think compliance with that provision may be limited, but again, it is sort of a work in progress.

I wanted to mention, too, that as I looked in this issue, OMB and OIRA routinely investigates significant rules. They have the executive order that tells them to at least make the changes clear, or the agencies should make the agencies clear that result from OIRA review. There is

no similar transparency requirements for any other offices of the White House. White House Council, OSTP, Office of the President, they are completely excluded from just very limited transparency requirements.

I wonder if we look only at OMB, whether we are potentially missing other places where lots of changes can be made sort of at the last minute without any public transparency that actually affect the characterization of science. In an ideal world, at least we would want a log of those changes.

DR. MORGAN: So Wendy, in the government, in the Sunshine Act, the amendments to the Administrative Procedures Act, I think that internal agency deliberation is protected.

PROF. WAGNER: Right, the deliberations, I am just talking about, would it be, in an ideal world of science, transparency and integrity, would we want at least a log that the President came in at the last minute and flipped the standard 180 degrees, including the characterization of the literature.

DR. GOLDMAN: I guess I would not want to do that, and for similar reasons to what Granger said earlier. That is that if you tried to say that there couldn't be conversations within the executive branch, say that close

to the political process, then you would just drive those conversations somewhere else. Those conversations need to occur. I don't think that there is any practical way of saying people can't have conversations that are held in executive privilege, especially as they concern the president. I don't see any practical way of doing that.

PROF. WAGNER: Again, I wasn't suggesting the conversations at all were subject to any transparency requirements. It is simply that if changes were made to a final rule, those changes are identified. Do you still think that is problematic? That isn't getting to the deliberations.

DR. MORGAN: The changes are identified or the, for example, underlying political considerations are identified. I mean, it is quite a different.

PROF. WAGNER: Right, I agree, so what about just changes?

DR. GOLDMAN: But they should under 12866, the changes should be identified.

PROF. WAGNER: That is only for OMB and OIRA, as I understand it. It doesn't apply to the other White House offices. It does?

DR. GOLDMAN: The reality is that what comes out at the end, it is just an integration of all of that. It

is true, I mean, you don't see how that happened. You see a document that has changes, you don't know who changed which words. All of the changes would be identified.

DR. MORGAN: In the regulatory space, this is a very leaky system. I am not aware of a major regulation where OIRA has intervened and nobody can figure out why. Read the trade press, it will tell you in gory detail.

DR. GOLDMAN: Inside EPA.

DR. MORGAN: Or its equivalent, in other agencies.

DR. GLEDHILL: My name is Jonathon Gledhill, Policy Navigation Group. More importantly, I was a civil engineer in the Office of Information and Regulatory Affairs. I know a lot about what you are talking about, and the practical application. I guess I would submit very much like Professor Granger was saying, you're missing the question. The question really for science, when it gets to OMB, is the trans science or what I call science policy issues. Those areas that can be framed in science, but there is fundamental uncertainty of the time we need to make a decision to fully answer the question in the language of science.

That are the issues that come before OMB, and that is where the majority of the discussions are. It has

to do with model uncertainty, it has to do with uncertainty about toxicology effects. It has to do with uncertainty about weighing this public policy value. You can always do more in one area, but there is a cost in some other part of society.

As a civil engineer in OIRA during the early ‘90s, I got called to do all sorts of things throughout OMB. Wind safety standards after Hurricane Hugo, Antarctica. Basically, I speak geek. Anything that came with an equation they called me or one of the two other engineers that were there.

Now, my job was not to review the science, although I certainly could, because having followed study with Professor Zeckhauser, and his colleague, Dorothy Zinberg at Harvard, and then Professor Von Hippel at Princeton in science and public policy. What they drilled in you as a young student was, anyone could understand the science with sufficient time. Now, with the internet, you can. Distilling out the science and the science policy questions are what public policy officials need, and that is your price to the president and the Office of the President.

Wind safety standards, civil engineering standards made a perfect box. The problem is, we couldn’t

afford that box. If people couldn't afford a new mobile home built to civil engineering standards, they lived in their cars. The public policy tradeoff was not whether these were good safety standards, but were they the right thing to do, the public policy response.

Granger Morgan brought up about the Americans with Disabilities Act. I know that one because our firm was hired by the committee, the part of the Department of Justice that does that. The question was setting ADA standards for national parks. As a civil engineer, they said, well, we want all of our trails and campsites accessible. I said, are you sure? And they said, yes, and they were a bunch of lawyers.

I showed them, I said, let me take one park. I took Acacia National Park in Maine, and I showed them what the cost would be. I laid it out, using Means Construction Guide. I brought in forder(?) trucks and grading equipment and all of this. They said why do you need water? I said, well, you need to make a certain grade. You have got to compact that soil with water, if you are going to pave it.

Pave it, we don't mean to pave it. Well, according to your data from technical experts from your committees you have got, the only way you can get a wheelchair up to these places if paved to a certain

compactness. They said, oh, oh, well, wait a minute. We don't want to pave all of the parks. Good.

The question is not extending a right, but the application of that relative to other public policy tradeoffs. That is the primary role of OIRA, that is the primary role it is set up to do in the short period of time. Frankly, the application of science is more, as I call myself, a policy engineer, not science. We must preserve that role of engineering, i.e. the application of science, the application of policy engineering, to come up with craft against different public policy tradeoffs.

Transparency is fine, but as we know in engineering, the best test is does it work. Some of the applications of science in engineering aren't necessarily ones that can be disclosed or explained, but simply seen by the practitioners of the field. That should be the standard that OIRA held to. Thank you.

DR. LOCKE: Thank you for your comments. Let me see if the panelists would like to respond.

MS. SASS: I have a question actually. Granger, it was you who brought up the example, I liked your phraseology where EPA shrugs its shoulders and said, are you nuts? Do we have to take this? I want to ask you, and any other of the panelists, what do you mean by that? My

question to you is, you used it in the mercury rule example, what process are you suggesting?

Are you suggesting there are some things that shouldn't have to go to OMB? Are you suggesting that there are different kinds of dialogue with the OMB? Are you suggesting that there is another kind of process? My follow-up is going to be, how might the outcome of that particular example been different had it followed a different process that you might recommend?

DR. MORGAN: I guess what I was proposing in that specific case was that requiring a quantitative benefit cost analysis, I mean, I understand, yes, they are allowed to consider qualitative factors, as well. But this notion that one must always quantify and do a benefit cost analysis for every major rule, whether it is to establish a right.

If one could simply show, for example, that significant numbers of children would suffer IQ decrement, isn't that sufficient? Do I really have to go the next step of figuring out what the expected value of the reduced earning potential over the next 75 years of those kids is? I am not opposed to doing benefit cost analysis when it makes sense. Indeed, I think in most cases, it does make sense.

The point I was making on that slide is that this notion that we must do benefit cost analysis for absolutely every major rule we undertake, and we must quantify it, just strikes me as nuts. In a situation like that, if I were an administrator in an agency, and my staff came to me and said, come on, this is really crazy, I think administrators ought to go to the White House and say, look, we have got to figure out some other way to do this than to go through all of this numerology, in order to meet a requirement that doesn't apply, and clearly doesn't apply in at least some circumstances.

DR. GOLDMAN: If I can add, and put a slightly different spin on things for this, that mercury standard under the Clean Air Act, cost benefit analysis is not part of the decision-making process. It is a mac standard, which has to do with the achievable control technology.

Actually, EPA leadership, I can tell you, has gone into OMB to discuss that kind of situation where a benefit cost analysis is being mandated by executive order, not by Congress. Regardless of the outcome of that, there is still a Congressional mandate to do it. Is that at a great use of taxpayer's resources? Some people think it is because they want to have this comparable data for everything, and they feel that it is important that no

matter what Congress requires, that if you have those data, then you can compare everything.

However, and this is a great case in point, there are a lot of non-quantifiable benefits to something like a mercury rule. We are kidding ourselves when we say that just because we have that dollar value, that we can make these comparisons in some rational way. There is a lot of unquantified benefit and cost to a rule like that. People have said something about it, Granger. It is just that it hasn't gone anywhere.

DR. MORGAN: I know that, and don't get me wrong. This is not a general argument against the executive order that requires benefit cost analysis of all major rules. I think, in general, it is probably a pretty good idea. Lynn is correct that for things under the Clean Air Act, it is an exercise one goes through, in order to sort of, in a separate box, say, now is what the agency is doing actually cost beneficial. In most cases, it is highly cost beneficial.

All I was trying to say in that case was to illustrate the broader point I had made of a slide or two back, that there is not one size that fits all. Agencies need, on occasion, to push back. If the White House says, yes, we are not willing to fold on this one, you have got

to go figure out the expected decrement in lifetimes' earnings of IQ-reduced kids. Well, okay, then you go and do it. I mean, you ought to go make them squirm.

PROF. WAGNER: It sounds like we have another ACUS study here on whether there should be a cookbook approach to cost benefit analysis or how we might think about it.

DR. MORGAN: Yes, well, you see, that's the point. I am not arguing that there ought to be a algorithm written down that says when you do and don't do this. I am saying that agencies should.

PROF. WAGNER: But it shouldn't be a cookbook.

DR. MORGAN: They should take the initiative to occasionally say, we have got to do this a little differently in this case.

DR. LOCKE: We have two people, at least, who want to offer some questions or comments, and about five minutes left. What I would like to do is actually hear both of their comments, and then maybe ask the panelists to respond to both of them, if that is okay with you guys.

MS. CASANO(?): I don't do FDA work, I don't do NRC work. I read Wendy's draft report from the perspective of somebody who looks at OIRA assessments. In my experience, limited as it may be, the problems that

Professor Wagner have identified really aren't the big problems

The big problem, as I see it, is what Professor Goldman said, is that too often, there is a lack of a study design. Decisions as to what criteria should be used to evaluate studies, to include, to exclude, to weigh, aren't laid out. You read a draft assessment, for example, and you read about one study which has certain factors apply to it. In the next paragraph, you read about a different study and those factors aren't mentioned, something else is discussed.

The formaldehyde assessment and the Bipartisan Policy Center both offered very concrete recommendations, I think, for addressing that issue. I would like to suggest that that would be a very fruitful area for Professor Wagner to explore in the next version of the report, or a different report.

DR. PASQUAL(?): Three points, the first point, I would like to point to the comment made by Professor Zeckhauser about costs and the cost of transparency. I hope that when the administrative conference considers cost, it also considers the cost of non-transparency. I think there is a lot of gaming that goes on in the system, associated with opacity, and those are real costs that I

think have to be considered, as well, when considering the recommendations of Professor Wagner.

The second thing also has to do with cost. Whatever the costs are, I think that the costs are distributed in varying degrees, as to who bears the burden of persuasion. In the decision rule that Granger pointed out, it is quite right, I think, that there is a bias against false positives. If the administrative rules were modified, so that we change that bias and guard against false negatives, we also have to consider how those costs are going to be distributed through the regulatory process.

Then, the last point, I think it is fairly clear that unless the statute says definitely, that a rational basis for decision does not equal a scientific basis. I don't begrudge the agency or OIRA's ability to make these judgment calls. However, when they do result in the rule, I would like to know the basis for those judgment calls, so that I can determine and assess whether they indeed were rational. That is it.

DR. MORGAN: Let me just clarify to make sure my comment about decision rules was not misunderstood. I think it is entirely appropriate in science to avoid false positives and to set the bar very high, because if you start allowing stuff into the refereed literature, which

turns out subsequently to have not been appropriate or correct, then it wastes a lot of time and resources. You ought to use that when you look at published data.

On the other hand, for regulatory decision making, there, I think, essentially a public health decision rule is the appropriate one. If there is significant doubt, be precautionary. The point I was making is that often people in public debate argue about, well, you shouldn't be doing this because there is not definitive evidence that this is a hazard.

On the other hand, if there is doubt, then a regulatory decision maker ought to be exercising some precaution. That was the distinction I was trying to draw. If everybody in the audience sort of thinks the decision rule is the rule of science, whereas in fact the appropriate rule is the rule for public health, there can be great confusion. This is a confusion that advocates use to their advantage all of the time.

PROF. WAGNER: Those are all really helpful comments. Just to pick up on two that definitely will find its way into the next revision of the report and recommendations. The decision rules and pulling out more types of decision rules I think is an excellent point. Dr.

Morgan raised it and the last commentator, Dr. Pasqual, mentioned it, great.

Also, the study design point that Dr. Goldman mentioned and the first commenter mentioned, excellent. I think that is an absolute brilliant sort of addendum to the beginning of the process. Again, it will find its way into the report. I think that is a wonderful way to think about it, so I very much appreciate those comments. Thank you.

DR. LOCKE: Before we close out the panel, just let me see if the panelists have any last comments. I would like to thank the panelists and I would like to thank you, the audience, for this great session. I think at this point, we are adjourned for lunch.

(Recess for lunch)

AFTERNOON SESSION

Agenda Item: Session 2 – Roundtable Discussion of Recommendations – Issues Related to the Integrity and Transparency of Science-Based Regulation, David Korn, Moderator

DR. KORN: We have learned that Judge David Tatel is not going to be able to be with us. I am not a pinch hitter for Judge Tatel. Let me make a comment or two, just while the last stragglers come in.

I spent in between Stanford University and Harvard University a delightful dozen years in Washington. I was the head of research policy at a not for profit that represents all of the medical schools and teaching hospitals in the United States and Canada. In that role, and as a member of the Committee on Science Technology and Law, we took notice of Congressional and regulatory actions that had an effect on biomedical research, which was, is, always will be my passion.

Therefore, we were very interested in the Shelby amendment, which was, as I understand it, one of these midnight amendments on the last day of his session. Then, about a year later, there was another one that, depending on your preferences, it was either the son or the daughter of Shelby. Both of those amendments led to OIRA actions

requiring transparency, peer review and other such for agency science-based decision making. Susan Dudley, who is the expert, can correct me if my memory of the history is wrong.

Because some of those proposed rules that OMB was issuing to the agencies, would have and could have had very deleterious effects on health decisions and health announcements. For example, the National Institutes of Health learns that a clinical trial that is funded by the government has been stopped by a data safety and monitoring board, because one of the arms of the trial was either dying or being made ill or whatever, a drug failed. The drug might have been one already marketed that was being tested for other purposes to get an expanded marketing approval from the FDA.

I am using this as an example. When that happens, it is the duty of the NIH institute director, who is responsible for that trial, or the NIH director, to make a public announcement because people are at risk. They have to make a very fast decision based on the data available to them, and vetted by an independent review board, without going through any kind of regulatory process to allow them to make them the announcement.

I am mentioning this only to say that in my dual roles on the Academy committee and at the Association of American Medical Colleges, I developed an extraordinarily productive and enjoyable relationship with Mr. Graham when he was the director of OIRA, I think just before Susan Dudley. He and I had many conversations, and I went down to his office and I would talk to him and some of his senior staff about some of these issues, where the impact on public health and on regulatory action were at stake. They were very, very valuable, and I was very grateful for his receptivity.

That is the extent of my interactions with OMB. We have three experts, and I will just ask them, one after the other, to come up here as we did in the first session. I will sit quietly and try to learn.

PROF. DUDLEY: Thank you, David. Thank you to ACUS and the National Academies for having me here. I am not going to be able to speak to that, because I am not quite sure what OIRA's role would have been in those decisions. I am really happy to see all of the people here.

Good public policy depends on good scientific information. Yet, the acrimony surrounding many decisions with accusations of politicized science and junk science

and advocacy science really hinders informed discussion and the achievement of policy goals. We should be wary of politicians trying to influence scientific studies. But as the Bipartisan Policy Center observed, and I brought a prop, in its 2009 report, which I would highly recommend if you haven't already read it, many disputes over the politicization of science actually arise over differences about policy choices that science can inform, but not determine.

As we search for ways to improve the use of science and public policy, it is important to evaluate whether the source of a particular controversy is A) political actors trying to influence science or the politicization of science, or B) policy decisions masquerading as science. I am going to paraphrase David Goldstein and call that the scientization of policy.

My own experience supports the BPC conclusion that this latter problem is behind much of the controversy related to science-based regulation. I think Granger Morgan this morning made that point very nicely when he showed us the decision path. It isn't just science and then a decision, and science alone doesn't give you the decision.

I think the scientization problem is also the main contributor to what Wendy has termed the science charade, where regulatory agencies quote, and camouflage controversial policy decisions as science. And yet, I don't think the report that was presented to ACUS recognized that problem.

In public policy settings, we never have the luxury of waiting for complete information. We have to depend on assumptions and rules of thumb, what Granger referred to as trans science. Often, there exists several scientifically-plausible alternative risk assessments, depending on the choice of studies, and on the assumptions used to bridge gaps in the information.

Yet, risk assessments often generate very precise sounding predictions that mask considerable uncertainty about actual risk. This puts key policy choices in the hands of risk assessors, and allows policy officials to avoid making hard decisions. Decisions that are thought to be based on science are heavily influenced by hidden judgments about what policy should be in the face of uncertainty.

Reports of the National Academies and numerous other reputable bodies have recognized that current procedures often blur the lines between science and policy,

hindering not only the resulting decisions, but the development of scientific knowledge itself. They have encouraged greater transparency in models, assumptions and risk assessment policy choices, to facilitate more open constructive debate. I hope in the panel after this one, we will hear more along these lines.

Improving these practices will have little impact, as long as legislators, judges and policy officials, as we are talking on this panel, the external influences, don't recognize that science is a positive discipline that can inform, but not decide, appropriate policy. As long as they operate on the pretense that science alone can make the normative determination of what policy should be, both science and policy will suffer.

I think we see this in statutory mandates, such as those directing EPA to set the National Ambient Air Quality Standard's under the Clean Air Act. That can make scientization of policy almost inevitable. I was surprised that Wendy referred to that as a kind of role model. It is probably the most, or at least one of the most, litigated, most controversial types of decisions that EPA makes. With each of the last three presidents has had to intervene on those decisions. We can't be getting it right if that is the case.

I just want to walk through how the NAAS works. Congress directs EPA to set the standards at a level that is requisite to protect the public health with an adequate margin of safety. But it restricts it from considering key factors, establishing instead the pretense that science is sufficient to determine a single point concentration that meets that protective definition.

The courts have reinforced a limited interpretation of the act, as well as tight deadlines for revising the standards. EPA has no choice but to respond by developing scientific sounding explanations to justify one standard over another. Analysts have an incentive to downplay, rather than reveal, the implications of key assumptions. Decision makers point to science as either requiring a new standard or as being so uncertain that a new standard cannot be set.

The interagency review process is often truncated by very short timeframes, and a limited range of options established by EPA and its Clean Air Science Advisory Committee. Public interveners vigorously defend alternative standards, based on their own interpretations of the science. This has really evolved into an adversarial process, characterized by harsh rhetoric, in which each party claims the science supports its

recommended policy outcome, and questions opponents' credibility and motives, rather than a constructive discussion regarding appropriate assumptions and data, and the reasonableness of the standard.

The Bipartisan Policy Center recognized that distinguishing between science and policy is not always easy or straightforward. It is essential, nonetheless. I think the failure to do so represents the biggest impediment to the integrity of regulatory science.

As we consider on this panel external barriers to the integrity and transparency of science-based regulation, we must be careful to understand that distinction, and to evaluate each recommendation through the lens of what it would do to deter both the politicization of science and the scientization of policy.

MR. GILMAN: I have to say, when I sat down this morning and looked around the room, a scene from the Adventures of Tom Sawyer came to mind. I looked around and I felt like I was in the funeral. Tom and Huck and Joe were all around me. The players in this game are right here in the room, so many people who have been involved in this, in what we are discussing today.

I guess I get to be both Tom and Huck because I sat in the EPA, in the Office of Research and Development,

where IRIS and at least two-thirds of the NAAS scientific process took place. I also had a stint at the Office of Management and Budget.

As I think about those external constraints, especially those that relate to recommendations of the OMB, I have sympathies with both sides. In the end, if what you are trying to write down are principles necessary to for transparency or good government, I don't know how you walk away from asserting that what is good for the goose is good for the gander, when it comes to the OMB.

Especially when you consider that a number of those rule-making processes, where there is interagency review, the agencies aren't just in related fields with technical input that might be useful. In many instances, they are regulated parties. You have people participating in the process, opining on where the rules should come out, who are directly affected by that rule. I think that special case needs some consideration in the recommendations for the report.

I do think the level of recommendations for the report, as far as external influences and constraints are concerned, is appropriate for many federal agencies where there hasn't been a great deal of work done on transparency and peer review and the like. When you start to talk about

an agency like the EPA, where it has been the focus of attention for literally decades now, I do think the recommendations don't go deep enough.

One needs to drill down. Granger touched on it, talking about the decision rules. There are a number of documents within the EPA that essentially lay out the methodology that the risk assessor might use in doing the work that they do. They serve the purpose of educating new staff, but they also serve the purpose of informing stakeholders as to the detailed decision making that goes on within the process. How assumptions are decided upon, how different models are decided upon, how the literature is to be used or not used.

To the extent we focus on transparencies, probably for an agency like the EPA, at that level, where we need to call more on the agency to make its practices known, the norms, to be enumerated and elucidated. That will also serve the purpose of setting some best practices, I think, for some of the other agencies that aren't as far along.

Another point of focus, I think we have touched on it. It is the people. The process will only be as good as the people. It isn't just a matter of having highly qualified individuals, but they have to be trained, as

well. It is back to understanding the norms, the decision rules and the like.

There has to be a level of scientific integrity within the individual. I am reminded in a past life, I worked in this building for the National Research Council, one of the constant points of discussion was what were the responsibilities of an entity like the National Academies in promoting among students, not just science and engineering and students of medicine, but all students, the principles and the notions of scientific process and scientific integrity. I do think that ultimately, we can't expect policy makers who have only had high school science to do the integration well, if part of that science wasn't also a discussion of scientific integrity.

Let me also speak to a very significant issue that I don't think the report really touched on, except in saying that agencies are resource constrained. The truth of the matter is, it isn't a matter of just laying out all of the knowledge and finding your way through the path. There are very significant knowledge gaps.

The Pollyanna side of me would say, if we could just do more on those knowledge gaps, we would do better. At the same time, I have heard Granger eloquently argue that closing knowledge gaps doesn't necessarily reduce your

uncertainty. Just the pursuit of the knowledge isn't necessarily the solution to the problem.

Let me say something about the whole notion of the OMB transparency. I didn't touch on it when I was speaking to that. We talked about the needle coming off of the record. I think the report does that, Wendy. There are other places that do that. You are in one.

The NRC process is one of closed-door deliberation without record. The only record of the deliberation is the final product. Having said that, there is a process in it that is all about balancing biases and points of view, for the process. That is not necessarily something that we see in the interagency process.

I think one of the things that you might focus on is the next step, Wendy. It is not so much the use of science in the activities you have talked about. I recollect a report that was done by the OMB. It was actually just a compilation of comments. There was a call for comments on the quality of science at the EPA 2004ish.

It resulted in a staff paper from EPA scientists on risk assessment practices. One of the things that really came to the fore in that was that most of the comments that focused on EPA shortcomings were going to the processes that actually take place in the regional offices,

in day to day decision making that affected communities, companies and the like, whether they were super fund-like activities or other implementation of the responsibilities of the agency. That was actually more of a focus of the disgruntlement of folks, I think, almost than the more lofty IRIS assessments and the like.

DR. GRIFO: Good afternoon. I am Francesca Grifo. I have been doing scientific integrity work at the Union of Concerned Scientists for the last seven years. It is hard to believe, it has gone fast.

Thank you very much to the organizers for the opportunity to be here. I may appear a little disjointed because I am trying to respond to all of the things that I have heard this morning, on top of what I have already prepared to say. We are only supposed to take five minutes, so here we go.

I think in short the main point I want to make is that it is really important to remember, and this was made this morning, that the scientific expertise resides largely in the agencies. Yet, some would say, routinely, I would say, on occasion, their decisions can be modified or overruled by the various offices in the White House. That is the structure that we live in. This is a democracy.

I think we have been talking all along about the separation and the problems with separating policy from science. I think part of that is because we elect officials because of their judgment and for them to make those political decisions. It is a tough nut, I think, that we are trying to crack here.

I think one aspect of the problem lies in the fact that, while the agencies have made some progress in addressing the scientific integrity issue, you will remember, and I think it is outlined in Wendy's report, very soon after the inauguration and even within the inauguration, scientific integrity was very often mentioned. There was the Holdren memo and the directives and so on, and the agencies have been really putting considerable time and energy into scientific integrity policies.

The White House hasn't. At this point, we don't have even a draft or even a notion that OMB or OSTP are going to have, or other offices of the White House, scientific integrity policies. It remains very much a black box, how they make these deliberations and what these deliberations end up being.

I think it is not that their scientific integrity policies would look like those of the other agencies, but

nonetheless, making that effort to think about these issues and put out there what their best practices are, I think is important. I would say that increasingly, the challenge is again that definition, that separation of science and policy.

I think the recommendations in the report are by and large really good. I was very sorry to see a second draft that significantly pulled back on those, and I will mention just a couple that I think are really important. I think what we are seeing is that very well-intentioned people are influenced by politics. I think at the beginning of the administration, when everything was shiny and new, it was really easy to say, yes, scientific integrity, awesome.

As we proceeded down that path, it became more and more complex, and more and more obvious that that was going to be actually a really hard thing to do, and that it was going to be at odds with things like the message and politics, even in a very well-intentioned administration. Again, it is a tough challenge.

I do believe that OMB and OSTP and other parts of the White House may, in certain unusual circumstances, indeed merit less transparency than agencies across the federal branch. I think they are unusual situations. They

are not business as usual. I think that, and again, listen carefully, because I am not saying everything needs to be transparent. I understand the deliberate process and the need for some of that to happen in a black box behind closed doors.

I think that when the deliberations are about the merits and the meaning of the scientific basis of decisions, that those ought not to be secret, that somehow there ought to be a way to summarize and report those out. If there are aspects of the decision-making that are around politics, that is, as I say, a very different matter. Review and further analysis of the scientific underpinnings of a decision should, with narrow exceptions, be part of the public record.

I heartily agree that someone does need to make those judgment calls and bring in the values. As I said, that is why we elect these folks, to make those hard decisions that clearly science can't make. Science can just advise. I think it is about our leaders having the courage to say, yes, I see the science. That is what the science says and that is really important. But I am weighing these other factors, and so therefore, I am making this different decision. That is really hard to do and that is why I think we don't see it all the time.

I think that as was mentioned this morning, I forget who said this but the disclosure of everything may be the disclosure of nothing. I would say the disclosure of nothing is still the disclosure of nothing. I think, as hard as this is, we have to keep trying. We have to keep trying to find that sweet spot and that space where we can do it.

I think OSTP has a really critical role to play in identifying best practices. Sadly, they are woefully under resourced and understaffed, and I know they would love to be doing more of that, and be exerting more leadership on the scientific integrity issue. They only have so many people to do that, speaking of external constraints.

I think it was really interesting this morning that people talked about all of the various steps. I mean, I think all of those steps matter when we are talking about study design and literature review and all of those various pieces of the scientific conclusions. To me, this is also why transparency matters, because each of those steps along the way is a place at which the science is somewhat unprotected without transparency.

I am going to sound like one note Jenny here, singing that transparency song. I would really love to

know of better ways. I don't know of a better way to protect the science frankly, as it moves from one agency to the other, or as it goes into other parts of its review. Except by having it out there, so we can all see what the changes are and when changes are made, and hopefully understand why.

I think that authorship and attribution, you know, the discussion that we had this morning about that, is really important and a really good thing. I would add that, if we are going to put out there who the scientists are that are doing that work, then we are putting them out there to be influenced, as well. We have to be really careful of that double-edged sword, and make sure that we think of ways, as well, to protect them and to really figure out what to do about access to those who would seek to influence them in the way they think.

I think, Paul, you mentioned, the role of agency leadership is huge. When I look out across the horizon of the scientific integrity policies that are out there, the two that are the most operational and doing the most are doing that because of the leadership of those two agencies. I would say that at EPA and at NOAA, they have leaders that are very committed to this issue, and have really worked hard on it.

Leadership really matters because it is through that leadership that you create this culture, where descent is something that you do. It is just normal, it is what scientists do. Any of you who have ever been to a scientific meeting know, scientists descent loudly, sometimes obnoxiously. That is a really important part of the process, and that is something that agency leadership can really engender and support.

I would say in terms of stopping rules, I mean, I think stopping rules might be great. I think we have to really address the delay. I am thinking about the silica rule, I am thinking about the egg rule that was in OMB forever before it finally came out and so on. There are many, many examples of that. If stopping rules will speed that up and let us move forward with some of these rules more quickly, I think they are awesome.

The last couple of things in conclusion, I would say I was really glad to know that in another part of the National Academies, they are revising and updating their research integrity publication. I was really thrilled at one of their opening meetings to hear the agencies that are requesting that update talk about how they wanted to talk about scientific integrity in broader terms than just F, F and P, which is falsification, fabrication and plagiarism.

They actually wanted to see them wrestling with these bigger, broader issues, and I think that is a good thing.

In conclusion, looking at my analysis of all the scientific integrity policies that have been submitted to OSTP, and subsequently released to the public, there are several needed reforms that are beyond the scope of the agencies to act independently, four of them that I will just briefly mention.

First are whistleblower protections, we haven't really talked about that here. It is not really mentioned so much in the report. I think that if we are going to put that pressure on scientists, that is the protection that we want to give them, again, as a last resort, as the last line of defense.

Transparency in interagency review, again, I think Wendy's original recommendations address this. It is really important. I think Paul addressed it a little bit about how, as certain pieces of science are reviewed by other agencies, well, clearly, they are not without a conflict of interest on some of those things, and that is very problematic and really requires transparency.

Visitor logs, you know the White House is releasing them, except for narrow exceptions. Other agencies, some agencies claim that the senior folks are

releasing their calendars, but somehow, I never can find them when I look on the website. I think that is something that again we don't want to divert massive amounts of government resources to creating this giant bureaucracy of visitor logs. There are certain steps that could be taken in a pretty efficient way.

Definitions of conflict of interest, I should say that there has been recent progress on what these should look like, has been made by a group called the Research Integrity Roundtable, convened by the Keystone Center and comprised of such normally really disparate groups, such as the American Chemistry Council, industries such as Dow and Bayer, and groups like the Union of Concerned Scientists.

Their report that really talks about these issues is going to come out. It does exist, I can hold it up, but I can't' share it yet, on the 17th of September. I think that will be something that will be worth taking some time to look at. What it does is take the BPC report and take it to a next step with further conversations and deliberations. I think it makes progress on that.

I think it is a tough road back from publicized risks and privatized profit. It is just not tenable for us to continue to have doors open for politicization. I think that, as I say, if there is a better idea, if we think that

transparency is not the best thing, I would love to hear about it. In the absence of other less difficult to implement solutions, I think we have to go with the transparency, so that we can make sure that the scientific information which is pulled together and there is no scientific truth.

If you go back outside, I recommend that you look up and read the little thing about the dome, because it talks about science as a guide to truth, not the truth. I think as close to the truth as that gets, we have to continue to try and protect it. Thank you.

Agenda Item: Discussion with Participants

DR. KORN: Do we wish to ask for questions from the audience.

PROF. DUDLEY: I will start. I actually agree with Francesca that we do need to try to separate the science from the policy. I think the statement that the science tells us something, and then the policy may be different, is naïve. It assumes that science is a normative thing that can tell you what a number should be, what is protective or what is the appropriate number. I think that is where we have the problem is disentangling what is science and what is policy.

With respect to the disclosure and transparency, I just want to run through how transparent the Office of Information's regulatory review is. If you go to the RegInfo.gov, the GSA/OMB website, you can see what regulations are under review. You can see when a regulation was concluded, what the conclusion action was.

That is why when Rena said that she did some empirical research and found that 84 percent of the rules had been altered, well, that is because you can see that because there is a searchable database that tells you that. That is how transparent OIRA is. You would not be able to go to an agency and see whether the general council office or the enforcement office changed any aspect of the regulation or anything that scientists might say.

Second, the meetings with the public, several people have mentioned those. That is a requirement under 12866 that OIRA has an open door policy. When it meets with the public, it reveals the fact of that meeting. That is adhered to rigorously, so that the attendees of the meeting are docketed, agency staff is invited. OIRA reads them their rights, they talk about it as reading their rights.

If you go in as an entity going in for a meeting, you are told, we are here to listen. We are not going to

tell you anything that is in the regulation we are reviewing. We have the regulatory agency with us so that they can hear everything that you tell us. Any material that you give us, we will also post on our website. Again, very, very transparent.

If you go, ask OIRA and see the docket, you can see the draft of the regulation that was originally submitted for review and the draft of the regulation as review was concluded. You can see the changes that were made. As Lynn mentioned in the earlier panel, you don't know who made what changes. In fact, some of those changes, the issuing agency, the original drafting agency, makes changes in the course of the review. Often, they will send things to OIRA when they are not quite done, so they are making changes. OIRA coordinates interagency changes. Again, transparent.

Somebody said earlier, you don't know when OMB returns a rule why. Yes, you do, because OMB sends a public letter that says the reasons, the elements of the executive order that the agency didn't comply with, and why it is being returned, so again, transparency. Then, I would say the ultimate transparency is the public docket itself. The agency's decision has to be based on what is

on that record, and there is nothing in the interagency review that changes that.

I think all of that transparency is good. I think it is positive, but I would reject fishbowl transparency, which I think is some of this stuff that we are talking about. I liked very much Professor Zeckhauser's A, B, C, D. To it, I would add an E. Does everybody remember his A, B, C, D? Advocacy, bias, cynicism and distortion, and I would add an E, which is evasion.

Because OIRA is so transparent, if you said, OIRA, you have to document every interaction you have with the agency, those discussions are going to be taken offline. They are going to be done in OSTP or other parts of the White House, the vice president's office, et cetera. You won't know any of the things that you now know, when things run through OIRA. I think you actually have serious unintended consequences that will make much less than is available today. Rena would not be able to do that report if that were the case. I guess I will stop there, but reserve the right to say more things.

DR. KORN: Paul, do you want?

MR. GILMAN: I wasn't going to say much more about transparency, but I think I have to. When you work at OMB, you start to learn the rules of thumb, of how to

get things done. One of the first ones I learned was if you wanted to slow something up, the best way to do it was interagency review. That would get it in the holding pattern for a while.

Another great way to slow things up would be to send them to the National Academy of Sciences for review. There are many different tools.

PROF. DUDLEY: Where did you work at OMB?

MR. GILMAN: I was the Associate Administrator for National Resource Energy and Science. We know how to do delay, too. There are also lots of little things. I discovered, I didn't know it at the time, that the OMB has to approve any survey of greater than seven or ten?

PROF. DUDLEY: Ten or more respondents, the Paperwork Reduction Act.

MR. GILMAN: That was a marvelous tool. I had a study, trying to understand the effect of pesticides on children that was held up through that approval process. In fact, it is not a matter of driving the process out into the other offices of the White House. It is already driven there.

There is a cottage industry in this town, of folks who specialize in influencing the regulatory process, whether it is when it is in review at the National Academy

of Sciences, or whether it is in review at the OMB. The doorways into doing that are through the office of the vice president or other various offices of the White House. There is some transparency, but I am not sure it is necessarily transparent enough.

PROF. DUDLEY: Just let me clarify, it doesn't happen through OIRA. When something is under review at OIRA, it is very transparent that it is there and anybody who comes to speak to OIRA about it. That is where the White House officials come to those meetings, and their names are also put on that docket. I think OIRA's transparency adds to the transparency of the entire executive office of the president.

MR. GILMAN: It is the meetings after those meetings.

PROF. DUDLEY: Yes, and I don't think telling OIRA they should do more documentation, I think it would make more of those meetings than less, because at least when I was in the White House in OIRA, the other offices also complied with that and tried not to meet with outside parties on regulations under review.

DR. GRIFO: What he said. I think there is an enormous difference between theory and practice. It is a

giant bureaucracy, of course there is, but that is where these challenges arise.

PROF. DUDLEY: Well, a giant bureaucracy, OIRA has a staff of under 50. Two of them may be scientists, or a handful of them scientists, but when you think about it, there are really only 30 or 35 policy analysts. I think we can all agree, OIRA is too small. OIRA needs more staff, and then we could solve all of these problems.

DR. KORN: Full employment act for OIRA. Let me ask a question. As the least expert and least knowledgeable, at least in the room, part of the issue that I find conflating is whether or not the fear or the perception is that OIRA is changing the science that undergirds a proposed rule that comes to it for review or whether it is accepting the science and making a judgment, a different judgment from the agency, based on a host of different political and practical reasons?

I think there is a difference there, because the implication that I got from reading Wendy Wagner's report was the concern that the science itself, or the interpretation of the results or whatever, was being manipulated for political reasons, without revelation to anybody of what that manipulation was all about, which is where I see the transparency issue.

I don’t think anybody really believes that an executive office of the CEO, or the president or whoever, has to have everything it does in public display. I don’t think that is the argument.

I think I read Wendy’s report as expressing concern that it was the science and the conclusions from the science that were being changed, or rejected or whatever, without any kind of explanation, call it disclosure, if you wish, as to why that was happening. I didn’t get the sense that it was the political decision that might differ, which was the cause of the problem.

Now, maybe I misread Wendy’s report, but that is the concern that I had coming into this meeting. Can you all clarify that?

PROF. DUDLEY: I think that gets to the crux of the matter, and that is defining what science is. Now, Wendy’s report interviewed agency staff, and it was largely, I think, EPA that were concerned that science was getting changed. If anything, once you do that, everything is going to be defined as science. A scientific study is based on the scientific method, which is you have a hypothesis, you gather data, and you test that hypothesis. It is a rigorous, challenging exercise where you are open to challenge and discussion.

What comes out of, say, risk assessments, ambient air quality standards, that involve a lot of trans science. Trans science involves a lot of policy judgments. How do we want to air some of the things that were talked about on the morning panel? Are we always going to air on the side of precaution? Do you multiply times 10 to adjust from the species that you looked at, to get to another species, do you multiply again by 10? Those kind of assumptions all get into something that you might call science. But I thought that the value of the OIRA scientists was they helped try to parse out and say, this is pure science and this is not.

DR. KORN: Let me come back to one thing that I do know. Particulate matter in the atmosphere, right, particulates, ozone, let’s just say particulate matter. There is excellent science that is done, very elaborate epidemiological studies that correlate the presence of a concentration of particulate matter with serious health disorders involving children, as well as adults, asthma and bronchitis, and this, that and the other thing.

EPA collects those published data that have all been peer reviewed and published in frontline journals in the fields. On the basis of these reports, multiple reports, big studies, proposes a change in the standard on

particulate matter. This might actually happen, but I am just sort of quasi making this up.

They present all of those data and they go through all of the vetting they are supposed to do. Then, they propose a regulatory change that the threshold, instead of being 10 parts per million should be lowered to six parts per million or something like that. There is a transparent open, much of it public record, evaluation of science with real consequences to people's health. It goes up the ladder, up the pole, to OIRA.

Now, obviously, industries that produce particulate matter are not going to be happy about this. They are going to be fighting as hard as they can, to not let this happen. Somebody is going to be making a political decision with the advice of OIRA or OIRA makes the decision about whether that change in the standard happens or not.

Is that refusal to change the standard based on the rejection of the science, and the interpretation of the science? Or is it based on an economic consequence? I mean, maybe if you would go through that, it would put a concrete example on the table.

PROF. DUDLEY: It is a good way to look at it, for particulate matter and I think also ozone. What comes

out of the science analysis is a linear dose response curve. That means that we know that at high doses, there are certain effects, and we draw a line down to zero. That means that at every exposure to particulate matter greater than zero, you have some effect. You have this linear dose response. The question is, where do you draw that line? What is protective?

Well, some might say, well, protective is zero, especially if the statutory language is protective with an adequate margin of safety. How could you set a standard that is bigger than zero? We know that if you set it at nine or six, in your example, if you set it at six, well, why not set it at five. If you set it at five, why not seven? While there is science that may indicate a correlation, and I think there is more dispute on the science on causation versus correlation, but let’s not go into that. Let’s just accept that linear dose response curve. Where do you draw that line? That is clearly a policy choice.

This is the point I was making, that science is positive. It can tell you we think, again, based on numerous assumptions, we draw this line to zero. It can’t tell you where on that line to stop. That is, I think, where there is discussion among different parts.

Certainly, there is a lot of discussion within EPA, there is discussion with EPA and other agencies, and OIRA is part of that discussion, and I think appropriately so. That is why I think the last three presidents have intervened on the ozone decision as part of that discussion.

DR. KORN: Do the other panelists have comments on that?

DR. GRIFO: I would just say that I think, how to be simple in this, setting the standard is one piece of it. Figuring out what to do about that standard is a completely, ought to be, and I think is by statute, a separate process. I think what we have seen, and the reason that people have been objecting, is that concerns about what that means economically, and what it means for industry, have crossed from the decision of how quickly do we implement this standard.

What timeframe do we do and over what period of time and how and so on and so forth, has clouded the conversation about what the standard is. I think the Clean Air Act is pretty clear that that cost benefit piece is really not to be a part of that standard setting, and that is the problem.

PROF. DUDLEY: Well, it is and yet it is not a zero standard. I don’t see how you set that policy

standard along that continuum, other than at zero. In fact, when we were looking at the lead ambient air quality standard, I suggested in the interagency review, let's set it at zero. If all the data really suggests that lead is a serious childhood problem, even at the low levels we have reached now, how could we possibly stop at anything other than zero.

I could tell you the people at EPA were very upset about that notion, because they thought they needed to set a non-zero standard. There are value judgments and policy decisions going into the standard as it is being set. There is no doubt about that, or else they would all be set at zero. I disagree that it is economic considerations, although it is hard for me to know how you would make that judgment non-zero. I think I am just rambling now. But it is not a clear distinction between the policy standard, because unless you set it at zero, you have made a policy judgment. You have made a tradeoff and it is not pure science.

DR. GRIFO: I can't remember who said it this morning, somebody said something about that if you give people enough time and enough information, they can make good decisions and understand the science and so on. I guess that principle may apply here. If we say, okay, here

is what that process is. We have set these people up to make this decision. We have chosen them carefully, we have given them information, we have given them directions. Then, for my mind, I would say, fine, let them set that standard.

PROF. DUDLEY: We have, as you mentioned, I think quite right, that we have a democracy so that the people in the executive branch are accountable to the elected official, and that is the president. President Obama, like presidents before him, have given OIRA a role of reviewing agencies' decisions, and coordinating the interagency review.

I think that is why ACUS chose not to present these recommendations to the committee, because the redline that you see was actually before the committee saw it. I think the committee made further changes that may be not reflected here. That is that this is not the appropriate place to weigh in on whether the president should be able to oversee his staff, and how the president should choose to do that.

DR. GRIFO: I would say that I don't think the recommendations go that far. I think they simply challenge the notion of figuring out a way to summarize and reveal more of that deliberate process, while at the same time,

holding onto a certain amount of it that is deliberative and should be behind closed doors. I don't think we are as close to that openness as we could be. Again, I think you are talking about just OIRA. I am speaking more broadly about the entire White House, and that may be the basis of some of our disagreements.

DR. KORN: Paul, do you have a comment to offer?

MR. GILMAN: No.

DR. GRIFO: He is between us, but he doesn't really want to be between us.

DR. KORN: If it is okay with my co-panelists, we are five minutes early on the audience, but why don't we just take questions from the audience?

MR. SARVADI: We do a lot of science-related law. One comment about the NAS committee, I didn't see any legal practitioners on the list, which surprised me. One comment and one question, Ms. Dudley made the point about scientists doing research to find a number where you can see effects, and then drawing a line to zero. How you draw that line is a value judgment. I don't think we are ever going to have an answer from scientists about how to draw that line, until we get more information about the shape of that line and the nature of that line.

One question, does everybody who is involved in this know about the Sterling drug case with FDA? Sterling Drug was a D.C. Circuit Court decision that said agencies' scientific evaluations are not part of the deliberate process and are not subject to the exception in FOIA for deliberative process, and have to be disclosed to the interested parties.

If I go to EPA and I give them my tox studies for my pesticide registration, those evaluations have to be made available to me. They can be made available to anybody who does a FOIA request. The only thing you have to certify is that you are not representing a foreign entity in obtaining that. I would suggest that maybe you want to take the Sterling drug case into your calculations here.

DR. KORN: Comments?

DR. GRIFO: I would say how to draw the line is indeed a value judgment. There are assumptions that go into that. Again, I think that I can't quote it exactly, but there is a very good paragraph in the Holder memo that talks about revealing those assumptions whenever it is possible. I think the key thing about the scientific piece of this here is that you want it to be repeatable. If you don't reveal those assumptions and you don't reveal that

methodology, then theoretically, if you do reveal those, you should be able to repeat drawing that same curve.

MR. GILMAN: If I could just add, I would not say it is without basis that we draw that line. The question is, how much biology do we know that can inform the drawing of that line. This goes to the point I was talking about, where the agency writes down how you go through that process, how you make those decisions, and the norms and the rules that you follow in your decision-making process.

To the extent, when people are struggling at OIRA or in that interagency review process, or even in the peer review process, it oftentimes is simply about how much information was available, was the judgment to go one way versus the other the appropriate judgment or not. That can turn the whole number on its head, based on that judgment call. It is why one of the more noteworthy risk assessment documents that the Academy did was called Science and Judgment in Risk Assessments.

PROF. DUDLEY: I would just like to agree with my fellow panelists. I think Francesca is right, that that is one of the key things. If we can be clearer on the assumptions that go into it, and maybe go one step further and lay out, if we made different assumptions, we would come up with different outcomes, and to provide that kind

of a range. That, of course, is our next panel's discussion, but I think it would be something we should toss to them.

MR. GILMAN: A number of groups are making recommendations on that, as we speak.

PROF. DUDLEY: Including my colleague, and Lynn Goldman's colleague at GW, George Gray, has a current article, Rethinking Chemical Risk Assessments in the current issue of Nature, which I think people here would appreciate.

PROF. STRAUSS: At the moment, I teach administrative law at Columbia Law School, but I was once general counsel of the organization that Francesca's organization was born to destroy.

DR. GRIFO: I have no idea what that could be actually. I mean, really.

PROF. STRAUSS: The Nuclear Regulatory Commission.

DR. GRIFO: Well, we disagreed before he even starts.

PROF. STRAUSS: I am not sure that we do. Susan has used, and others have used, this word, trans science, a lot. It does seem to me that that is the setting, this is kind of in the form of a question, where these issues

principally lie. It is very standard in the literature that you ought to separate risk assessment from risk management. Risk assessment is where the scientists are, and risk management is where the politicians are.

The problem is trans science makes the risk assessors also kind of politicians, and makes the risk managers maybe also kinds of scientists. The question as I see it is, is there any way of domesticating that difficulty of bringing into public view.

Now, back to my experience with the NRC. The most important thing for the NRC, and its discussions with its staff, was to understand from the staff, okay, what of what you are bringing to us is known and what of what you are bringing to us is your engineering judgment. Engineering judgment was often 50, 75 percent of the mix. That is where it seems to me the crux of our issues lie. It is not only the Freedom of Information Act, it is good, solid D.C. circuit law judge, notwithstanding, that when an agency engages in rule-making, it has to put the science in the record, period. It doesn't have to put its judgments about trans science in the record.

MR. GILMAN: I think it is an oft repeated, somewhat incorrect reading of the red book that there was a demarcation between the risk assessors and the risk

managers. In fact, it was recognized in the red book that it was an observation of the way government worked and the way risk assessment was used. At that time, really the focus was on the FDA.

It is an iterative process. Unfortunately, or fortunately, just as we described the NAAS process, it has evolved to being an iterative process. Groups are pining on how to do risk assessment better are advocating that early risk assessment process. One of the advocates of it is at the microphone, and maybe I will defer to him.

MR. WALKE: I am the clean air director for the Natural Resources Defense Council. I was also an attorney in the general counsel's office in the EPA in the Clinton administration.

In listening to this morning's discussion, it strikes me that if one were to design a system in which scientific decisions could be overruled and interfered with, and made without scientific basis, but to do so under the pretense of trans science or policy analysis or hybrid science policy decisions, it would look exactly like the system we have. That is what the defense immediately rushes to those policy justifications.

The authors of the 1990 Clean Air Act Amendment, seeing the rampant interference with clean air rules by the

Competitiveness Council and OIRA actually required all comments by OIRA on proposed and final rules to be docketed, something that is not always done under the executive order, but is under the Clean Air Act to that statutory amendment.

What we have seen is that transparency helps. It has resulted in two phenomena, though, that I think we should be aware of. The first is that I have been told by EPA staff, and even witnessed this myself, that OIRA will often deliver comments on rule-making over the phone. In one extraordinary instance, instructing an assistant administrator to take notes, subject to dictation, over the phone, so that the comments of the agency and the comments of OIRA and the edits of OIRA would not appear in the docket, in a clear attempt to circumvent the Clean Air Act requirement.

The other phenomena that has occurred is that the edits and comments are not always provided when conducted, pursuant to emails, because of alleged deliberative privilege. There was actually a very helpful, at least helpful for democracy exchange, surrounding the ozone standard with former administrator Dudley, where there were two very high-level memos exchanged, mere days before the rule was adopted in March of 2008, in which EPA accused

OIRA of forcing a decision upon them that, quote, lacked scientific basis and that also ran afoul of a unanimous Supreme Court decision that disallowed the consideration of cost.

Now, those were deplorable in my opinion, but at least they were transparent. Those types of very high level memos are exceedingly rare, which I think administer Dudley would acknowledge, because it came to a political head before going to the White House, whereas she said, the president made that call. This president did the same thing, I will also note. It is also a bipartisan phenomenon.

I think at the end of the day, the greater transparency along the lines of what we saw in the memo from administrator Dudley, extending to emails that are currently not docketed, would be of great assistance. At the end of the day, though, it is going to take political courage. If you are going to have an official that is going to circumvent the law by telling someone that you must accept our comments over this phone call, that person should be fired.

That takes the type of political courage that we have not seen in our democracy from either political party. I could hope for the day when it does. In the meantime, I

would welcome any comments or reaction from the panel. Thank you.

PROF. DUDLEY: I am sorry that you didn't think that my memo was equally convincing, John. I have no evidence of your other examples, so I think OIRA staff are very contentious and careful about complying with all of the transparency requirements.

DR. GRIFO: I think, just to comment for a minute on political courage, I think that is what I was trying to refer to, which is it is very hard to come out and say, this is what the science says. I am making this decision based on something else. Now, sometimes the statutes prohibit that, but that is actually fairly rare where the statute says science and science alone.

There are many, many cases out there where someone could come out and say, just not to bring up another controversy, but I am thinking back to the plan B decision, which was clearly a science-based decision, based on science. The science was there.

I mean, we can quibble over that, but the fact that the head of FDA was overruled by Katherine Sebelius at that next level was really, I think, on Sebelius' part, and I am a mom and I get it, a value judgment. It is just too bad that we don't have a situation where she could have

come out and said, yes, I get it that there are signs there. I am deeply uncomfortable with 12-year old girls having access to this particular pill. She couldn't say that and she didn't. I think political courage and leadership is huge, hugely important.

DR. RODRICKS: I want to make a comment on the issue of science and policy, and their separation in this issue of trans science. I think many of you know about the Red Book from the National Academy of Sciences, I think Paul mentioned it. It came out in '83 and it grappled with this issue of the uncertainties in science, and the issues in risk assessment that go beyond normal science.

It offered a solution to that problem. It said that, for all of the assumptions in risk assessment, there are a range of plausible assumptions that regulatory agencies ought to examine those, and ought to select some assumptions that they would use all of the time, on a consistent basis, whether that is a linear model or the way you extrapolate from animals to people and so forth.

You would stick to those assumptions. You would incorporate those assumptions into written guidelines, explicit guidelines, which describes how you use the science, how you then incorporate the assumptions and which ones. Those assumptions have come to be known as default

assumptions in risk assessment. The notion behind that was to avoid case by case manipulation of assessments. You would stay with a consistent set of assumptions.

Every Academy study of risk assessment since ’83 has affirmed that as a good approach to dealing with trans science issues. It is not great, but it is the best we have. EPA has incorporated assumptions like that, that defaults into its guidelines for the conduct of risk assessment. They also say, and this is what the report in ’83 also said, that if you have got some good scientific basis for departing from those defaults, in specific cases, you ought to do that and justify why you have done it. That has always been a problem.

Those assumptions are a kind of policy, I agree, but they are distinct from the kind of policy that is typically involved in risk management, where Ms. Dudley mentioned, for example, what risk level do you seek, where are you going to draw the line on risk. Those are clearly outside the range of risk assessments.

There are some policy choices within the assessment itself, guidelines, explicit guidelines on what those are, perhaps the best solution to that. I think that recognition, from what the Red Book proposed, has not really penetrated a wider audience, and I think it should.

It has been reaffirmed in every study from the Academy on risk assessments since ’83, including a major one that came out in 2008 on science and decisions. I just wanted to make that point.

MR. GILMAN: Joe, can I see if you agree with a clarifying comment, that the intent was not that these be arbitrary defaults, only good because they were consistently arbitrary. There was a basis in science and in fact for them, although it may not be as sound as we might like.

DR. RODRICKS: That is exactly right. The notion was that you ought to look at those that fall within a range of scientific plausibility, knowing that you cannot support anyone on purely scientific grounds, and then describe why it is you picked one to follow. If agencies, if EPA, has been lacking in that, it is probably in the discussion of why it ended up with a linear model or with a certain model for animal to human extrapolation.

They are in the guidelines, and again, the key point was to avoid case by case manipulation of those assumptions on the risk assessment process itself, unless you had very good scientific reasons to do so.

PARTICIPANT: I am a second timer, so I will be really brief. The statutes that we have been discussing,

especially with respect to EPA, delegate the decisions under all of the laws that we have been talking about, to the EPA administrator, not to the president. In fact, what is trouble about OIRA's role is that people are not dealing with the president, they are dealing with career economists who have been part of an institution that perhaps resist change administration to administration, which is the lack of sensitivity to elections is partly what troubles a lot of us. I just want to make those two comments.

I know that Professor Strauss, in his excellent article about who gets to decide these things, is very well aware, of course, and would have said it himself, I am sure, that the statutes delegate to the administrator of these agencies.

PROF. DUDLEY: A quick comment, I think the first person who came up to the mic noted there are no lawyers on this panel. That is definitely a debate among administrative lawyers, which is why I think it is probably not appropriate for a report and recommendations on science, because that is a much bigger question is the president's authority over the executive branch agencies.

In terms of the OIRA staff, I am glad that you recognized that they are career staff, because earlier you said it is a political body. OIRA, it is a career staff,

and every president has continued to ask them to do the same thing. President Obama, as we saw when he first came into office, he sought public comment on what should my regulatory oversight procedures be. He ended up keeping the same ones that have been essentially unchanged for the last 30 odd years.

MR. ROSTKER: I just wanted to respond quickly to something Francesca said at the very end, and that was even when decisions are supposed to be based upon science and science alone, and the one thing I keep hearing and the one thing I see through my work is that there is no such thing as something that could be said to be science and science alone. Even those decisions that we place in the hands of scientific advisory boards, in the case of the Clean Air Act, CASAC, are determined to a very great extent by the scope and the charge of those bodies. They rarely are given carte blanche to consider all available science and all available options.

We see this in many cases when we talk about the NAAS process, where the considerations of CASAC are often limited, both time and resources, to those options presented in the staff paper. We have instances where scientific advisory bodies ask EPA or the charging organization why are they being limited to those specific

charge questions. It is what we saw in the case of the formaldehyde review of IRIS, where NIS had to go beyond the limited question of an evaluation of formaldehyde, and talk about the entire process. Why was this an issue?

The charging of those organizations, even before you start talking about the science they consider, the charging is a policy consideration and it makes it really hard to even use the three-body concept, science, policy analysis and decision, because the science itself, the consideration of science, is often limited by the policy considerations that lead to the questioning of the science.

DR. GRIFO: Actually, can I respond. I will just give you another example that agrees with what you are saying. One of the strongest statutes that I know of that says science and science alone, best available sciences, of course, listings under the Endangered Species Act.

What we found is that where there is a will, there is a way. You can get around these things very effectively. I will just tell you, for that one, what they were doing at the Department of Interior was, typically what happens is someone can say, hey, I think this thing should be listed. I am just really going superficially here. They ask for it to be looked at. Traditionally, Fish and Wildlife looked at everything in its files, looked

at what the person who was asking for it to be listed offered up, put it together into a report and that moved through the bureaucracy.

Well, under a certain administration, they said, no, actually the practice is going to be, from now on, we are not going to look in our records. We are going to decide on this listing, based only on what the petitioner puts in. Yes, it was supposed to be a decision based on the best available science. Clearly, if you are not gathering all that science and putting it together, you defeat that, no matter what.

MR. CONRAD: Jill Rogers did a nice job of explaining how in the risk assessment paradigm over the last 30 years or so, there are these default assumptions that are kind of bridging trans science assumptions that allow us to make decisions where the science doesn't really tell us the answer about, well, if you give rats this does, what is the effect on humans down at this dose.

A lot of those conundrums date back, I mean, were first really identified in the '60s and '70s. The difference between them and I think a sort of more purely policy type considerations like employment and so on, are that they are often referred to as safety factors, but also as uncertainty factors, because they were meant to address

scientific uncertainty, which is defined as something that we don't know a lot about. But if we did more study, we could reduce it.

Obviously none of this has much to do directly with the question of external constraints. It would, I think, over the long-term substantially help the kinds of debates that we have here. If Wendy's report or ACUS' report were to recommend that agencies really focus more on generating and encouraging the development of science that actually begins to answer some of these uncertainty factor questions, mechanisms of action type studies and so on.

As we get a better understanding of the molecular basis of a lot of disease and so on, we can get beyond some of these 1970s uncertainty factors and a lot of the debate. To sort of tee it up a little more dramatically, the reason why I think this is controversial is because in many of these standard kind of risk assessments, you end up with an uncertainty factor of cumulatively of about 3000.

There are people like David Finkel who say, well, that is really probably not protective enough, we ought to have more. Most people, I think, tend to think that they are overprotective, that after all we are intended to be conservative. If, in fact, we reduce them all by a lot of scientific inquiry, it is quite likely that the result

might be that the numbers, the sort of safe numbers that come out are actually higher than a lot of the ones we have now. There is a lot of resistance to that, because that is rollback. That is sort of the political underlay, but I think it is an important issue to be addressed in the report.

MR. GILMAN: I think it is important to point out that, with the cancer guideline revision, the switch was turned the other direction. The presumption is that you don't start in the default position, that you have to evaluate the data first. If there are insufficient data, then you fall back to the default position.

I know some people disagree with that, but that has substantially changed the approach, at least in the cancer arena, at least in the agency. I think it has placed a greater emphasis on the scientific basis of the default assumptions. While there hasn't been a targeted research effort aimed at reducing the uncertainty in those various areas, I think it does start to push things in that direction probably far enough.

MR. CHIU: I guess I would caution against getting into the whole default assumptions and these type of things. A lot of this ground was covered in Science and Decisions in 2009, in terms of use of default assumptions,

replacing uncertainty factors with probably distributions that are based on what is known about different chemicals and different species.

As well as one of the previous speakers pointed out about the role of the proper formulation is sort of defining what is the information and science that you would need to best inform the decision. That is sort of a necessary feedback loop between the policy decision back to the policy analysis, and back to the science. I think that ground has really been covered, and I would urge this exercise to not really delve into all of those again, given that there was an extensive review of that earlier.

MR. GILMAN: We'll be covering this ground 10, 20, 30 years from now.

DR. GLEDHILL: As an engineer, I am still just sort of practically scratching my head and saying, how would you actually do this? The question, I think, before us is would more transparency at the interagency level really improve the process. Engineering wise, I say, well, when I was OMB, and Susan and Paul were there and their policy, science isn't the only uncertainty that comes as part of a policy decision. There is legal uncertainty, there is economic uncertainty about the costs of things. There is uncertainty about future structures. One of the

things that we always do at OIRA is worry about how our new entrants are going to come in. Is this fair to allow dynamics in our economy?

The question is, if transparency is the solution we want for the science uncertainty at that level, is transparency the solution we want for the legal uncertainty, the economic uncertainty, all of the other things that come at that level. For example, what if Department of Justice had to right a memo to the docket telling, here is all the legal risks we are taking by doing this policy at this time. The lawyers would never allow that, nor do we have transparency on what future entrants are we not taking care of by allowing this policy versus not.

Who are we discriminating on in the economy. What interest groups are we discriminating against. All those things are things you take into account when you have to make a decision at this time, at this place, with this information. If transparency is what we think is a solution for science when we are making those scientific uncertainties at that level, I guess I would say it’s not really a good fit. We wouldn't want to apply transparency to all of those other policy uncertainties that come at that level.

I just really question again, for the focus of what we are talking about, is that really the right solution, given all of the other uncertainties in the policy world we come with at that level.

DR. KORN: Could I just say that I think it is common practice in science to identify the limitations of a study. In fact, in many medical studies that get into the best journals, you are required to discuss the limitations of your study.

I don't know whether that is what you mean by transparency, but it is part of the protocol of a high quality scientific study that you acknowledge the limits. The things that you weren't able to take into consideration, or the things that you weren't able to examine, that may in fact be limits on the generalizability of your results. The fact that is the way you do science doesn't necessarily mean it has to extrapolate to legal decisions it does affect.

PROF. DUDLEY: I actually think it does extrapolate. I think it is the way we want to do science, but I think it is the way we want to do it. We want to think through all of the legal consequences, all of the economic consequences. I think that is what a regulatory

impact analysis does. It is a transparent accounting of everything we know about the effects of the regulation.

I think the transparency that I am a little bit concerned about, and maybe you meant to be referring to, is who said what to whom about those topics, rather than transparency about the information that formed the basis of our decision. That, I think we should be as transparent as we can possibly be. The who said what to whom, I think, is irrelevant.

DR. GLEDHILL: That is exactly right. That is what I meant, in terms of disclosing all those kinds of things of where you are getting the different inputs, because that is the complication, then you don't routinely see that as part of all of the other parts of information that come with due decision.

I agree with your thing on the medical thing. We exactly want that, just like we want in engineering, about the ability to know what the limitations are, things that a policy official can use inappropriately, or medical practitioners can use the science appropriately. That is a great example of the handoff from science to the practitioner, which is what OIRA and the regulatory agencies are, the practitioners of using the information.

MR. GILMAN: Let me just return to one element of this discussion. When the Academies goes behind closed door, take the needle off the record, they go through a process where they make sure their biases are balanced. I mentioned this before, but there are no conflicts of interests. If there is a conflict of interest, the party is removed from the study. There is no such process in the interagency process. There are instances where there are conflicted parties at the table. I think that special case may merit further discussion, at least.

DR. KORN: We have one more question, and then I want to make a suggestion before we all run for the snacks.

DR. GRIFO: Just one quick thing, I mean, I would just add to that, if these deliberations are so above board, so logical, so necessary, then what is the problem with revealing them? I don't get it, but anyway, go ahead.

PARTICIPANT: Well, in reverse order, a quick follow-up on what Dr. Korn said about one of the hallmarks of a quality study is acknowledging the limitations. One of the problems that I have seen with the IRIS assessments that I follow is that there is no set of criteria that are used to determine whether a study is high quality or not. Going back to Dr. Goldman's comment about study design,

that is one of the things that is missing, and would be very useful to have. What are the marks for good quality?

Then, going back to what Dr. Gilman said, I was a little surprised by his comment that there is no balance in the interagency process because it would seem to me you would have a perfect balance. EPA, as a regulatory agency, has an interest in regulating. The other agencies, as regulated entities, have that perspective to bear. It seems to me that there is a perfect balance there.

MR. GILMAN: I have been in situations where questions have been put before an interagency group of 10, and there were nine yays and one nay, and the nay one. That is your balance.

DR. KORN: I used to run executive committee meetings at Stanford, but I was the one. Listen, can I make a suggestion? I have a feeling that there is some conflation of issues that have been circling around. I would like to suggest that the product of this exercise might be enhanced if one could separate the issues.

One issue is, is there a way to strengthen the use and integrity of science in the agencies that use science to drive their analysis and their decisions. In Wendy Wagner’s study, there were a number of examples that she pointed out of desirable technique that were being used

in certain agencies, but not generally, raising the question of whether OSTP, or someone like OSTP, could issue a set of guidelines for all of the agencies on best practices, addressing a whole bunch of different areas.

Entirely different, I think, I am suggesting is the whole issue of how OIRA works. If that is what you all want to discuss, that is your choice. I think there is something practical and concrete that could come out of this in terms of following on Wendy Wagner's idea of pulling out best practices as they exist in different agencies, and recommending that they be more widely adopted.

Let's thank the panelists and it is a 15-minute break.

(Brief recess)

Agenda Item: Session 3 – Roundtable Discussion of Best Practices

DR. RODRICKS: We are going to do in this session what Dr. Korn said we should be doing. We are going to be looking entirely at the question of internal agency processes that might be where the best practice notion arises, and talk about those. They are presented, the ones that we are going to be talking about, and particularly not cover every one of them, but certainly the more important

ones we will try to cover are in Professor Wagner's summary report, the recommendations report, beginning on page four through page five. Best practices for agency decision making processes, so that is our purpose here today.

The panel consists of, I think we are all scientists and a science administrator, as well. Starting at the far end, Professor Tracey Woodruff, again, you all have her bio information. She bicycled here, I understand, all the way from San Francisco. She is at the University of California at San Francisco. In the middle, Dr. David Michaels, who is the assistant administrator for OSHA at the Department of Labor, and Dr. Tom Louis, who is a professor of biostatistics. So we have got a statistician now on the panel. That is very dangerous.

By the way, I have a quiz for the panel, and as a matter of fact, for all of the audience. Fifty years ago this month, a book was published that had perhaps a big influence on the kinds of things we have been talking about today. The quiz is, what book was that, 50 years ago this month?

PARTICIPANT: The Silent Spring.

DR. RODRICKS: Exactly. We are going to focus on those best practices, Dr. Korn, just as you suggested, for internal processes. I am going to ask each panelist to just

say a few words, sort of a high level view on the notion that they can be applied across all agencies perhaps, that are involved in science-based decision making. This is a presumption in Professor Wagner's report. She is careful to say that we don't know enough to really make a strong proposal at this time, but this is a presumption that we want to explore. Cross-agency application and what might be some limitations on that.

Then, just highlight the practices you think really require further elaboration, that are really important here. Then, anything of your own that you want to bring up, as well. I don't care who begins. Maybe we will just start down at the end. Tracey, do you want to begin? This is just a brief introduction to your views here.

DR. WOODRUFF: First, I wanted to say it is so great to be here. As you know, I am from California, and I will endorse the bike program that you guys have here, where you can go between bike stations. I would highly recommend it because it is great to ride your bike here because it is quite beautiful.

That aside, I just wanted to say that it is so great to be in a place where we can talk about this issue that is so important, in terms of thinking about how to use science in policy. It is a little bit wonky, and that is

why it is so great to be here in D.C. to talk about it. It is so fundamental to the decisions that are being made. I really enjoyed that the speaker said this morning about how it has influences across, not only the U.S., but internationally.

I was reflecting on some of the comments that were given this morning, and I wanted to come back to the purpose that Wendy Wagner gave for the report, which was to improve the process by which science is used in the decision-making process, which I thought is very helpful to remind myself about.

Because sometimes during the discussion today, I got, I have to admit, a little bit lost about very many things that this issue can bring up, which is so many things that have to be talked about, but to try and remind myself about the meta level issue, which was the science and the decision-making. How can we look at this process and see how to improve it, because it is a continuously improvement to it, that will improve ultimately our decisions.

The other thing that I really thought was excellent about the report, that keys into best practices is that the things that we want as elements of the best practices are transparency, ideally reproducibility,

consistency across approaches, even if we have different questions. It is on a kind of similar consistency across questions. Then, this was raised many times, being able to distinguish between science and judgment. Then, at the end, which I think was brought up by Granger Morgan, is to have a place in the decision-making process that is about incorporating values and preferences.

The thing that I really liked about this report, that reflects back onto best practices, was this review of what different agencies are doing to look at how they integrate science into their evaluation of their evidence, and then how it feeds into the decision-making process. I thought, well, this is great, it compares EPA and the Endangered Species Act and the Nuclear Regulatory Commission.

I also thought, there is another whole area of decision-making that is going on, that is relevant in the government, that I think would be very useful for integrating in the terms of best practices, which is the experience in clinical medicine. This is something that we have been very interested in at UCSF is the area of how do you use systematic, transparent, evidence-based evaluations in environmental health, but learning from what is happening in clinical medicine.

Clinical medicine has gone through this very same evolution, but starting in the 1990s, where they were looking across many disparate pieces of information. There was a movement started by someone named Archie Cochran, who said, why can we not take all the available evidence in a transparent, systematic matter, and condense it into one place, and then use it for us to make decisions, whether it is the decision that the doctor makes about their patient, or the decision that you might make in a health care policy setting.

This has evolved starting with the very famous paper that was published in 1992 in JAMA, where they actually showed that you can actually see the difference between an evaluation that is more systematic and transparent, compared to sort of expert judgments, which is a lot of, at least in environmental health, are right now.

What that paper showed was that a more rigorous collection of the science results in decisions that are different than expert judgment, whether it was the evaluation for science, this was for cardiovascular medicine, said don’t prescribe certain drugs because they are harmful, even though people were saying to do that. Or do prescribe certain drugs because they are helpful, even though people were saying exactly the opposite.

This was a very revolutionary paper in clinical medicine. What ended up happening is that this has evolved into what has been called Cochran or systematic reviews, now where the latest evolution is grade. The reason I also liked it was it follows some of the elements that are covered in page 102 of this report, in terms of best practices, which was discussed earlier this morning, which is clarity about what it is you are trying to answer in the policy context, so the policy question.

Assessment of the evidence, and this I would actually recommend to be more, and Dr. Goldman talked about this this morning, and actually is inherent in one of these recommendations, I would draw that out a little bit in terms of there is collecting the evidence and evaluating the evidence. Then, the application of the evidence, and then the bridge of the evidence to the policy question. All of these elements are also covered in this approach and grade, but it has had 20 years of experience.

One of the recommendations I made is that we should go back and look, and see some of those things, and see where they are relevant to perhaps dissemination among some of the agencies, in terms of best practices. To give a very specific example, I was looking at the recommendations, and the first one is make a list available

of the scientific literature that is consulted. I think this seems very obvious to me, so I am not sure why this hasn't been done. I used to work at EPA, so that could be why.

The other thing that is actually I would say is how did you identify the literature. In best practices, it would not only be what is the literature used, but what is the method for getting the literature, because that actually matters. It has actually been shown in clinical medicine that the tools that you use to collect the evidence can actually result in different types of evidence being collected. Even being very clear about how you search, this sounds very micro, but even how you do search terms matters, so I would expand that.

The other recommendation I would expand on is this idea that a priori, and this was raised this morning, decide how you are going to collect the evidence, evaluate the evidence, including which you include and exclude in your decision-making process, and then synthesize the evidence. That is up until the policy decision. I think that is really important. Basically lay out your method, that can become part of the public record. You do it a priori, because here is the thing. I have done this myself, so I am not accusing anyone of anything. You get

the results and you are like, oh, I didn't really like how I got to that decision, and I don't like what this study says, so I am going back and revise how I decide how to use it.

The idea is you a priori decide. It doesn't mean that you don't have judgment, because there is judgment in every step of the process. You have clarity so everybody can agree up front how that evidence can be evaluated. Then, you go out and do it, and then any judgments that you have to make, which happen every step of the way. Should I look at this paper, is this paper biased in some way? You have to document it.

That doesn't mean we can't disagree or agree. We can do that, for sure, and we will. The fact that it is documented then leads to more transparency, which then feeds back into the process. I think I am over my time, so I think I am going to stop. I would say just one more thing is that in the grade approach, the synthesis of the evidence is different from the strength of the recommendation. You can have weak evidence and make a strong recommendation to do something, because of values and preferences, costs and benefits, all of the things that we are talking about.

This idea that there should be transparency in the science decisions that are prior to the policy judgments. I think that should be throughout all of the government. There is no reason not to.

DR. MICHAELS: Well, first, let me begin by thanking ACUS for kicking off this process. I think it is a tremendously useful one, and from a regulator's point of view, I think there is a tremendous amount that the agencies can learn. Let me thank Wendy also for her paper, which I think is a great beginning also, raising a bunch of very important issues. Also, as she pointed out this morning, regulatory agencies don't speak that much with each other. Often when they do, they are in conflict.

The idea of actually learning best practices from each other is one that I think I welcome. I learned a great deal from reading about EPA, Fish and Wildlife, et cetera. Also, to have an outsider come in and give their perspective. We often get lost in the weeds.

I think Wendy was able to come and say, okay, this is really how this flowchart works. While it sounds like a simple procedure, it is really not. That is a tremendously useful process that we have just begun here, so it is great that we are having this meeting.

Joe asked us to think about are there best practices that we can all adopt. Obviously, I think we have to consider a bunch of issues, what authority we have, the staffing and culture of the agency, the resource, et cetera. I don't know that there is a one size fits all or anything like that, or anything we should all adopt. Certainly, taking from each other and seeing how we can move forward makes lots of sense, not just in practices, but actually in our findings, I think, and I will get back to that.

One thing we have to be very cognizant of, and I think this was something grades several times did, but first by Professor Zeckhauser, is the cost of doing all of this. OSHA has a fabulous process where we have a tremendous amount of transparency and input from our stakeholders, with many, many, many points of input, including public hearings where we go through a peer review of our scientific documents. We also have public hearings where anybody who testifies can cross examine anybody else who signs up to testify.

When you talk about an active peer review, we have got scientists who represent very different interests. They are actually talking to each other and saying, what do you think about this. The downside of that whole process,

though, is it takes eight or more years for OSHA to get out of regulation. There are tens of thousands of chemicals out there, in OSHA's 41 years, it has issued regulations on 30 chemicals. It has inherited about 400 or 500 other ones. The rest are not regulated or inadequately regulated.

By putting more resources and putting more time and getting a better process, those other chemicals are unregulated and workers are paying for it with their health. That is an important trade-off. We could do a better job on every chemical, there is no question, but is that worthwhile.

Wendy was critical that Fish and Wildlife was under resourced. They are given $250,000 in a year to get this regulation out. In some ways, that is my pipedream. Tell us you have a year, at the end of the year, you have to have it out, and here is $250,000, do the best you can. We would be way ahead, so we have to think about that in that context.

I think there are a lot of things that we could do. We could learn from each other to really improve it. I think it is actually focused on this question that came up at the last session, which is sort of what science, what policy. There really is a science that is under discussion, and that science is separate from the policy.

We have the debate over the science because many of the advocates and stakeholders don't like the policies, so they go after the science. Certainly with risk assessments, you could debate the assumptions, but look, I don't have to talk about any examples, other than global warming.

There will be people who will be well-funded, who will come in and attack every single point in the science. Obviously, the long history of tobacco shows you the same thing. That will go on for decades, if it is well enough funded.

How do we improve the science that goes into that thinking? I think there are a couple of things we can do, that we could talk about. A lot of them are actually written in papers, several of which I have actually co-authorized with Wendy and some others, to ensure that private science gets the same treatment that public science, access to data, for example, issues are on conflict of interest.

Right now, if you write a paper for the New England Journal of Medicine, not only do you have to disclose any sort of financial conflict of interest, but the first author has to say, if she or he could publish this paper without getting permission of the sponsor, and the sponsor played no role in vetting the outcome. As a

regulator, I can't ask for any of that same information. I don't know who paid for the study, the relationship of who sent the study into stakeholders in the process. At minimal, I would think regulators should be able to ask for the same information that the Journal of the American Medical Association gets, for the same set of reasons.

The final issue I will just talk about in this sort of 3000 foot thing, relates to this question I think Susan brought up earlier, or a number of people did. This debate over what is the right number for protection. Maybe that is not the way to go, because we are never going to agree. Some of us will say, well, the science says this. In fact, that is the policy decision. What considerations do we take into account, including the law. The laws often say we should go down to no risk. Then, that puts the agencies in a very difficult position, because you can't go down to no risk.

The example of radiation is an interesting gone. The energy department has an occupational exposure limit of five rem per year. I was Assistant Secretary of Energy during the Clinton years, and that's terrible. You don't want anyone to get five rem a year for their lifetime. It would be quite dangerous.

We also have the concept of as low as reasonably achievable. Even though it's five rem a year, you're trying to drive exposure down all the time. Maybe we should try to move away from this paradigm of what is the safe level, because we are not going to be able to come up with that number. Recognize that for many chemicals, lead being a great example, because we don't think there's a safe level of lead for babies. We should be working hard to just drive exposure down as much as we can, without saying five is safe and six is dangerous, or something like that. Anyway, we will come back to more, I hope, of this.

DR. LOUIS: It is a pleasure to be here, and at this point in the day, many things have been said. What I am going to do, instead of giving many of the prepared remarks is dance through a few of them, and focus on a few things that I think haven't been emphasized sufficiently.

I agree, at least in principle, with virtually all of the recommendations. I won't list them for you. I think that they have various digress of do ability and various degrees of impact, but at least, I think, working on them is a very good idea.

The comment on stopping rules, I think it is also a good idea, but maybe should be augmented by what I will call checkpoints. Frequently, especially when there isn't

a mandated deadline, it would be a good idea to have an internal, and possibly external, report of progress to date, that might even document we need more information before we can make a decision. The very act of having a headline, as you know would focus on consolidation of evidence thus far, and I think improve the process.

Related to that, a strong proponent of reproducible research. That doesn't mean that we can have an algorithm that pushes a button and everything spews out. As much as possible, have it that you, the individual or the agency, can reproduce what you did, and therefore, other stakeholders can do it. In fact, the very intention of having reproducible research or reproducible policy changes the process and improves the process by knowing that you are going to be doing that, and making sure to prepare for it in real-time.

That docks into the issue of a protocol. In some sense, the notes I've prepared in the last few days are an interesting kind of protocol in that I had the ideas I was planning to present. Many of them I still will, some were presented by others, others I now see are a little bit bankrupt. I wouldn't have known that if I hadn't written them down. I think it's very important to have protocols.

It is very important to have points where you can change the protocol. The virtue of a protocol, whether it be in clinical medicine or elsewhere, is that you actually know that you have changed it, as opposed to simply having things floating around. Now, there is a proposal in both documents, Dr. Wagner's and also in the ACUS document, about in some sense a suggestion of a bright line between science and policy. I think we have heard today that line is very fuzzy. I would take it a step further and say, forget about it.

What I mean by that is, definitely document literature sources, decisions made, analyses done, and maybe wait until later to worry about, well, was this science or was this policy or was this trans science? Spend your energies on the documentation side, and then, later maybe try to draw lines, or maybe never draw lines. I'm a statistician, so uncertainty is, in some sense, my job security. I am going to give a little bit of discussion of uncertainty.

I think we all know in this room, some far better than I, that policy decisions are made in a sea of uncertainty, whether it be on the science side or the sociology side or the economic side or the moral side, whatever side you'd like. Generally, there's insufficient

direct evidence. We don't have a lot of direct evidence, for example, of risk assessment for humans on chemicals. We have a fair amount for rodents. Even risk assessment for rodents is dicey, let alone risk assessment for humans.

There's a lot of model-based uncertainty. What I mean by that is standard errors, even within the context of a well-posed model, let alone the more dominant kind, which is model uncertainty, what shape is the dose response curve. What are the hydrodynamics of percolation of certain things in the ground water.

Usually, there is disagreement on the evidence. I mean, we can talk about here is the body of evidence, and now we may disagree on both the analyses of it and the conclusions thereof. Usually, there is disagreement on what studies should go in, how relevant are things from a long time ago. What about a threshold for quality, what everyone might mean by quality.

Even when we agree on the evidence, there will inevitably, as others have mentioned frequently in this today and elsewhere, disagreement on the take on that evidence. As much as possible, I certainly push for agreement on or at least posting of the evidence, and then let the decision that's political, ethical, sociological, whatever it might be, economic, take over. Again, not with

a bright line, but at least with some idea that here's the stuff we are talking about, as opposed to having the evidentiary basis float all of the time.

A few more things, and then I will turn it over to the next round. I think it's been floating around a little bit today, but I want to emphasize that at some level, we need to have a degree of trust. Now, I think it has to be trust, but verify, but we need to have processes that we trust. We need to have agencies staffed by people that we trust, both in terms of their science and their integrity. Ditto for the executive branch, and every other branch. I am not trying to be Pollyanna about it, but I think ultimately, since these decisions are made in a sea of uncertainty, society needs to somehow work for a degree of trust, and we have to push it.

The other thing I am is an educator, so I am going to mention some things about education. The more we communicate and identify uncertainty, the easier it is for people to get uncertain about decisions, poke holes in any decision, whether it be a decision to do something or not to do something. Some of that is never going to go away, but some can be improved, I think, by education. I mean by that a Congressional staff, policy types and the general

public that needs to understand that we are making decisions in the context of uncertainty.

Then, actually, a lot of times, an uncertainty is what drives the decision, protect the most sensitive 2 percent. Don't give the mean height level of the Grand Forks River, if you read the little article in the New York Times on Friday, maybe do the 95th percentile level of that river, if you are thinking about levy control or evacuation.

I won't bother with a lot of others, but there are clearly a lot of others, wherein fact, it is not the center of something that matter, it is the edges. It may just be the degree of uncertainty itself drives the decision, and that the decision has to say, we have to be ready to adapt because we don't know yet enough to make a final decision.

Consolidation of case studies across agencies is very important, in terms of educational rule. The Red Book has been mentioned. Since we are in the National Academy here, I will mention another one, there is every four years, or I think it is going to happen again in 2013, the Committee on National Statistics issues Principles and Practices for a Federal Statistical Agency.

It is not a regulatory agency, but it gets handed out to all Congressional staff and many others to say, here is what we do and here is how we do it and here is why it is important to have a firewall between statistical agencies and executive and other branches. I think those kinds of documents are very valuable in other contexts.

A few other quick points and then I will stop. Science and technology evolve, we all know that, but I've been involved in many situations where agency heads or agency staff are very nervous about making changes, even if it is only a change of statistical analysis in the light of some fancy new procedures.

At least the conversation is such that it seems to be implying that it was being done incorrectly previously, and in a sense, an admission of guilt. I think we have to get a culture going where everything evolves, and at regular intervals, things will be revisited, and that is good, not bad.

Then finally, I would like to propose that we balance the books. What I mean by that is that the ACUS report, the Wagner Report, talk about proper practice for regulatory agencies. Even though we can't legislate it, I think we can try to insist that critics of agency decisions

and critics of other decisions are held to an equally high standard.

If they are going to complain, whether it be because something was done or wasn't done, that their complaints and their input should be as evidence-based and as reproducible as anything we insist upon the agencies. I think if we balance the books a little bit, we can handle the uncertainty issues better, and in fact, improve public policy. I will stop.

Agenda Item: Discussion with Participants

DR. RODRICKS: There is some food for thought there. Let me ask a couple of questions, follow up on some of these points. If you like, Tracey, on the clinical medicine model, which I found interesting, you discuss its possible use as a model for a process, for moving from evidence to some kind of decision. Isn't that quite a different kind of decision context, though, from many that, let's say, EPA engage in or other regulatory agencies? What is the policy science nexus in that situation? Is there one, how does that work?

DR. WOODRUFF: I didn't set that question up. I just want you to know that before I answer it. That is a really excellent question because when I talk about clinical medicine, of course everyone could be thinking two

things, or you could be thinking nothing, too, because it is kind of late in the afternoon. One thing is that it is largely about pharmaceuticals. It is like a lot of this was developed around, should a doctor give a drug to somebody who is sick.

The context of pharmaceuticals is different for a couple of reasons. One is that the laws require, in the United States, that we test pharmaceuticals for safety and efficacy prior to entry on the marketplace. That is one context that is already, if you are in environmental health, you know is different. I guess that is true with OSHA, too, is that environmental chemicals don't have that requirement right now.

Then, as part of getting on to the marketplace, pharmaceuticals go through a particular type of experiment, which is randomized controlled clinical trials, where people are deliberately given the pharmaceutical or the drug, and controls. As you can see, that is another difference. We are not going to do that. We don't really do that with environmental chemicals usually, in a very experimental setting.

Right now, you may be thinking, well, how could clinical medicine techniques really be used for environmental health because of these differences? That is

why I was careful to say, and I think this is so great about your comments, Wendy's comments this morning is it is really the process that we can learn from.

For example, what do we use in environmental health. We use a lot of animal studies. Well, the tools that have been developed and actually tested, the great thing, I know I sound like I am a big advocate for this, but I have drank the Kool-Aid of this whole thing, so I will just say that right now. The tools have been empirically tested.

It is really nice in that way, that you can go back and you can look and see, well, if I do a randomized search, or if I do a very thorough search for the literature, does that make a difference? Well, that has actually been tested. Do the tools that I use to evaluate the quality, I am going to use that loosely, of the studies, clinical medicine has tested that. Well, those are the same kinds of things we really want to see in evaluation of other types of evidence.

Transparently collecting information, decision about we are going to evaluate the information, and then some of the things we have to adapt. The way we look at randomized and clinical trials, randomization, whether people knew they were going to get the drug or not, well,

you can apply that to animal toxicology. Not quite in the same way, but you can adapt it. You don't have to go through their 20 years of pain. You could probably decrease that a lot more rapidly.

I agree, I think that relates to your comment. It is not going to be cookie cutter, somebody else said that this morning, but we can learn from the principles. I think that is the key, is like what are the best practices, that is what we are talking about, which also were discussed in the report, too, trends that relate to how do we improve, because it is really an iterative process. How do we improve the way that we apply our scientific methods that we might use in experiments to really evaluating all of the evidence? I think that was also brought up this morning.

DR. RODRICKS: Good, thank you. David, you said, if you don't like the policy, you attack the science, that is a common theme. Is there some way around it? Isn't' the notion behind a lot of what Professor Wagner is proposing, it is to, I guess, in way, make the science bullet-proof, if you like. That if you go through good processes of internal review, external review, you end up with a product which should not be attackable. Isn't that

the whole notion? It is done with high integrity, of course.

DR. MICHAELS: That is the ideal. I think, in fact, we are always going to see issues around the science, because we are rarely dealing with clinical trials. There are always going to be interpretations. There are ways to address it and ways that have more integrity. An example, there was some controversy some time ago around the Harvard Six Cities Studies. I think that came up even this morning, as well, about particulate exposure.

A multi-year study showed that levels below current EPA-allowed exposure levels, you had kids getting sick, you had mortality effects from particulate exposure. There were some industries involved in putting particulates in the air. It didn't like those results, and because of the Data Quality Act, essentially we have access to federally-funded studies.

I think, in this case, they did the very honorable thing and insured that the reanalysis of the data was done by a group in Boston, the Health Effects Institute. We set up a very open and rigorous process to do the reanalysis. Alternatively, there are mercenary scientists out there who will give you whatever result you want. I could do the same thing. If someone gave me a

data set, and said, here is the study that was done by the government, here are the cut points, here is what they found, I could reanalyze it and give you a totally different result. I think we could set up rules for the way data are treated. It will at least get us all the way there, get us most of the way there. It is not going to be perfect, but I think there are things like that we should be thinking about.

DR. RODRICKS: Very understood. Did you want to comment, Tom, on that?

DR. LOUIS: I was involved on the Six Cities Studies. You might think of it as nine monitor studies as opposed to a six city study. Industry did not like the results, and in some ways, the critiques were reasonable. It was, could it tax rate as opposed to pollution, could it features of the cohort. It did evolve and into the National Mortality Morbidity Air Pollution Studies that HEI funded.

Those were more cohort studies and at least convincing on having different biases and different weaknesses. The complementary set, I think, produced information that was very valuable to EPA. Here is a case where I think the dialectic actually helped, even though at real-time, I wasn’t very happy with it.

DR. WOODRUFF: Do you think it changed the answer? The effect estimate from the Six Cities remained essentially the same, right?

DR. LOUIS: It didn't change the qualitative answer.

DR. RODRICKS: Let me ask both David and Tom a question, though, on, to me, one of the really important recommendations that has to do with this process, which Professor Wagner describes as a four-step process for integrating science into the whole policy process, and achieving clarity on how that works. I just wonder, you didn't really express an opinion. I think maybe Tom did and you said, don't worry about it. Did I misinterpret what you say?

DR. LOUIS: You misinterpreted it a bit.

DR. RODRICKS: Okay, so clarify that point, because I think I worry about that a lot. I am sure David, you find it so difficult to separate science from policy in your decisions, and how do you think you achieve that.

DR. LOUIS: Just quickly, I was saying that the boundary is fuzzy, and I still will say that. Certainly, there are some things that are clearly science, the in vitro test for the NTP is clearly science, and some other things are clearly policy.

I think there is a middle ground, and so my point was, worry about it a lot in terms of documenting your assumptions, your data sources, what you do with them. At least at that boundary, don't spend a lot of corporate energy in deciding whether it is science or policy. Spend the energy on doing a good job in documenting what you did.

DR. MICHAELS: I think that is very reasonable. I think from OSHA's point of view, we look at the science and the risk assessment. But by law, we also do all sorts of additional analysis, technological feasibility, economic feasibly, that are taken into account. Those are clearly policy decisions, so we don't pretend that the science forces the decision. In fact, we say that we will look at these other issues, as well.

DR. RODRICKS: So the science didn't make you do it all the time. We have some time, I want to make sure I cover a few other of the questions, or at least best practices that Professor Wagner mentions, the stopping rules are pretty interesting. I think you already commented on those, Tom, and talked about checkpoints. How does that then get you to a stopping rule? What are those checkpoints, and I will get comments from Tracey and David, as well, on this one. Are these important, do you think?

DR. MICHAELS: I think so, but they are agency specific. We will issue a certain period for public comments, and we will say we will analyze everything in the record, up to that point, and we won't add anything beyond that. I think at some point, you do have to stop and that is pretty straightforward. You have to say, this is the point where the record closes, and that is where you were. Obviously, we work under the assumption or the context that we are using the best available evidence. It would be great if we could come back and revisit all of our standards every five years. That again is a resource question that most agencies only dream about.

DR. RODRICKS: So let me just follow up. You are working towards some kind of regulation on some chemical, and there is an epidemiology study of mammoth proportions just around the corner. How do you decide whether to wait?

DR. MICHAELS: That's a rare event. We know what's out there. You know who is doing the studies. It would be very surprising to us if there were a study to come out that would absolutely change the game that we didn't know about. If we thought it was very important, we would likely to be in contact with the authors in any case beforehand. I think that is less of a concern to us.

DR. RODRICKS: I think this question does come up a lot in the IRIS process, there is always research underway.

DR. WOODRUFF: I agree that I think the stopping rule is an excellent recommendation. I think the challenge is the implementation, because there are legal mandates in some of the cases, the NAAS and the Fish and Wildlife, they have legal mandates. There is no legal mandate on this IRIS risk assessment. I think this idea of sun shining, stopping rules and trying to be more adherent to it is a first step in probably a longer process.

I know this is kind of a sideways thing, but it also could be that you could evaluate this. I love the case studies idea, that you could continuously evaluate how well you are doing through these case studies, in terms of, for example, if you decide your best practices are going to be to go with these four, maybe five, recommendations about how to evaluate evidence, and then you go and do case studies, to see how well that works, compared to what you were doing before, the stopping rule could be another case study where you could see, well, if we had arbitrarily stopped at these different points in time, did it really change our decision? I mean, that can be empirically tested.

DR. LOUIS: If the phrase stopping rule was being used the way we use it in clinical studies, I would not have to replace it with checkpoints. We have monitoring plans, monitor at regular intervals. There is a stopping rule, but that rule may say don't stop.

What I want to make sure is that there is regular monitoring, and that there is a decision process that, if it isn't a jurisdictionally dictated deadline, that there are purposeful decisions on whether there is enough information or whether society is better served by waiting. I am fine with stopping rules under that definition.

DR. WOODRUFF: Just to go back to clinical medicine, they actually have shown empirically that, once you lay the information out, you can actually see when, if you look at the actual data, when doing more studies doesn't matter anymore. If we were to do that more often, I am just speaking to environmental health, with the animal and human health studies, you can see that the effect plus the confidence interval isn't going to change, even if you do another study.

As again, that Altman study showed that doing more studies on this particular drug didn't matter. You were just wasting time and money by continuing to study it. Again, this is kind of like a case study idea that you

could actually evaluate this, or at least set up the tools so it can be evaluated.

DR. RODRICKS: Every time I am on some group with a decision analyst, they bring up value of information analysis. That is what you are talking about, I guess.

DR. WOODRUFF: Yes, exactly because that is a perfect example of trying to figure out the costs and benefits of going or stopping.

DR. RODRICKS: Everyone likes stopping rules. Professor Wagner does bring up the difficult problem of whether they should be simply arbitrary, or there is some rule about stopping rules that you really ought to revoke.

Let me cover the issue, I think these are related issues in a way, staff authorship of documents or at least attribution. Whether that is a good idea, whether tracking, I think the language in the report is tracking the norms of science in this respect. What is typically done when you look at authorship for scientific review. The right to dissent might be related, so any comments you have in those two areas would be welcome.

DR. MICHAELS: I found that very provocative. I hadn’t thought about it really before reading Wendy’s paper. My plan is actually to meet with my staff and raise

it with them, and ask them what they thought before I would opine on it. I will give you a report.

DR. RODRICKS: Since you are a manager, let me just read this comment from the report itself. The observation in the report as an important and related point, the programs understudy provide at least preliminary support for the observation that staff-authored analyses tend to be more evidence focused, nuanced and likely to concede limitations, gaps and assumptions in the available evidence as compared to analyses that are heavily influenced, if not written by managers.

I think that is just an observation from limited interviews, but that is certainly one of the motivations here, I think, behind this. I don't know if you had the review or not.

DR. MICHAELS: I think my staff is worried when they write something about something I know too much about.

DR. WOODRUFF: Speaking from having been in an agency and authored documents, at least from the perspective of it is good to be rewarded for the work you do. I think that is very valuable, in terms of that aspect of it that was raised this morning by Dr. Goldman. I like that part of it. I think it is important to know who wrote the document, as well. It also lends to transparency in

the decision-making process, if you know who has authored it. I am not sure I see what the downside of saying what the authors are. I guess that is where I didn't, so why would we not do it, then?

DR. LOUIS: I haven't worked in a federal regulatory agency at least, but I think in general, it is a good idea. I would expand it to, not that there is a bar in this in general, but sometimes there is, an encouragement for staff to then take the experience from developing those reports, and submit articles that are appropriately protected and necessary to the peer-reviewed literature and have a little more encouragement for that. In addition to, and sometimes maybe in place of, the authorship of the report itself.

DR. WOODRUFF: Actually, I would like to comment on that, in terms of the ability of research staff to publish findings that they have done, when they are at the agency, that may be related to the evaluations that they do. I know there are some variation in clearance processes, for example, for staff at agencies, in terms of publishing either their scientific studies or the results of reviews. That is not covered in here, but I think it is a really big issue, because it does lend a dampening approach to science issues within the agency.

I know some agencies have very extensive clearance processes for publishing in the peer-reviewed literature. I do not agree with that, because you already put a disclaimer on the paper when you send it, saying that it doesn't represent the views of the agency.

DR. RODRICKS: The related question of descent, if you have got someone who has been in the process and now decides that he or she doesn't like the way the science is being treated, should there be some formal policies on this matter? I think the NRC is cited as a good model for this.

DR. MICHAELS: That is part of that same question, to ask the staff, do you like this idea? I mean, it singles people out, sometimes people don't want to be identified in various ways as being a leader in something or the center of something. I mean, I think theoretically it makes lots of sense. I know Lynn Goldman was convincing in her support of it this morning, but I think we have to look how it really works.

DR. RODRICKS: We should have some written record that person X disagrees with this interpretation. Yes, that would be on the record.

DR. WOODRUFF: Well, and I thought it was very interesting that the people at NRC really liked the policy that they had in place. I thought that was supportive of

that policy. I was not familiar with it. I thought it was so interesting that they actually give out awards. I don't know if we should do this, but give out awards for dissenters. I thought that was a very interesting idea, but it could encourage people to dissent.

DR. LOUIS: Authorship issue, although it is more general than that, and that is a lot of speakers have mentioned the importance of having high quality staff. Of course, agencies have to attract and retain, and career develop, such staff. I think anything that can be done to make the positions attractive to start and attractive to continue is vital to any of the successes that we are trying to produce or enhancements that we are trying to produce.

I will add one more comment about that, in terms of external peer review, which anybody who does external peer review for federal agencies and thinks they are doing it to make money probably needs to have their head examined. At least, there has been a trend for good deeds to go punished, and I think at least the federal government's rules could make it a little bit easier to travel, a little bit more comfortable to stay, and a few things like that, to make sure that we can maintain the cadre of external peer reviewers that are necessary.

DR. RODRICKS: I have one more issue in the list of best practices I want to cover. That is the issue of transparency. I think the recommendation urges agencies to apply the deliberative process protection very sparingly in this. It seems to call for a very complete record of the decision, everything both the science and the policy and the decision. It goes to talk about all information received from any source and how it is explicitly dealt with in the document.

It seems to be a pretty fishbowly recommendation. I am not sure, I may be mischaracterizing what Professor Wagner says. What is your general take on that?

DR. MICHAELS: Well, my fear, I am reminded of a document put together by a consulting firm, when OSHA was moving towards an indoor air quality standard, which was taken on by the tobacco industry. There was a memo written, and I don't remember the exact words it was written with, but essentially say, you know, we can send these comments in and tie OSHA up for two to three years just answering them.

Again, you have got to think about, how do we get efficient and effective regulatory agencies. We have a record with everything that is given to the agency, every meeting is transcribed, everything is sent in. It is there

and we try to really answer them, and say this is how we address them. Depending on the level that you want, you really could tie up an agency for many years, and none of us have the resources we need to be able to do this. It is just one thing you have got to weigh out.

DR. WOODRUFF: I think it is very challenging partly because the science and the policy, you can often get mushed together. I do think that having high transparency on the science side is very important. I am not saying everything is science, like you were saying, it can't be definitive, but there are judgments that should be documented.

I do think if you have this, you moved more towards, which was mentioned this morning, that NTP is going this way and it is something that we have been working on, this sort of a priori, coming up with your methodology, and have that vetted. Then, maybe minimize what happens after that, that that could make the process more efficient.

I think the other issue, in terms of transparency, is I do think that it is important to have the science and the science judgment issues transparent, either between the agencies and then between the agencies and OIRA. It just was very interesting on the discussion,

not the deliberative process, I get why the deliberative process is not going to be made public.

When I've looked at this chart that you did on the different agencies and the role of OMB and the role of interagency review, I just wanted to point out that there are two different results that you are evaluating. One is rule-making, so the NAAS processes are rule-making, the Endangered Species as a rule-making. IRIS is not a rule-making.

There is no incense that policy issues of like cost benefits or values and preferences, and all that kind of thing. That shouldn't come into an IRIS assessment. I am not sure why they have the most interagency and intensive OIRA evaluation of all these processes. I mean, it is sort of unbalanced in that way.

DR. RODRICKS: That is an interesting comment. I hadn't thought about that, which I think you were right. Tom, did you have any comment on that?

DR. LOUIS: I have nothing to add, really.

DR. RODRICKS: Nothing to add on this? Just a question, I guess peer review, anything in particular to point out there? It is not very prescriptive on the question of peer review, the recommendation for best practices.

DR. MICHAELS: I thought Wendy's point that by pulling your peer reviewers into a room to essentially work together gets you a much process than farming them out individually and then having to respond to each one, is an excellent point. That is sort of a best practices we could learn from.

DR. LOUIS: I would like to moderately, if I heard correctly, disagree with that. I think I would like to make sure to have independent opinions in the peer review that might then be coalesced into a less heterogeneous or less variable set of opinions. I personally don't want to lose the information that individual experts or stakeholders have when they initially look at the evidence or draft report.

I think if some of the issues and expert elicitation that end up with overly homogenous portrayals have actually served a negative influence, as opposed to if you'd like, again, as a statistician celebrating or at least honoring the uncertainty that is there. Not disagreeing with eventually coming to either consensus or your consensus, but I don't want to lose those earlier steps.

DR. RODRICKS: Any last minute thoughts? We are going to turn to the audience.

DR. MICHAELS: I had one other thought. It became clear to me this morning, thinking about some of these different agencies and the work we do is actually not just learning from each other, but it would seem it would make sense to actually try to share some of our products.

I mean, for example, if the Environmental Protection Agency is looking at various chemical exposures, there are a number of other agencies that are concerned about those exposures, and perhaps different forms of exposures. OSHA, MSHA, the Consumer Product Safety Commission, the FDA, USA, might be thinking about some of those chemicals, and actually performing some of these analyses in a way that other agencies could use them, would actually be of great savings to the taxpayer, and it would make a lot of sense. That is something that we should try to encourage, as well.

DR. RODRICKS: We will take some comments or questions from the floor, if you would like. I am still curious to deal with the issue that Susan Dudley brought up, about the process by which NAAS are produced is treated with pretty high regard in the report. Yet, you commented that those rules end up to be the most highly contested rules of all. I guess cost issue is certainly a part of that. Why should that be the case when you've got what

seems to me, at least in my perspective, also, quite a good process. Maybe that is too big of a question for this time of day. Paul?

MR. GILMAN: I wouldn't mind answering that question, but I have my own question. On the Six Cities Studies, your comments led me to believe that maybe the recommendations of the report about data availability aren't needed. Do you have a view on that, either for federally-funded studies or private studies?

DR. MICHAELS: No, I think having access to raw data is a good thing. There are two things that I would add to that. One is that it should be everybody's raw data. Right now, if a study is produced, it is either done by federal scientists or done by scientists paid with federal money, the raw data become available to anybody who wants to examine it, to reanalyze it.

I think there should be equal treatment of private science, if that is going to go into the regulatory process. Then, the studies that are paid for privately probably should go through that same process and be available.

The next step, though, is thinking about what are the rules of reanalysis. I actually have a paper on that, the International Journal of Epidemiology a couple of years

ago, with a number of other epidemiologists saying, if you are going to reanalyze, it would be essentially maintaining the integrity of it. You can't just go fishing. It really is very important to follow certain guidelines and steps with essentially starting from the beginning, saying, here, what are priors are, here is how we are going to analyze it, before going in and just essentially coming up with the new results. I think more access to data is a good thing, but it has to be done in a way that is balanced and equal.

DR. LOUIS: Just a quick one, having to do with son or daughter of Six Cities, or at least NMAPSs. In a way, it was easy, or still is, because all of the information being used are publically available. They may not be easily conssolidatable , but they are publically available. There is no issue of disclosure. In fact, on the Hopkins website, there is iHAPS, which has all of the data sources for our various analyses, and our programs that were used to take from database to graph and table, and so on.

On one level, that was easy because there were no propriety information that we are needing to be protected or at least worried about. It is at least the kind of thing that has made it easier to say, if you don't like what we have done, go do it. It is all there, available.

Then, we try to hold people to the same standard of debriefing on assumptions, methods, so on and so forth.

DR. WOODRUFF: I like the idea that you have to say up front what you are going to do for your analysis, a priori just doing this fishing expedition idea. I think that is good, because people do spend a lot of time collecting and analyzing the data. It is unfair, you should have to have a sort of scientific method in place first.

DR. GRIFO: In the process of our analysis of the scientific integrity policies, we did put together a 40-page thing on best practices across the board in these agencies. The NRC Dissenting Opinions Policy was one of those. Another agency that has a policy in place for that is the FDA. It was part of the previous FDA act. In addition to that, the EPA is hard at work, I know right now, on trying to pull together a policy on those dissenting opinions.

The other thing that I would say that we haven't really talked about, there was a little mention of clearance and publication policies. I would say Fish and Wildlife Service has pretty much the gold standard publication policy. Yet, that didn't make its way into the Department of Interior's Policy, which is kind of crazy.

It is very simple and straightforward, and just says you need to be able to publish, and if you give it to somebody and say, I am your supervisor and want to get that clearance, and the clearance doesn't come, that there's an expiration date, so you're not in this limbo forever, waiting for that kind of clearance.

The other thing that we haven't talked about at all, which I think is very important, are media policies, giving scientists in the agencies easy access to the media, and the media obviously easy access to them, which doesn't mean a free-for-all, because obviously this is just to talk about the research results, not to talk about agency policy and official agency policy.

I am wondering, how important do you think that is, and just any thoughts you have on those. Thank you.

DR. RODRICKS: Can I ask before you answer that last question, are those formal policies you are talking about, with respect to media contact?

DR. GRIFO: Yes, in the scientific integrity policies, the 28 or 29 agencies have done, there are formal media policies in most of them that say that basically what we were hoping to see in those policies was that you didn't have to go through public affairs clearance in order to

take the interview. Rather, you had to recap after the interview and make sure that they knew who you talked to.

The problem with this is that, if you have to go through this lengthy process, deadlines for reporters come and go, and you miss the opportunity to take the science and make it accessible to the public. As I said, obviously, this doesn't go for making agency policy when you're not authorized to make agency policy. It does allow for you to take off your agency hat and say, now, I am speaking for me, and this is what I think.

I think this goes back to something that came up this morning, which is how do you do this kind of work and maintain your scientific integrity. I think one of the important things is what I call the three basket rule. You are very clear about what is in each basket. These are the data, there are what the data means, and this is what we should do about this data or do with those data. Obviously, to talk about the second two, you really do, in many cases, have to take off your agency hat.

DR. RODRICKS: Any comments on these remarks?

DR. WOODRUFF: Well, I really like the idea of the clearance, but you have an expiration date on the publication. I think that would be, because I have personally been involved in papers with agencies that will

remain unnamed, not EPA, where it went on for months and months because they were having some argument between different agencies about who was going to clear it and who had jurisdiction over the clearance. I think that that would be an excellent rule that could be done from an OSTP level, because there are a lot of stories that go on, that we hear about.

Your media thing is interesting because, on one hand, as EPA, I should be able to say anything I want. On the other hand, I see the challenges. You are part of the government, and how to have people to know the difference between talking about their study, which always has uncertainty in it, and the reporters are always asking you, well, what does this mean? They kind of care about what you found, but they really want to know what it means.

It is tricky, and so, I think if you are going to have an open media policy, which I think is generally a good idea, you should probably also have training for people. Having talked to many, many, many reporters, it is challenging. They really are trying to like get you to say something, and a lot of people are not used to it. I respect that the government wants to have a clear message on what they are doing.

DR. LOUIS: Just a quick comment. I think as part of a media policy, as happens frequently at agencies, but maybe not enough, is media training. That might allow more people to be let loose.

DR. ZECKHAUSER: There was a lot of enthusiasm for stopping points. I just wondered whether the panel would consider generalization of that, and perhaps some qualification of its reasons for its enthusiasm. I believe that the FDA is doing a much better job now, that it makes decisions and it has post-marketing surveillance. First, it is getting many more drugs on the market than it ever did before, in a relatively rapid time. Secondly, it is taking drugs off of the market, after the fact that they prove to be dangerous.

They have said, we haven't gotten all of the evidence that we could get, and we are going to get some other evidence. Two of the arguments for stopping points, one was, well, we couldn't change our mind. New evidence won't change our mind. I would like to suggest that lots of times, it is worthwhile to make a decision or issue a regulation when you so could change your mind.

Indeed, let's assume that the most dangerous workplace element came along today, we never knew about it, and we expect that we are going to spend $10 million on it.

It might be perfectly reasonable to spend $5 million, saying, given what we know today, this is what we are going to do, and issue a regulation, and expect that we would continue to do work or continue to do studies. Five years down the line, we might decide to have a tighter standard or a looser standard or no standard.

I am just wondering if we think of decision points rather than stopping points, would that make you happy or unhappy? If it would Thomas unhappy, I am going to have to debate with him about statistics and two-arm bandit problems and the optimal stopping rules and the optional stopping rules.

DR. LOUIS: It would make me very happy, because for me, stopping rules are checkpoints. They are stopping or not-stopping rules. I will make two quick comments regarding FDA and early decisions and post-marketing surveillance. It is a wonderful concept and it works well. It needs to be resting on a much more solid basis of data collection. I am sure you would agree with that.

I think the same thing will hold with regulations. A decision is made, but that doesn’t stop the energy on proper collection of data and studies, so that we can have the right kind of information to make either decisions to continue with that regulation or to modify it.

I am all in favor with it, with an infrastructure that supports it well.

DR. WOODRUFF: I would just say, in terms of IRIS, that we have kind of a default stopping rule right now, which is everything is assumed safe until we get the risk assessment. I think the problem is that if we don't put a timeline on actually making. It would be one thing if there were interim numbers in there, like you were saying, okay, and then that would allow decision-making for whatever the regulatory programs are. Right now, if you haven't gone through IRIS, you get zero.

Then, in effect, you are being assumed safe until some long, drawn-out risk assessment takes place and it has been evaluated by the GAO and I think the NAS, the Science and Decisions was largely premised on the fact that IRIS is IRIS. The risk assessment process at EPA is bogged down. You could speak to this much better than I can. I don't know if stopping points help that, but there is a lot of concern about these lengths of time it takes to make a decision on a risk assessment at EPA.

DR. MICHAELS: From OSHA's point of view, that is a wonderful, sort of theoretical approach. The reality is it takes us so long to get a standard out that the last evidence we looked at is often several years before the

final standards published. Then, we are sued, always, and we generally prevail. There is not a health standard that OSHA has ever put out, where we haven't been sued by at least one, and often multiple industries. That is where the resources go. At the end of that process, the idea of going back and revisiting that one standard, when we got 70,000 other chemicals out there, is clearly what is going to take precedent.

DR. WOODRUFF: Maybe you should decide sooner, because you are spending a lot of time with the lawsuits.

PROF. DUDLEY: Let me first respond to your question about why. At least, I can tell you why I think that NAAS has the problems. It is because the statute makes everybody pretend that their decision is based solely on the science, because that is all the statute allows. Nobody can discuss openly why we would set it at a level that is not zero. Everybody waves their hands and says the science says it should be nine or eleven or two or forty, and nobody can say why they really think it should be somewhere along that linear dose. It is the statutory language that really makes that.

DR. RODRICKS: Forces that kind of thinking.

PROF. DUDLEY: The science charade, as Wendy called it in her earlier paper, her 1995 article, it is

inevitable with a statute like that. I have a three-part question for the panelists. With respect to the attribution and dissent, would you apply that only to scientists on purely scientific documents? Since I agree with Thomas, that is going to be a rare situation. That you really are going to have that fuzzy part in the middle, would you also allow attribution and dissent on these documents that involve policy choices. If so, would you stop with just scientists, or would you also allow lawyers and policy analysts and economists to dissent on policies?

DR. LOUIS: I think it is a fabulous question.

DR. MICHAELS: These are tough questions. We are not a science agency. We don't do research, so it really is all policy. That is exactly the sort of tough issue, which I am not ready to grapple with.

DR. WOODRUFF: This is interesting because this issue came up at EPA. There was a person who was dissenting on a climate policy decision, but was not a climate scientist. This was raised in the news, and people probably read about it.

This all came out via sideways, leaked emails, but should there have been a process for someone who is not a climate scientist to comment on climate science. I think that possibly one solution is to have people who have a

dissenting opinion be able to publish their dissent in the peer-reviewed literature. Then, let their peers decide if it is actually a real dissent, or in this case, didn't get out. That could be another way to deal with it.

I am a scientist, so I don't really like lawyers commenting on science. Then, someone said, anyone can learn anything, so maybe I could learn to be a lawyer.

DR. LOUIS: Susan, my comment was a bit flip, but I really mean is I don't feel I have the knowledge, both in terms of the ground truth of what goes on in OMB, to answer that question. I am sure you do at least have your view. I think the line is so fuzzy that I'm not sure how far you can go beyond it, but I think it is worthy of discussion study, whatever other things we need to do.

DR. WOODRUFF: But I do think that if you are more clear about documenting what studies go in, how you evaluated the quality of the studies and along the way, then, when you have the dissent, you can see more easily where in the process it occurred. I think this issue is one that we are struggling with, so clearly, it is probably an area that you could use further case studies or evaluation, because I think it is tricky. There are a lot of things to trade off on that issue.

MR. GILMAN: Tracey, I just wanted to comment on the IRIS statements you made. It was an assumption in the Science and Decisions report that, in the absence of the value in the IRIS system, the agency did nothing. I was a reviewer of that report. I pointed out that that was untrue. I cited other EPA individuals, and it still didn't find its way out of the report. That is not the first time that's happened.

DR. WOODRUFF: You should argue with him, he's from over there.

MR. GILMAN: In fact, the programs do typically adopt numbers at that point, whether it be Cal/EPA (?) or a European standard and the like, if an issue rises to a regulatory concern.

DR. WOODRUFF: It is true, and I will correct myself, that for some situations, they will look to other agencies that have like Cal/EPA, because I was involved in an air toxic assessment where EPA didn't have a number. We went to Cal/EPA and used their number, and then we went and used the HEES numbers, which then really people at EPA start to get really nervous about that.

There are thousands of chemicals and there are only several hundred IRIS assessments, and there are only several hundred Cal/EPA assessments. There are literally

several thousand chemicals that have nothing. That is what I mean, in terms of those really will have zero. It is a vicious cycle, too, because it's like, well, if we are going to do, for example, TSCA, we are going to pick a chemical and we are going to do a rule-making on it. But we don't have any data, so then how do we, because the law requires that we do a rule-making on something that we have data on, but we have none, you know what I am saying? Then, who makes a risk assessment?

MR. GILMAN: Typically, within an agency, the program office that sees an exposure level that is of concern, regardless of whether the hazard is well-documented, will begin to work through something.

DR. WOODRUFF: Right, but how do they know, A) they have to measure the exposure, and then how do they know of the concern if there is no risk number?

MR. GILMAN: If they have no exposure and no hazard, then typically it hasn't risen to the levels.

DR. WOODRUFF: There's 200 chemicals measured in NHANES. We have shown in our own analytic chemistry that there is probably hundreds of more chemicals that are present in people, that we don't have methods yet to analyze. I think you and I are arguing because I think there is a whole section of we don't know. What we don't

know can equal we are going to do something, or it can equal zero. I would argue that currently, the whole debate about TSCA is the default right now is to do nothing on all of these chemicals.

MR. BROMBERG: Since we are supposed to be talking about mechanisms to enhance scientific transparency, I think we should say a little bit more about the importance of peer review. There was some discussion earlier this morning. I thought one thing we should talk about in peer review is the EPA handbook, the fourth handbook on peer review. It talks about the importance of having external peer review instead of purely internal peer review for topics of more major significance of policy significance. You would be bringing a topic for peer review to an external audience. In the case of EPA, that could be the science advisory board.

To capture what Tom was talking about, instead of having group think, put some words in your mouth, instead of having what the individual people were saying, an excellent practice, which I think I have seen EPA do, is to have the individual scientists draft their comments before they come together in their big meeting.

Of course, you want to give them adequate time to do so. Then, they bring those comments together, they have

that discussion. EPA needs to do more work. I am sure other federal agencies need to do more work, on having a good dialogue with the public at those peer review meetings when the peer reviewers get together.

Instead of a day and a half, perhaps they need some more time, but where they have a dialogue where the public commenters, the peer review process can work its magic and do a good job. EPA is spending a lot of time on IRIS today, reforming that process, to allow a more robust discussion at the SAB level.

DR. LOUIS: Could I make one quick comment? I think I certainly agree with everything you said. I think the other place for peer review, especially for issues that are coming up, that are relatively new, is to get peer review of the protocol, whether it be called a process or something else. I am taking again my experience in both clinical and epidemiological studies.

You want to avoid the equivalent of come to think of it, you can't get there from here. Make sure you have a preflight checklist, checkup, if you like, that is both internal, but I think importantly, external on bigger, more novel projects, so that we make sure from the start that we can get there.

MR. BROMBERG: It was a whole subject as to what do peer review and the scope of the peer review and the charge questions, that would be too long for me to comment on.

DR. RODRICKS: There are a number of recommendations for future work that Professor Wagner has out there. One of them, I think, has to do with how do you select peer reviewers, all those kinds of questions come up.

MR. BROMBERG: The other area that we talked about a little bit, but perhaps we should have done more in this session, is on the transparency and how to handle weight of evidence, selection of literature, review of literature, how do you systematically review the evidence. A good source of that for ACUS is the NAS recommendation that was mentioned this morning, on the formaldehyde committee, where they talked about the importance of collecting.

Obviously, you have a list of the literature you reviewed, a list of the literature that was deselected, based on some kind of quality criteria that would be spelled out. Having a systematic way of evaluating the quality of that evidence, and selecting the evidence, and

then of course, doing your study, your protocol, your evaluation.

The recommendations that came out of this NAS formaldehyde recommendation are really excellent roadmap, it is chapter 7, which now EPA is implementing for IRIS. DD NAS has a separate exercise on providing advice to EPA for that IRIS exercise. That would be a source for Professor Wagner and ACUS moving forward, on the side of what to do about that side of the process.

DR. RODRICKS: Those are important points. Tracey, you made the point, and very interesting, right at the start about how you collect literature can very much influence where you end up on the science.

DR. WOODRUFF: Right, and actually the whole process goes through exactly all those pieces, collect the literature, decide which literature to include or exclude. Though I will say that quality scores are not favored in systematic reviews and clinical literature right now is shown not to be useful.

Really, you evaluate risk of bias, so you decide all of your risk of bias tools, and then evaluate the evidence. Then, come up with a recommendation for how to label the strength of the evidence. It has all been put out, but again, has to be adapted to the environmental

health context, which is animal studies and human observational studies.

I will just put out that we have been working on this ourselves, at UCSF, and to declare my own conflict of interest. That is clearly an area which I think is true, it is very important and we could learn a lot from in terms of moving forward. It is helpful to look back.

My point on this is to look back and see what another discipline did in their own sometimes painful acceptance. I am not going to say everyone, because there are probably not very many physicians here, because not all physicians like this method. There is a part of it that requires that we be more true to the evidence. I think that is hard when we are very use to just using our internal judgments that we don't always want to make transparent.

MR. BROMBERG: One last thing is that the ACUS recommendation probably could directly incorporate the information quality requirements that the agencies are already requiring by their rules, to follow and incorporate that as one of the things we should be looking at, as part of developing their policies for ensuring data quality, peer review, et cetera.

DR. RODRICKS: I don't see any more questions from the floor. Let me just ask if anybody here has a final word or two. Let me thank you all then. Tom, David, Tracey, very good discussion. Alan, are you going to go right to the roundup now?

PROF. MORRISON: No more breaks, no more coffee, no more food, but if any of the panelists would like to stay up here, for the next panel to get asked more questions or make more interjections, without having to stand up at the microphone, you are welcome to stay here. Anyone who has been on it in the previous panels, would like to come back up, we are going to try and go, and look at some of these questions again.

Agenda Item: Session 4 – Roundtable Discussion: Moving Forward

PROF. MORRISON: While we are getting one more chair, a couple of preliminary matters. I am Alan Morrison. I am a member of both the Science, Technology and Law Committee of the National Academy of Sciences, and a senior fellow at the administrative conference. My job is to try to pull some of these things together and review some of the things that have been said, and perhaps a few of the things that have not been said, if that is possible.

Before we begin, let me just issue a word of thanks on behalf of everybody here, to the Alfred P. Sloan Foundation, which financed the workshop today, There is a very small acknowledgement on the back page of the program about the Sloan Foundation, but I wanted to be sure everybody was aware of it. Without them, we would not be here today.

Let me begin by talking about a couple of things, and just some observations about Wendy's report. To me, what was one of the most surprising things was, and I am a lawyer, not a scientist, how differently science is done, not only among different agencies, but even within the EPA, depending on the nature of the inquire that they are doing.

One tries to generalize about things, recognizing that even among good practices, let alone best practices, it is not always easy to tell what the right thing there is to do. It suggests, at least partially, that one size may not fit all, and that we have to keep those things in mind, including the questions about cost and importance and time, and everything else that may be part of the process.

Second, there was much talk today about science and policy. One thing I didn't hear very much of a couple of times was mentioned the long arm of the law, not in a police sense, but in the fact that the law constrains

administrators in what they can do, must do and cannot do. In particular, the question about what role, if any, cost should play in the process is often determined at least ultimately by what the law says, even though it may not be clear in the law itself. When the agencies are setting up to undertake a rulemaking of some kind, it is important that they keep the law, as well as the policy issues, in mind.

I fully agree with Tom Lewis that the lines between science and policy are fuzzy at best. It seems to me that we, being agencies, ought to at least to try at the beginning of the process to see if they can think about what issues are likely to be able to be answered by science questions, what are sort of science but get into the realm of prediction, and then finally, ultimately, what are the value judgment questions.

And that it is worth examining those questions at the outset, and trying to set them off, if for no other reason than it prevents, in some respects, the crossing of the lines, and that it is harder for agencies and everybody else to say that politics has taken over a scientific question, if the question is not identified as scientific at the beginning of the program.

Take something like tobacco regulation, all the science is not clear, but I think everybody agrees now that tobacco is bad for you. The question is, over how much and how long and what kind of harms can it occur. That gets into the somewhat realm of prediction, is it scientific prediction or something else.

Then, finally, the ultimate question of once we decide that, what do we do about that. If we at least recognize that there are those differences, and that some of them may be constrained by legal questions and some of them not, it may help avoid the blurring of the lines that we see in some of these cases.

The last thing I want to observe is that I didn't understand entirely what the word, study design, meant when it was first used in the first panel. Paul was kind enough to explain to me at the break, and I understood exactly what he meant when I understood how he was using the term. The study design is how you go about figuring out what studies you are going to consider, and on what basis and what criteria.

I always get amused, somebody said to the agency, did you consider something. I always never understood what the word consider meant. Did it cross through my mind at some point, and I quickly dismissed it as being

nonsensical? Did I actually look at a study that said something about that? Did I talk to somebody about that?

As I understand it, there are various criteria that have been used in prior situations, and ought to be set forth at the beginning is how, among all of the published studies, you are going to identify those which you are considered to be the most likely to be useful, and on what basis you are going to put some kinds of studies in and some kinds of studies out. Whether that is called protocol or study design, it seems to me to be a good idea at the beginning of the process, so everybody is operating on the same premises.

It doesn't mean, nor should it mean, that if you get into the study and you change your mind, it is wrong to change your mind. Changing your mind is not a bad thing. It may be a good thing, but at least you recognize that you are changing your mind, and you want to give an explanation for why you changed your mind based upon what you actually discovered along the way.

Let me say what I would like to do. I would like to then go over the question of peer review, and talk about it at least from one perspective, talk a little bit more about peer review, including the question about whether OMB decisions, with respect to things that are science or

science-related, because we don't know what exactly it is, should those kind of changes made by OMB, subject to peer review, as the recommendations suggest, or is there something different about OMB that makes the peer review system inapplicable to what it is doing on the science side, if we can do that.

Then, I am going to talk a little bit more. I would like to ask a few more things about the deliberative process, and then ask the panel to say a few more words about authorship and dissent, and perhaps some of the other issues. Any of the panel have any reactions to what I said at the beginning, or should we just get onto the other subject?

DR. MICHAELS: One of the issues you touched upon, I thought was important, and I wanted to sort of add more texture, which is sort of this question of what are the standards of evidence that we use. There are attorneys in the room, and I know that in criminal cases, you have got a proof saying beyond a shadow of a doubt. Certainly in epidemiology and much of clinical medicine, we look at statistical tests, and we have a convention of .05 in many cases, and various ways we might use that.

Neither of those really apply in this case. We often apply what we are used to using. We have to think

very consciously about what is the standard of evidence. Obviously, when we are thinking about regulating the public health, and this was an issue that came up this morning, how protective do you want to be. That is also going to relate to how significant the problem is.

That has to be, I think, laid out in advance, as well. They will say what standard do we need to reach, what is our evidentiary threshold to decide whether we are going to do something. Then, later we can get into the question of what the number is, if we are talking about specific numbers. We are never going to be absolutely sure. We are not going to be that criminal court requirement.

On the other hand, it may be that there is a risk, in a very simplistic way, that we are concerned about, even if we are not 95 percent sure it is there.

PROF. MORRISON: David, am I right that what we are talking about is reviewing literature, whether it is published or unpublished, or done by somebody else. The point is that the agencies are doing relatively little independent research on their own at this stage of the process.

DR. MICHAELS: I think that depends on the agency. I think the agencies have a great deal of variation in how they approach these questions.

PROF. DUDLEY: I agree with you. I think one of the things that was clear from Wendy's report is that a one-size fits all approach doesn't really work. I thought we talked extensively about how the legal requirements dictated that, that legal requirements are the reasons that agencies have to take different approaches, even within EPA.

I have to disagree with you, though, that the legal requirement, let's see, how did you characterize it, would help avoid the blurring of the lines. I think some of the legal requirements make you blur the lines. I know I have said this so many times, but in response to your comment, I have to say it again.

The National Ambient Air Quality Standard, that legal requirement says it has to be based only on public health and only on science. Therefore, everybody pretends that is what they are arguing about when they are not.

PROF. MORRISON: Doesn't it say appropriate, also?

PROF. DUDLEY: An adequate margin of safety, so it is necessary to protect public health, allowing for an

adequate margin of safety. If I were to read that, I am not a lawyer and I am not a scientist, I would read that and I would think, gosh, if we think that there are health risks all the way to zero, that means set it at zero. Yet, nobody does that. Instead, there are five years of very expensive costly, to taxpayers, research to come up with a number that really is just hand-waving.

I think that kind of a legal standard actually harms the science, and I think it creates that blurring. Study design, I fully agree. I think your point on that is very important, that setting that out in advance is important. Now, the peer review in OMB, do you want me to address that, or did you want the audience to?

PROF. MORRISON: The question is, why is there peer review? One of the points made in the report is that, in the old saying, two eyes are better than one. The different people, even within the agency, it is worth having somebody else look at it besides the people who develop the standard. The outside peer review is obviously a better system because they are less invested in it.

At the agency level, we heard both about the desirability of having individual comments, so they don't get blurred, but the desirability to have consensus if, for no other reason, then you don't get so much of a mixed

message to the agencies. It is not that the people are saying the same thing differently.

Are there any other considerations that are relevant, on the question of what kind of peer review ought to be done, when it ought to be done, who ought to do it and everything else? Or should we just assume that peer review, by a scientific advisory board, for example, is always a good thing and all the agencies should strive for that?

DR. LOUIS: I am not able to come up with prescriptions on exactly when and how it should be done, except by looking at specific context. There, I think, you can make progress on paradigms and scenarios, in terms of early on for some situations that are novel kind of approaches. Definitely in the mid-game and at the end, both internal and external peer review of important decisions.

I think there are a lot of issues, including when is information available to the peer review team. I will leave it to others, but I want to end with the thing that I mentioned a few times, and that is I don’t know whether to call it the sentinel effect or the halo effect. It is just the very act of knowing that you are going to be peer reviewed generally improves what you do.

I use the analogy when I am talking with junior faculty and students. The intention to submit an article to science as opposed to a lesser journal, it actually improves your research and improves your writing. That aspect of peer review is not the only thing that is important, but to me, it is very important.

DR. RODRICKS: Just one comment on the peer review process that I did not see mentioned in Wendy's report, and that is the question of whether there is uniformity in the response to peer review. Always a clear record of what you considered from the peer review, whether you accepted it or rejected it, and why. Do you need that kind of clarity and completeness with every kind of peer review, I don't know.

PROF. MORRISON: Do you have a recommendation on that?

DR. RODRICKS: I don't have a recommendation on that, but I have seen so-called peer review cases in which their comments are sent in. Somebody considers them, but you don't know they affect the final document.

PROF. MORRISON: It is like the comment box up at the top of the ceiling, yes.

DR. WOODRUFF: I just had one thing. Of course, when you say, do we like peer review, it is like, well, of

course, right? It is like saying do I like apple pie or my mother or something. Anyway, I think the key, though, is what we don't want is an infinite peer review do loop, which I think is where there has been some challenges is, formaldehyde is a good example.

We didn't like the SAB review, didn't like the internal review, go to the SAB. We didn't like that review, so we are going to go to the NAS. We don't like what the NAS is saying, so we are going to go back again. It is like, well, okay, those are all good, but I think you have to combine your peer review with your stopping rule, because you can't have one without the other. You could peer review things for a very long time.

PROF. MORRISON: What about the problems of cost and delay, with regard to peer review? Can agencies legitimately consider that as to the type of peer review they are going to have, how often they are going to have it? Or aren't we to say that the agency ought to have the gold standard in all cases?

DR. MICHAELS: How could we do that? We produce, as a small agency, a large number of documents. Even if we could afford it, you couldn't find the experts who would agree to do it, to spend all their time doing peer review. It has to be essentially a graded system where you have

important documents, that you use the best people in the country, and then you have a lot of others. You would like someone to look at it, but you also assume there is a public process involved, where you do hear from other people who weigh in, who may not agree with you.

PROF. MORRISON: You do some kind of internal peer review, at least?

DR. MICHAELS: We do certainly that. But then we use, and I think all of the agencies use, contractors who set up peer reviews for less important documents. Outsiders read them, but they are not given to the top academics in the field.

DR. WOODRUFF: Peer review is not a perfect process. There is a whole field, an academic field, a peer review congress, I mean, they are like people who write many scholarly articles on peer review. It is very challenging, but it is kind of like transparency. It is kind of the best system that we have.

Of course, we should always strive to improve our peer review process, whether it is through, you mentioned disclosure, which I think is entirely critical. Not every journal, for example, has disclosure about conflict of interest or various things to improve it. It is always

going to have imperfections, like science has uncertainties in it.

PROF. MORRISON: Let me now turn the question to OIRA review on these issues.

MR. GILMAN: Just on the peer review, I mean, it ranges from agencies that do no external peer review of any product in a given year. I looked at 2002 for EPA. There were over 900 various studies that were subjected to a process that tiered where that review would be. Was it a three-letter review or was it Science Advisory Board or the National Academy of Sciences and places in between.

Over 800 of the products were reviewed in some form or another, and the other roughly 10 percent were deemed to be sufficiently repetitious of previous peer-reviewed work that they didn't need independent review. That process cost about almost $10 million at the agency. Where do you want to be in that spectrum?

PROF. MORRISON: Somebody mentioned this morning the issue about important decisions being made at the local level on a routine basis with ongoing businesses. It is pretty difficult to have peer review in those kind of situations, it seemed to me.

PARTICIPANT: I just wanted to say that one of the things that has been missing in the discussions

throughout the day, from my perspective, is the sense of urgency about the productivity of the regulatory system. This is something that Tracey and David have mentioned, from their perspective as agency officials.

As just one example, IRIS omits 70 of the hazardous air pollutants that have been listed for regulation in the Clean Air Act since 1990. We can criticize IRIS, we can chew it over and spit it out, and we can pick it up again and chew it again. It is moving at such a snail's pace, as are other aspects of the regulatory process, that these layering on of more and more and more is disconcerting, to say the least. That urgency is something that I urge ACUS to keep in mind, and I am sure that the Academy will, as well.

PROF. MORRISON: Speaking only a little bit for ACUS, that probably is a subject of another study or two. Agency delay, it has been a subject of studies in the past, but I don't think that is the subject of this current study. Although your point about adding layers on may depend upon which layers you are adding, from whose perspective you are adding them on.

Let me just ask this one question to the panel first, and then we will come back to it. Suppose for the moment that there is an important rule, and OIRA has a

difference of opinion about things that are on the scientific end, whether you call them purely science or not, or whatever it is. OIRA says, we don't think that scientific judgment is adequately explained by the agency, and we reach a different judgment, and they actually say that they are doing it in part, based on the science.

Is that kind of judgment by OIRA ought it to be subject to peer review of some kind, or ought OIRA, as the current situation is, not be suggested that it actually go out and get some of the other scientists to look at it, as well.

DR. WOODRUFF: I was thinking about that question, because there are two parts really. There is does OIRA have to tell people why they made a different science decision. That doesn't happen, right, the transparency in that piece, versus there is peer review, which is a second piece to that. I definitely think you should have to be transparent about your judgments that are science-related. Not deliberations, that is fine, but the science judgment should be made transparent.

PROF. MORRISON: When you are using transparency there, you are using it in the sense of explaining what they did and why they did it, rather than actually sitting in on the meeting where somebody talked about it.

DR. WOODRUFF: At the end, I say we are making this judgment about the dose response is EPA says it is 10, and OIRA says, oh, no, we want to do five.

PROF. DUDLEY: I think there is a real confusion about what goes on in the OIRA process, so let's just start there. That is not the kind of thing we are talking about. OIRA doesn't say, oh, you have a scientific study that says it is 10, and I really think it should be five, therefore, change your rule so that it reflects five.

If that happened, I think, sure, OIRA should go through peer review. But just think about the logistics of that. OIRA has 90 days to review rules. It is engaging all the other agencies, so that in essence is a form of peer review. It is bringing in the other agencies that also have scientific information.

Now, in addition to that, we are going to stop the presses for what, a year or two, to get peer review. It is completely impractical, even if there were situations where it made sense. I think that, first of all, the whole idea I think misunderstand OIRA review.

PROF. MORRISON: That assumes, of course, is that there is one kind of peer review that you could have. If you had a different kind of peer review that is not the

scientific advisory board, but something else, it might produce a different kind of operative delay and cost.

PROF. DUDLEY: OIRA has had peer review on things like some of its guidelines. It sends out its annual report to Congress. It sends it out to peer review, so it does do review on some of its own products.

PROF. MORRISON: Does anybody think that OIRA makes judgments that are on the scientific end, and that end up causing changes. Maybe there is a suggestion in the report that that is what OIRA does. It second guesses the scientific determinations. If it doesn't happen, obviously there is no need for peer review.

PROF. DUDLEY: It gets to the original point, we really are blurring the lines between science and policy. I can't think of a situation where OIRA came to me and said, the agency says, I can't even think of how to depict it, I think it is a confusion of how OIRA works.

Certainly, if I were working at an agency and I had policy views, which everybody has, views of how the policy should come out, otherwise we don't work in government. If you are working in government, it is because you care about policy. I would love to characterize everything as science, because then nobody else could interfere with me, because it would be my

decision and mine alone. I think that is why it is so important to try to make that distinction and understand where the science ends and the policy begins.

DR. GRIFO: You started off with that very question of which are policy questions and which are the science questions. Who gets to do that? The science and policy God? I just don't know who would do that? Who puts this in this column and this in this column. Obviously the statutes do it, where the statute exists and it applies, but that is not every case.

DR. WOODRUFF: That is actually a really interesting point about what you are saying, in terms of deliberate process. My experience in a risk assessment that EPA was doing, where we had to have the peer review charge that IRIS had, reviewed by OIRA, because I actually worked on this peer review charge. It came back and it was changed. Now, should there be transparency in that? It was changed pretty significantly, I would say.

PROF. MORRISON: Is there a policy aspect to the IRIS determination?

DR. WOODRUFF: Yes, but is there an aspect to changing the peer review charge itself? I mean, one has to ask that question, isn't that kind of important about how

even the peer review is conducted, if there is weighing in on that aspect?

PROF. DUDLEY: I think the peer review charge is very important, because it drives what the peer reviewers are asked to think about.

DR. WOODRUFF: If OIRA makes a change to it, should they be made transparent about what that change is, so that everyone knows what went in and what didn't? That is my question.

DR. LOCKE: Could I just break in? Sorry to do this, but there is no one from the first panel here, so I am going to do a little channeling. I guess sort of wearing my lawyer's hat and my scientist hat, I just have one basic question. My question is, how are we going to know what is happening without the data? We have to have some way of gathering data on these questions, so we can actually analyze it.

I think one of the great things that Professor Wagner's report did is it raised this question. We should be taking the next step now in trying to figure out if that data is out there. If the data is out there, we can do an analysis, we can do a further analysis to find out if there are lines being drawn on the science and on the policy. If

it is not, we can figure out a way to maybe collect the data, so that we can actually answer that question.

DR. ZECKHAUSER: I would observe that there are battles going on, both between the agencies and OIRA, and basically in all of regulation, and in this room, that we are waging in terms of can we improve the science and the science process. When Alan asked a question, should we have peer review of OIRA, I really think the question he is asking is, should we find some way to tame OIRA.

I think that we should ask the questions. I mean, many of the people who have suggested that OIRA is waging into science and so on and so forth, really would like to have more of a thumb on the other side of the scale. The people who think that the agencies are a little bit excessive at times would want to preserve OIRA.

Certainly, when you start to say we are going to change the peer review process, that is a subtle way of engaging in the battle. Nobody ever says I am changing the peer review process, because actually I have found out that this professor at Johns Hopkins had more insight than that professor at the University of Maryland. Oh, that is what it is. It is that you think that it will come out more your way.

I personally would like to think more in terms of let's leave that battle aside and worry about how to improve the science, rather than have subtle questions which are really getting at the notion of how strict we want our regulations to be.

DR. GRIFO: Again, I struggle with that question, which is if we are going back to improving the use of science in the administrative process, to what end? Do we want to save more lives? Do we care more about the air? Do we care more about the water? Do we care more about industry?

That is not really a part of that, and I think that leaves open a lot of questions. To what end, what is it that we are trying to do? I think that is where we come into the problem with science meeting politics, because there are two different ends there. If you asked all of us at this table, we might have very different ends.

PROF. MORRISON: I suppose somebody might say that the end is what Congress said the end is in the statute. The trouble is that doesn't answer the question of what the right answer in a particular case is, to how the ends apply to the facts and to the substance we are trying to regulate.

MS. CASANO: I was going to ask if their comments had to do with OIRA, in which case I was going to pass. Given Dr. Zeckhauser's comment, I will go. It has to do with improving the science.

People might be using the term study design differently. When Dr. Goldman, at any rate, used it, she was speaking much more broadly than how do you evaluate a study. She talked about developing a hypothesis, and then explaining how you are going to test that hypothesis, and then testing that hypothesis, and explaining how you are evaluating the data that you are using to test your hypothesis. Well beyond study design.

I absolutely agree with Dr. Goldman and Dr. Woodruff, that if you did that at the beginning of any risk assessment, with significant public engagement at the problem formulation stage, as recommended by the Silver Book, at least some of these problems that we have would go away. One of the problems with peer review is it comes at the end or toward the end. It comes after an agency has already made up its mind about what the science says.

I think that if you did that, if you had really good study design, problem formulation, et cetera, at the outset and you read on it, then you could address one of the other problems, which is there are far more risk

assessments waiting to be done than any agency is capable of doing. You could turn it over to third parties.

Not all PhDs are in agencies. There lots of PhDs at universities, there are PhDs in industry, and they are perfectly capable of doing risk assessment, if the ground rules are well established and agreed on.

DR. WOODRUFF: We are very much into promoting the use at this of best practices from the systematic review methodologies. I would say it is not a panacea for disagreements, because you have to make a decision. You will document, when you get a study, for example, one of the things that you have to evaluate is issues about the study design.

Different people may conclude different things in that, about issues related to, I will just use the word, quality for lack of a better word, in terms of different issues about the study design. There will still be arguments, but at least they will be traceable and reproducible.

The other thing is I know it seems such a simple concept, but it is actually hard to switch over to this way of doing things. I mean, people take years for training and systematic review, to get up to speed on how to do it. It is not just something that you can just necessarily hand

off the shelf. To move toward this type of system is a big shift for agencies who haven't been doing that before. Those are just two caveats on that. I do think it makes it more transparent, and in the end, our initial investment up front will gain efficiencies later on.

DR. KORN: I am asking this purely out of my own curiosity. It is my memory that one of the data quality rules issued by OMB on the agencies requires peer review very explicitly of particular things at particular times, and requires that the peer reviews be posted and that the agency's response to all of the peer reviewers' request also have to be posted. Is that more or less correct? If so, I am asking whether OIRA believes that it should be itself subject to that same kind of peer review, that it is mandating on all of the other agencies for certain kinds of activities in which OIRA may engage.

PROF. DUDLEY: I don't speak for OIRA, because I am now actually a professor at George Washington University. I don't think OIRA engages in that type of activity, would be my short answer. Actually, the next person at the mic has more recently been at OIRA and might be willing to.

PROF. MORRISON: I think, David, the peer review rules or guidelines are an outgrowth of the data quality

act. I don't think they are required by the data quality act itself. OMB has specified in much broader terms, that is in much more flexible terms than they had originally done, what the requirements are for agencies when they are doing regulations.

MR. FITZPATRICK: Obviously, I am a two-time veteran of OIRA, so my perspective and agenda and biases are well known. I just wanted to speak to the question of OIRA in science, because I think it is a very important one, and to give some recent perspective.

First of all, I do agree with Susan. I think so much of this conversation tends to fundamentally misunderstand the nature of the OIRA process. OIRA runs an interagency review process. It has its own views, but it includes all of the other agencies and White House offices who have a view on a regulation.

Were OIRA not to exist, I can assure you that there would be a similar process that would be constructed. It would be far less transparent. There is no way any president is not going to exert some form of oversight over the agency, so that is the first point.

The second is, I think the question of science versus science policy versus policy is a very important one. In my experience in two administrations, I never once

saw an instance in which anyone from OIRA or a White House office or another agency asked an issuing agency to change the underlying science upon which it was relying.

I saw discussions, and robust ones, which I think happen in the scientific community all the time, about which questions were the peer review panel charged with. How did the agency respond to the peer review comments? Which studies were not considered, et cetera. Those strike me as legitimate questions to ask, because policy decisions, usually with some real discretion, are being made based on the science.

Let me add just a couple of other quick points. One, science is but one empirically-based input into a policy decision. There is also economics, there are also technical documents, there are the social sciences. I think we all need to understand that science is not the only input into policy, and all of these things, whether the economics or the technical basis for regulation, are examined during a review process.

Finally, just to the point on IRIS, and I can only speak to the IRIS process in the Obama administration. I helped EPA redesign the IRIS process from that which was used in the prior administration. It is my understanding, I think it is confirmed here, that any input by OIRA into

that process, in steps three and six of the IRIS process, including prior to peer review, is transparent. It is made publically available, just as the public comments are.

It is a fully transparent process. OIRA, CEQ and OSTP, along with other agencies, participate. I can assure that nobody other than the OIRA scientists really participate in the OIRA process. When I was there, Cass Sunstein and I had no involvement because we have this much expertise in the IRIS process.

PROF. DUDLEY: My only role was calling over to EPA to say, please, please move these OIRA assessments along. Please, they have been delayed too long.

PROF. MORRISON: Any other comments?

DR. GRIFO: Where do I begin? I mean, I think there are examples out there, and we have had this conversation before, Michael and I. I think what is important is to recognize that there is a whole process before the official process begins. A lot can happen in that process. Agencies perceive, maybe we could quibble and disagree over this, about that interagency review process before it becomes the official interagency review process.

I think it is hard. It is a very difficult process, it is a very difficult set of questions that we

are trying to address here. I do think that in the end, having that clarity about science versus policy, having that clarity about what are the questions that we are going to ask, having the clarity about what are the studies, all of these things will help to open it up and make it more difficult for the process to be manipulated.

Does that mean that really badly intentioned people, and I am not talking about anybody in this room, I am just talking out there, won't continue to seek ways of manipulating and changing this process, they will. They will because there is a profit motive incentive in many cases for them to do that.

I think that is why we have to continually pose these questions, so that we do end up with the most robust process that we can have.

PROF. MORRISON: Even if we don't use the word manipulate, we could talk about honest disagreements and different agreements about policy. One of the questions that Michael's point raised, he said we asked what studies you could considered and we asked a couple of other questions. It seemed to me that they were getting very close to the science side of the line. At least there is a perception, it may be wrong, but it is a perception that OMB, in fact, does question science, and the questioning of

the science affects their judgment as to what they want to proceed with.

DR. WOODRUFF: I think it is great that one of the things that has been discussed all day, and was raised again by the last speaker, is this issue about trying to be more clear about what is science and the judgments in the science, versus all the other parts of the decision-making process. I do think that, even though we talk about this among ourselves all the time, the more that you put out, that science is not a substitute for decisions, in terms of whatever the values and the economics and all those things which are, as every speaker has said, is legitimate parts of the decision-making process is good to continue to discuss in public and in these documents.

I think this idea about this discussion about OIRA could be better supported with actual data, as Paul was talking about. Let's empirically test this situation in terms of —

PROF. MORRISON: Both of you say a word about the kind of things that you would regard as data. As I said in other forms, the plural of anecdote is not data.

DR. LOCKE: He is asking us to write an RFP.

DR. WOODRUFF: I know, exactly.

PROF. MORRISON: Tell me what kind of data you are looking for.

DR. LOCKE: I have to admit that I am prepared for that question for two reasons. First, it is not an area that I have given any previous thought to. Two, I think there are a lot of different ways you could approach this. One way you might approach this is a case study approach.

Hindsight, of course, is always 20/20, but you might pick some key areas where you talk to the stakeholders and there is a legitimate disagreement. Some people feel, well, this was a case where science was impinged upon by OIRA. Other people feel absolutely not, or OIRA did just what they were supposed to. Then, collect the data that would allow you to examine that. A case study analysis might be one way.

There might be other ones that are more informative or give you a different slant, using data, numbers of situations where OIRA was involved. Beyond that, and I am not being overly articulate, I don’t have any great ideas or perfect ideas as to how to study this. I do know that you can, as we discussed today, design a methodology to study these things and to shed some light on it.

PROF. MORRISON: This is actually very helpful. One of the things that we hope to get out of this was some ideas for additional studies by either ACUS or by somebody else.

PROF. DUDLEY: Back to ACUS, that is really not within the scope of what ACUS asked for in this particular project. I think had it been the scope, maybe something like that would have been a better approach. You probably wouldn't have done it by interviewing EPA staff to see if they liked when OIRA reviewed their decisions. Probably not the way you would try to get at that problem.

PROF. MORRISON: The opportunity to get all of these scientists together in a room for ACUS, it has got to be something very (off mic).

PROF. DUDLEY: There are a lot of non-scientists in the room, too. I think we should be aware of that.

DR. LOUIS: Somewhat data, but maybe it is also just process. I don't know and I really don't know how much of the things that OIRA asks for and questions are a result of inadequate documentation of the process and decisions by the agency, and how much is what might be called meddling.

I think if we were to take some case studies where there was excellent documentation, and maybe even a

moot court, if you would like, for peer review of here, I am playing OIRA and here are the things I want to know about, to make sure that those are documented before it is submitted. We would actually be able to get a better idea of how much is simply what I would call very appropriate trying to understand how the decision process went, in terms of studies being included and whether it was low-dose linear or super linear or so on and so forth, and how much might be thought of as meddling or something like that. I think we can get some historic data in that and maybe also see what happens as the documentation process improves.

DR. MICHAELS: I don't know, this may be heresy, but having been involved and looking at this from the outside and the number of these really what are interagency discussions, not merely OIRA. We have these discussions where a lot of agencies have various interests, some of whom we regulate and some of whom have similar regulations, then they are concerned about our regulations.

This would be a particularly difficult study to do, given the deliberate process. I am not sure it would be very useful, frankly. I think there are lots of things we could do to improve the quality of the data that agencies get, and improve the agency process. Trying to pick all of this apart, I think frankly it is a dead-end.

PROF. MORRISON: We have disagreement about the applicability of the scientific method to studying this question.

MR. GLUCK: There is a lot of talk about creating standards, especially in the interagency process. I think there needs to be a step back, because what are the definitions of terminology. Some of the questionnaires, even some of the moderators, have been asking what do you mean by this and this. If you ask an economist, if you ask a scientist what they mean by safety, I am sure someone from the FDA will give you something far different than someone from the EPA.

Dr. Michaels brought up the legal standpoint of creating regulation is that you are getting sued for various industry or individuals. What a scientist may say is safe will have to translate into what it means in a legal sense of safety. I just don’t see that discussion of merging definitions, so everyone gets a clear understanding of when they have a standard, what everyone means by that standard.

DR. MICHAELS: If I could just add to that, you raised an interesting point because when we write our standards and we go through the scientific literature, we are actually not writing it for the scientific community,

we are writing it for judges. We know we are going to be sued and we know that things will be interpreted certain ways and pulled apart. In fact, scientists will read it and say, why did you go through this detail, or isn't that obvious, why did you even do that? We are worried, of course, so that is why we create these 2000-page preambles. If you were a scientist writing literature reviews, you would never do it that way. That is a very important point.

MR. GLUCK: I guess to go off of what you just said, the problem is also in the legal sphere of things, most science that is used in the court is based off of the Daubert scale. Based off of that scale, there is really no clear definition of what is common practice in science and things like that. Even if you create an opinion for a judge, he may choose to reject it based off of some other.

DR. MICHAELS: Fortunately, the judges who consider regulatory issues don't consider the Daubert rule. Is Barbara Rothstein still here? Barbara, who was the head of the Federal Judicial Counsel, I guess she has left, she has thought about this a lot. We don't have to deal with that, that is one of the few sort of impediments.

PROF. MORRISON: David is not a lawyer, but he is right. Daubert does not apply to the administrative

process, it applies to adjudication in court. That is at least one problem that we don't have to worry about.

DR. PASQUAL: The first thing is dismal, as though they may be, I would like to speak on behalf of my economists friends, who insist that they are indeed scientists. I would say that it is reasonable for me to expect transparency in their methods, the same level of transparency as I would expect from physical scientists.

The second thing, I have only heard data spoken about writ large, not so much data about this study, but in Dr. Lewis' response as a necessary corollary to implementing the FDA Act of 2007. I forget Wendy, whether you talked about data, but in order to do the certain type of meta-analysis and scientific integration that Tracey talked about, to formalize a stopping rule using value of information as Joe suggested we might consider doing. That really has to rest on data infrastructure.

I know that Dr. Gilman tried to do that when he headed up the research and development office at the EPA. It seems to be such a hard issue to find traction. I think decision makers within agencies don't see the downstream consequences of tending to data infrastructure. Having a placeholder of the importance of data infrastructure writ large, I think, is really useful in the report.

DR. ZECKHAUSER: I would just like to disagree strongly with one comment. As an economist, I have never heard my colleagues think of themselves as scientists. We have very few of the advantages that scientists have. We can't run randomized controlled experiments. Frequently, we have one observation, rather than dozens or thousands. I think that we have a lot of science envy. I don't think of ourselves as scientists.

DR. LOUIS: But you're useful.

PROF. MORRISON: The panel need not comment on the utility of economists. If the panel has other comments our time is just about up. I wanted to be sure if anybody has got anything else that they want to say about anything else that was said or unsaid today, speak now or forever we will call it an adjournment for the day. Thank you very much and we stand adjourned.

(Adjourn at 5:00 p.m.)