INTERIM REPORT ON THE ADMINISTRATIVE LAW, PROCESS AND PROCEDURE PROJECT FOR THE 21ST CENTURY

COMMITTEE PRINT

SUBCOMMITTEE ON
COMMERCIAL AND ADMINISTRATIVE LAW
OF THE
COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES
ONE HUNDRED NINTH CONGRESS
SECOND SESSION

DECEMBER 2006

Committee Print No. 10

Printed for the use of the Committee on the Judiciary

Available via the World Wide Web: http://judiciary.house.gov

U.S. GOVERNMENT PRINTING OFFICE
31–505 PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

F. JAMES SENSENBRENNER, JR., Wisconsin, *Chairman*

HENRY J. HYDE, Illinois
HOWARD COBLE, North Carolina
LAMAR SMITH, Texas
ELTON GALLEGLY, California
BOB GOODLATTE, Virginia
STEVE CHABOT, Ohio
DANIEL E. LUNGREN, California
WILLIAM L. JENKINS, Tennessee
CHRIS CANNON, Utah
SPENCER BACHUS, Alabama
BOB INGLIS, South Carolina
JOHN N. HOSTETTLER, Indiana
MARK GREEN, Wisconsin
RIC KELLER, Florida
DARRELL ISSA, California
JEFF FLAKE, Arizona
MIKE PENCE, Indiana
J. RANDY FORBES, Virginia
STEVE KING, Iowa
TOM FEENEY, Florida
TRENT FRANKS, Arizona
LOUIE GOHMERT, Texas

JOHN CONYERS, JR., Michigan
HOWARD L. BERMAN, California
RICK BOUCHER, Virginia
JERROLD NADLER, New York
ROBERT C. SCOTT, Virginia
MELVIN L. WATT, North Carolina
ZOE LOFGREN, California
SHEILA JACKSON LEE, Texas
MAXINE WATERS, California
MARTIN T. MEEHAN, Massachusetts
WILLIAM D. DELAHUNT, Massachusetts
ROBERT WEXLER, Florida
ANTHONY D. WEINER, New York
ADAM B. SCHIFF, California
LINDA T. SÁNCHEZ, California
CHRIS VAN HOLLEN, Maryland
DEBBIE WASSERMAN SCHULTZ, Florida

PHILIP G. KIKO, *General Counsel-Chief of Staff*
PERRY H. APELBAUM, *Minority Chief Counsel*

SUBCOMMITTEE ON COMMERCIAL AND ADMINISTRATIVE LAW

CHRIS CANNON, Utah *Chairman*

HOWARD COBLE, North Carolina
TRENT FRANKS, Arizona
STEVE CHABOT, Ohio
MARK GREEN, Wisconsin
J. RANDY FORBES, Virginia
LOUIE GOHMERT, Texas

MELVIN L. WATT, North Carolina
WILLIAM D. DELAHUNT, Massachusetts
CHRIS VAN HOLLEN, Maryland
JERROLD NADLER, New York
DEBBIE WASSERMAN SCHULTZ, Florida

RAYMOND V. SMIETANKA, *Chief Counsel*
SUSAN A. JENSEN, *Counsel*
BRENDA HANKINS, *Counsel*
MIKE LENN, *Full Committee Counsel*
STEPHANIE MOORE, *Minority Counsel*

TABLE OF CONTENTS

Page

Page

Page

APPENDIX:

Hearings

Page

Page

THE ROLE OF SCIENCE IN RULEMAKING

TUESDAY, MAY 9, 2006

9:00 a.m.—Intro/Welcome

Neil Kerwin, Interim President, American University, Director of the Center for the Study of Rulemaking

9:15–10:35 a.m.—Panel 1:
"OMB'S RECENT INITIATIVES ON REGULATORY SCIENCE"

Moderator:

Curtis Copeland, Congressional Research Service

Panelists:

Don Arbuckle, Acting Administrator, Office of Management and Budget—Office of Information and Regulatory Affairs

Al Teich, Director of Science and Policy Programs, American Association for the Advancement of Science

Bill Kovacs, Vice President for Environment, Technology & Regulatory Affairs, U.S. Chamber of Commerce

Rena Steinzor, Professor, University of Maryland School of Law, and Co-Founder of the Center for Progressive Regulation

NEIL KERWIN. Good morning everybody. I'd like to get us started this morning with a couple of introductory remarks. My name is Neil Kerwin. I am the interim president of American University (AU). I'm also a professor of public administration in the School of Public Affairs and the director of the Center for the Study of Rulemaking. I want to welcome you all to American University. I want to welcome you all to our still brand-new Katzen Center for the Arts, and in particular the Abramson Recital Hall. This is a session that I expect will be a stimulating and informative exploration of a topic central to the public policy process in the United States and in the process, of course, the quality of life in the United States.

I have a number of people I'd like to thank. We have partners in this this morning. The Subcommittee on Commercial and Administrative Law of the Judiciary Committee of the House of Representatives was the stimulus, I think, behind this particular session. The Congressional Research Service, and particularly Mort Rosenberg and Curtis Copeland were critical in the development of the session. And they worked very closely as an organizing committee with two members of the American University faculty, who you will hear from a little later today: Dr. Laura Langbein, who is the director of the doctoral program in the School of Public Affairs, and Jeff Lubbers, a professor in our Washington College of Law.

A session of this sort is one that the Center for the Study of Rulemaking takes as part of its mission. When we created the Center a couple of years ago, we were frankly still surprised and somewhat bemused that we were still the only one in the United States devoted exclusively to the study of a process of government that deserves a great deal of focused, organized, and institution-based attention. The field of rulemaking studies is happily, I believe, grow-

ing. It is diversifying, but frankly only slowly and certainly not—with regard to the amount of time and attention spent in the social sciences, at least, still not reached the points that other administrative processes have in terms of organized research. The intellectual debt that's owed to a still fairly small number of legal scholars, political scientists, policy analysts, and students of public administration is very great. But I happen to believe that their work has barely scratched the surface of a process that has become, in my view, irrefutably the most important source of law in America.

Today's focus is on the role of science in the rulemaking process. Whatever definition of rulemaking you prefer, whatever element of the process you choose to concentrate your professional attention and energies on, at its most basic, rulemaking is the transformation of information into legal obligations and rights. That information takes many forms, but the type of information that contributes most profoundly to a vast swath of rulemaking can be broadly categorized as scientific. Today, the panels focus on the state of scientific information in rulemaking, fully cognizant of the fact that scientific information contributes to a number of other stages in the regulatory process. I have been asked by the panels and the organizing committee to remind everyone that the focus is indeed today on rulemaking, so I would ask that all of us emulate the scientific method by staying to the extent we can on task, with discipline and perseverance, whatever the temptations to stray might be.

Again, I do want to thank a number of people for assisting in the organization of today's activity—Susan Jensen, Brenda Hankins, and Mike Lenn, Counsel to the Subcommittee on Commercial and Administrative Law, Mort Rosenberg, and Curtis Copeland from the Congressional Research Service, Jeff Lubbers, again, who I think many of you know as the author of "The Guide to Federal Rulemaking," which is, as best I can determine, Jeff, the major competitor to my text on rulemaking. It's a terrific book and a very bad career move.

[Laughter.]

Mr. KERWIN. And Laura Langbein, who is, I think as many of you know, a scholar of the regulatory process more than 20 years standing—they are the people who made this happen and who deserve the credit for the extraordinary group of scholars and experts that have been assembled here today.

So without further ado, and to introduce our first panel, let me turn to our colleague, Curtis Copeland.

[Applause.]

CURTIS COPELAND. Thank you, Neil. The first panel today is on the Office of Management and Budget's (OMB) recent initiatives in the area of science and rulemaking. In recent years, OMB has taken a number of actions—some unilaterally, some at the urging of Congress—that are expected to have a significant effect on rulemaking and in particular regulatory science. First, the Information Quality Act (IQA) or Data Quality Act enacted in December 2000 required OMB to issue guidance to federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by federal agencies. OMB published the final guidelines in September 2001 as required by the statute and repub-

lished the guidelines in February '02. The guidelines were highly detailed, imposed higher standards of quality on quote, unquote, influential science information with a clear and substantial impact on important public policies or private sector decisions.

In September '03, OMB issued a bulletin on peer review and information quality that proposed establishing a process by which all significant regulatory information would be peer reviewed. The proposed bulletin was extremely controversial and generated nearly 200 comments, including comments from members of Congress and prestigious scientific organizations. As a result, in April 2004, OMB published a significant peer review bulletin that was broader in scope than the earlier bulletin but gave agencies substantial discretion to decide when information was influential. But OMB also retained a great deal of discretion to decide when information was highly influential. OMB published a similar final version of the bulletin in January 2005.

And finally in January 2006, OMB published a proposed bulletin on risk assessment for public comment and peer review by the National Academy of Sciences (NAS). Risk assessment is defined in the document as that which assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment. The bulletin establishes general risk assessment standards and establishes special standards for influential risk assessments. Comments on the bulletin are requested by June 15, 2006.

What we want to do today is hear from a variety of perspectives on these initiatives, and we've assembled an illustrious panel to do so. Leading off will be Don Arbuckle. Currently—and Don didn't send me his bio so I had to make this up. Don is currently the acting director of OMB's Office of Information and Regulatory Affairs (OIRA). In that capacity, he oversees presidential review of regulatory, statistical, and information policy throughout the executive branch. Before becoming acting director in March—I believe this is your second tour, right? At least? It feels like more than that. Don had served as deputy director of the highest career position in OIRA since 1996. He has been at OIRA since its creation in 1981.

Don?

DON ARBUCKLE. I'm going to talk from here if you don't mind. There is no podium that I've ever met that has designed for the 95th percentile male. Curtis and Neil both have indicated that the focus of this seminar is on recent regulatory developments. "Recent" is of course—all is relative. There are some of you out in the audience who have been associated with this field of endeavor for many, many years. Mr. Tozzi, for example, one of those who was here at the creation, has been involved in this since Gondwanaland broke up and the Atlantic was formed. But others of you have been here for a lesser period of time.

But I wanted to point out that, in general, OMB's role in science, if you will, or the agencies that practice science is very broad and goes back about as far as OMB. The budget side in the budget process reviews agencies that are predominantly scientific agencies, or those programs that use science. We now have a management side that evaluates programs through an exercise we call the PART—Program Assessment Rating Tool. It has spawned, in an-

other case of Washington verbing the noun, a verb called PARTed; a program can now be PARTed. And our procurement and financial sides have of course looked at those aspects of agencies that use science and thus have some influence ultimately over those programs.

OIRA also—as Curtis noted, formed in 1981—has a long history engaging in all sorts of information collection and review, including regulatory, under the Paperwork Reduction Act, which specifically mentions information quality and the desirableness of this trait. Executive Order 12866 also indicates that one of the principles that agencies need to use when regulating is to use the best scientific, technical data available, the highest quality data. Our guidelines on performing cost-benefit analysis, now section A4, which is the, excuse me, most current version of those guidelines, also mentions the need to use the best possible scientific as well as other types of data and information when doing rulemaking, which is the very difficult task of trying to predict how humans and institutions will act in the future and how to direct that activity in a way that solves the problem that you're looking at and doesn't create a set of new problems—a very difficult job that the agencies have.

And then finally, of course there are these activities that Curtis mentioned, starting with the Information Quality Act, which was passed, I believe, in 2001. It has been alleged that this Act came in the dead of night—a one-line statute in the dead of night. This is a scurrilous lie. It's actually 38 lines long, although——

[Laughter.]

Mr. ARBUCKLE. —in that sort of bill text that the Congress uses, it's true that some of the lines are only one word long. Nevertheless, it is the law, and we met its mandates, publishing first guidelines to help ensure and develop the quality of information. The four standards in the act—quality, integrity, utility, and objectivity—were not defined so we started off by deciding that quality was the sum of the other three to sort of reduce our job by 25 percent anyway. So we defined and we explain in some detail in the guidelines themselves integrity and utility, which are reasonable straightforward and intuitive definitions, and objectivity, which is much more difficult and which takes up a good deal of the definitions section actually in the guidelines.

We do make this distinction that Curtis mentioned in information quality with influential scientific, financial, and statistical information, where we believe that the rigor of the application of the standards should be—should be higher, should be more. And in particular, the concepts that are focused on there are reproducibility and transparency. Literal reproducibility is not feasible, but it is, as a general matter, part of the scientific method. And transparency to make clear your assumptions and procedures and practices has definitely long been a part of the tradition that we call the scientific tradition, but it's part of a much larger breadth of thinking over the last 500 years or so.

One of the issues that we raise in that bulletin is peer review. That is, documents that have been peer reviewed are more or less assumed to have passed a test for objectivity. We issued a set of guidelines on peer review several years later after the Information Quality Guidelines, and these make a separation between influen-

tial scientific information, which—picking up on the Information Quality Guidelines—and highly influential, is—in sort of rough terms, information or documents that could be used that might have an impact of more than $500 million annually. That is a rough threshold that we chose in order to try to distinguish where it made sense to have peer reviews which can be, aren't necessarily, but can be very energy, financially, and time intensive—where it made sense to do that, given that the possible impact of the action might be that substantial.

And then finally, we have published out there, as Curtis mentioned, for public comment, Guidelines on Risk Assessment. These were published in January. The comment period is still in effect, still going on. We also have referred these draft guidelines to the National Academy of Sciences. The panel has been chosen, and they are planning a public meeting. The first panel meeting and public meeting is at the end of this month, the 22nd and 23rd. I imagine some of you will be interested in attending that. The panel has been asked to look at the Risk Assessment Guidelines and to try to make sure that we are following the practices that the NAS itself has recommended in several studies over the course of the years to try to articulate both the benefits of this method of increasing the information attached to certain risks and hazards. They are trying to have a guidance bulletin that is broad enough or, let's say, specific enough to present best practices for the government but flexible enough to—for agencies that deal in very different types of endeavors to be able to use.

So that's a summary of these various activities. We are very much doing this in a manner that encourages public comment. If necessary, as we did with the Peer Review Guidelines, if it turns out that we're far off the mark, we can publish the guidelines again for a second round of comment. That proved to be extremely beneficial in the peer review context, and I think we wound up with a document after that was generally regarded as being—as capturing the essence of that, even if you don't like OMB being the capturer of the essence. And we're certainly interested in doing the same thing with risk assessment. This can be very highly technical. It's involved in issue areas that are highly controversial and politically sensitive—human health, safety, and the environment. So it's extremely important that the government be getting this right as often as it can and be paying attention to the general best practices that have evolved over the past 20 years or so.

So I think I'll stop there and let my other panelists join in.

Mr. COPELAND. Thank you, Don.

Before I go on, I should say that we had a conference call on Friday afternoon sort of as the minimal planning that we did for this panel. And each of the panel members agreed to limit their remarks to about 10 minutes to allow for about 40 minutes of questions at the end because they all felt that the best part of this would be the questions and answers. So I encourage you to be thinking of the questions and answers as we go along.

The next panel member is Al Teich from the American Associqation for the Advancement of Science (AAAS). He is the director of Science and Policy Programs at the AAAS. In this position, he is responsible for AAAS's activities in science and tech-

nology policy, directing a staff of 40 and serving as a key AAAS contact on science policy issues. He is a fellow of AAAS and a recipient of the 2004 Award for Science Achievement and Science Policy from the Washington Academy of Sciences. He is a member of the editorial advisory board to several journals, the author of numerous articles and book chapters, including a chapter on technology and government in the Encyclopedia of Science, Technology, and Society, and the editor of several books, including "Technology and the Future," the most widely used college text in technology and society.

Al?

[Cross talk.]

AL TEICH. Good morning. So I'm representing the science community, I guess—the token scientist up here among this group of lawyers—and I'm going to talk about the Peer Review Guidelines and our experience with them and a few comments along the way. As Don said, OMB issued its Peer Review Guidelines or a proposed bulletin in September of 2003. This was—under the Data Quality Act—part of an ongoing effort to improve, as you can see, the quality, objectivity, utility, and integrity—all those good things—of the information disseminated by the federal government.

Peer review is a very widely used practice in science, but when OMB issued these guidelines, the immediate reaction was controversy and a certain amount of consternation in the scientific community. Why did this stir such controversy? As I said, peer review is very widely used in science. It's used for choosing projects by project sponsors, funding agencies. It's used for decisions in academia on promotion and tenure and other rewards that academic institutions give to their faculties. It's used for decision making in publication. People send out articles for peer review, of course. Journals send them out. AAAS's own journal, Science, has a rigorous peer review system. So what's wrong with the idea of peer review in the context of OMB, in a context of regulations?

Peer review can do a variety of things, and there are certain things that it can't do. In science, peer review can determine the significance of a piece of work or of a proposed project, or at least it can give you the considered judgment of a group of scientists who presumably are qualified to make that judgment. It can assess the soundness of methods. And when something passes peer review then is published, it's thought that this gives it a certain amount of credibility in kind of an imprimatur of science on a set of results.

But it doesn't mean that they're necessarily correct. It only means that they have been reviewed and that they are worth considering. It's not infallible—articles contain errors, and articles can even be based on misconduct and ethical breaches. So it's not infallible, and we had a very public example of that not long ago when Hwang Woo-suk from Korea was found to have fabricated results in the area of stem-cell research that were thought to be revolutionary. They had been published in a number of places, including our own journal, Science. Turned out that he never did the experiments. So peer review will not necessarily pick up those kinds of things, and it won't pick up science that contains errors necessarily either, although sometimes it does.

So, if peer review is such a widely used method within science, what were the reasons for the negative reactions to OMB's proposal? Well first of all, there was suspicion of OMB's motives. There were certain questions as to, what is the problem here? Here's the solution. What's the problem that we're trying to solve? Is there a problem with peer review of regulations that need to be addressed? And then there were the specific provisions of those guidelines, which placed strict constraints on the choice of reviewers—and I'm talking about the first proposal—the initial draft. There were questions about the potential anonymity or lack thereof of reviewers. There was the possibility for open public comment, which didn't have the constraints that the peer reviewers had. And there was the issue of possible litigation based on this, and that was one of the reasons for suspicion that people thought, aha, this is a way of undermining the regulatory process by tying things up in knots.

So scientists were suspicious of this in large part, I think, because the Data Quality Act, as Don said, was slipped into an appropriations bill in 2000. It was a very small provision. Nobody noticed it. It went completely unnoticed by the scientific community until it was written into law. There's no legislative history. There were no hearings, no floor debates, no committee reports. And yet, the Chamber of Commerce, called it the most significant change to federal rulemaking process since the Administrative Procedure Act. It was introduced in the House by Jo Ann Emerson; in the Senate by Richard Shelby.

If it is so significant, why is there no legislative history? One has to ask, you know, if this is such an important thing, is this the way we're supposed to be making laws in this country by putting provisions into unrelated acts without any kind of legislative consideration, especially things that are presumably as significant as they were said to be? Well, Jim Tozzi—his name was mentioned by Don. We have to thank Jim, I think, for this. Jim, are you here? I haven't seen him. Okay—hey, add to your fame here. Anyway, many scientists looked at this and said, well, this looks like a means of attacking regulation by attacking the science behind it. So as I said, they asked, what is the problem it was seeking to solve? And somehow they—you could draw the implication that the most important science in terms of regulations was not being adequately reviewed and had question whether that in fact was true.

So looking at the comments that came from the scientific community, they focused on a number of things. First of all, they focused on the constraints on the selection of peer reviewers. They gave little discretion to the agencies. Peer reviewers were excluded if they had expressed an opinion on a subject. Academics were excluded if they were funded by an agency, but employees of regulated industries weren't. There was a provision that called for, kind of, equal and opposite biases—if a peer reviewer had an unavoidable bias to find another one who had a counteracting bias without any discussion of the relative qualifications of the two reviewers. And finally, there was a question of attributions, which violated the generally, although not entirely widespread, procedure of giving anonymity to peer reviewers in science. And there was this question that I men-

tioned of delay, the prospect of litigation dragging out proceedings, and other factors that I've already mentioned.

I have to say that, as Don mentioned—and his predecessor, John Graham, actually was very open about this process at OMB—they read the comments that were received. And there were quite a few of them—almost 200, I think—and they listened to the science community. We met a couple of times with—together with the groups of other scientific society representatives, and they significantly improved these guidelines the second time around. The second draft was a much-improved version. It turned out to be relatively uncontroversial. It may have been a strategy in the first place. We don't know. But in any case, it certainly worked out, I think, to the advantage of both OMB and the science community.

The House Government Reform Subcommittee on Regulatory Affairs—as I said—held no hearings on the Data Quality Act prior to its passage. Five years after its passage, they held the first hearings to give an assessment—to ask agency representatives and public interests groups to give assessments of how they thought it was working. And of course, the predictable responses were given. The government agency said it was too early to give an accurate assessment. The public interest group said, well, they can't really talk because they're afraid they're going to lose their jobs. And the industry said, well, the agencies aren't really enforcing things strictly enough. So no surprises there.

The major development that occurred took place just a month-and-a-half ago in late March. The Salt Institute and the Chamber of Commerce had sued the Department of Health and Human Services (HHS)—the National Heart, Lung, and Blood Institute—for refusing their petition to change data that they had released showing that sodium lowers blood pressure. They said that this data was faulty. HHS said, no, it's not, and refused to do so. They took them to court, and the Fourth Circuit Court on March 21 agreed—saying that they don't have jurisdiction, that there is no provision in the act for judicial review and therefore that suit did not have merit.

Now, I suspect that there are people who are working on a legislative fix for that. It may be a little more difficult to do this time now that people are aware that this thing is going on. But we'll have to stay tuned and see what happens. Maybe we can get into this in the discussion period. There is also another piece of legislation. There is a bill introduced by Representatives Henry Waxman and Bart Gordon, two Democrats who want to abolish the Peer Review Bulletin entirely. They have the Restore Scientific Integrity to Federal Research and Policymaking Act. It was introduced over a year ago, and it eliminates this Peer Review Bulletin. That's my assessment of its chances of passage. That's a snowball by the way in the—those of you who don't recognize what it is.

[Laughter.]

Mr. TEICH. Anyway, I think I'll quit while I'm ahead. This is the place where you can find information on our activities in this area. That's my e-mail address in case you want to follow up anything, and that's our new AAAS bumper sticker with baby Einstein. Thank you for your attention.

[Applause.]

Mr. COPELAND. Thank you, Al.

Our next speaker is Bill Kovacs. Bill is the vice president for Environment, Technology, and Regulatory Affairs at the U.S. Chamber of Commerce. The Chamber of Commerce is the world's largest business federation, representing more than 3 million businesses—every size, sector, and region. Since assuming the position of vice president in March of 1998, Mr. Kovacs has, among other things, recruited and assembled the first science team to work in tandem with the policy staff to ensure that federal regulations are based on sound science. Mr. Kovacs is a frequent commentator on national, environmental, energy, and regulatory issues that impact the business community. He is regularly quoted in the nation's leading newspapers and appears on talk shows and television as a spokesperson for American business. He is listed in—and I wish I had this resume—Who's Who in the World, Who's Who in America, Who's Who in American Law, and Who's Who in Emerging Leaders. Bill?

BILL KOVACS. Well, thank you, Curtis. And it really is a pleasure to have this group assembled. And thanks to the Congressional Research Service because this really is an important talk and an important way of discussing an issue that really is a lot different. Let me just sort of respond, before I get into my remarks, to Al because everyone talks about, well, this thing was—Data Quality Act was slipped in in the middle of the night. Well, if you go back, there were five years of committee reports talking about having OMB be responsible for good quality data. And they used the same words—objectivity, utility. And the Congress asked and asked and asked, and finally they just put it into a statute. Now, we're going to have a question as to what the statute is worth, but we'll get to that later.

As you can tell from Al's comments, you know, the Chamber has been a very strong proponent of data quality and frankly all of OMB's guidance efforts. We really commend them because it was the first time, I think, in the history of the United States where we really tried to discuss science and how science is going to be part of the rulemaking process. And OMB systematically using the Data Quality Act went through and talked and required the agencies to do their own guidelines—start it on peer review, start it on good guidance, address cost-benefit. They did prompt letters if they thought the agencies' regulations were insufficient, and now they're on risk assessment. That is one amazing set of undertakings, and we really compliment them. Now, I'm going to get to the Salt litigation because at the end that puts everything that OMB does in question, but we'll get to that.

The Chamber's position is really clear, and you need to know where I'm coming from because as we talk about suspicion, you know, we're not dealing with Galileo here. We're dealing with a modern rulemaking process. And our position is really clear. We believe that the best regulation is transparent regulation, that all the studies and the models need to be put out in the public. We have even petitioned OIRA to do an open peer review process, at least to try it, to take one of the regulations and find out how it works because you don't have the four or five little anonymous people sitting in a hideaway making—trying to generate policy and manipulate numbers. You have put it out to the public to see what

all the scientists around the world might think of the issue. What's wrong with opening it up?

And the reason why the business community supports open and transparent regulation is because the community, of all of the people here, is the only one actually impacted. They pay $1.1 trillion a year to deal with regulations. And so the other thing is the business community is the only one here that is impacted. If they do something wrong, they can be sued by the agency. They can be brought before a court. They can have trial lawyers bring class actions against them. They are subject to huge civil and criminal penalties. This is a lot different than the European system where you have a group of really onerous regulations with literally no enforcement. So we've got to keep in mind that we've got a system that's very flexible and really based very strongly on enforcement.

The big thing is going over—and I think Al was right when he said the scientific community was very suspicious. They didn't know where anyone was going because no one wanted to affect all of the federal contracts that they might have. And yet there's a bill before the House which is to just identify who gets the money in a federal contract and the opposition to that. No one even wants to allow the American public to know who even gets the money. And yet the critics were saying, well, if you have—if the Data Quality Act passes, you're going to be deluged with petitions. The business community like the U.S. Chamber—we're going to use it to shut the system down. Well in 2003, there were 97 petitions. In 2004, there were 57 petitions. There were 28 appeals. And that is so much different than Freedom of Information Act (FOIA) where there are tens of thousands of FOIA requests. And the reason why there were so few is the Data Quality Act requires an enormous burden. We have to first go do our own science. Then we have to present it to the agency in a petition for correction. That is not a simple task.

But the U.S. Chamber did two petitions, and I just want to lay them out really quickly because I still think I have a few minutes. The first was the data inconsistency. And there what we had addressed to the Environmental Protection Agency (EPA) is we said, you have 16 databases—key databases—and within the databases you have chemicals which have been assigned—the same chemical has been assigned different values, some differing by as much as a billion. We think you have a problem. Well, this was two years ago. The only thing we asked the agency to do was to form an inter-agency working group to get it right. And it was very interesting; U.S. Geological Survey agreed with this. The Federal Swiss Environmental Research Institute agreed with this and said, look, these databases are used throughout the world. We've got to get it straight. There were even some environmental groups. The EPA two years later still refuses to deal with the issue.

The Salt litigation—this is frankly an issue where I just got frustrated by everyone walking around—you know, the environmentalists and the scientific community saying, well, the Data Quality Act, there's really no judicial enforceability. And our side wanted to live on the belief that we had judicial enforceability, and somehow, if we ever really wanted to make it work, we really could. Well, that's bull. You know, we sat there, and we said, we're going

to pick a case. And we picked the Salt case, and the reason we picked it is because it involved influential data that everyone understood. And we wanted to do reproducibility. The information was never put into the public domain.

And what we did is we said, we want the data for reproducibility purposes. All we wanted—let's be clear. We asked the agency for the data so we could reproduce the results. The agency denied it. We appealed. The agency denied. We then, after final agency action, went into the courts, and we lost. The courts said we have no standing. The court was very clear that no human being, no chamber of commerce, no business, no anyone has standing, that this is strictly an OMB situation.

So what are we left with? Well, what we're really left with is the Data Quality Act, for all intents and purposes, is a really nice academic exercise. But other than that, unless OMB wants to enforce it, there really is—there are no teeth to it. So in terms of forcing good quality data into the federal regulatory process, that does not exist. It does not exist. So what do we do? One is we could go back to the Congress—and certainly we are—to get judicial review provisions put into the law. We could get a more far-reaching executive order to require OMB and give them a little more of a policing authority over the regulations, but that can be abolished with the next administration.

And so I guess what we're really down to is we've got to decide as a nation whether or not science should be part of the rulemaking process and the best science, and that we use the best scientists and we're inclusive not exclusive. Or we just have to say, look, the whole process was a farce, and we really don't need whatever OIRA is doing other than data collection. And we need to move on, but we need to make a decision. It's a huge public policy decision. Thank you very much.

[Applause.]

Mr. COPELAND. Thank you very much, Bill. The last presenter—and certainly not the least—Rena Steinzor—Rena is the Jacob A. France research professor at the University of Maryland School of Law and has a secondary appointment at the university's medical school. She is a founder and member of the board of directors at the Center for Progressive Reform. Professor Steinzor teaches environmental law and two seminars on law and science, the first on risk assessment and the second on issues such as peer review, human testing, the precautionary principle, the relationship between science and economics, and the politicization of science. She is the editor with Professor Wendy Wagner of a book of essays entitled "Rescuing Science from Politics—Regulation and the Distortion of Scientific Research" to be published by Cambridge University Press at the end of June.

Rena?

RENA STEINZOR. And you can order the book on Amazon.

[Laughter.]

Ms. STEINZOR. I want to thank Curtis and Mort and American University. This is truly a rare opportunity for all the clashing sides to get together and have a good debate on this issue. I find these days that we do that less and less to the detriment of everyone, and I was struck when Bill was talking about how different

our worldviews have become. From his perspective, business is the only entity truly impacted by regulation as opposed to, from my perspective, all the kids who have asthma in the inner city and similar groups like that. And he also is very concerned about excessive enforcement when, from my perspective, there is barely a sign of life at most of the regulatory agencies. So it's always useful for us to compare notes and get a little reality check from both ends of things.

Now my kids are in high school and we always have rubrics that we work on as I play the homework police and they march around the house trying to evade my enforcement. And I thought I would adopt one today that was relatively simple and familiar: who, what, so what, when, where, and why.

First, the question of who. OMB is portrayed by Don and Bill as an agency with an important role in overseeing science. And yet there are virtually no scientists—very few scientists on OMB's staff. The staff is overwhelmingly dominated by budget analysts and economists. There probably are—and maybe Don can clarify this for us—more lawyers on the staff of OMB than scientists. So we do not need to resuscitate all the shopworn arguments about what the appropriate scope of OMB's oversight over federal rulemaking—we don't need to resuscitate all that debate to cringe at the prospect that economists and budget analysts would be pulling their chairs up to the table every time scientists and science policymakers throughout the government tried to perform risk assessment, which is not a pure science function to be sure, but is primarily involved with scientific evaluation.

The what of this escapade—which is, I would suggest, one of the potentially most prominent legacies of John Graham's tenure. By far, he was the most ambitious director of OIRA in its history, and this proposal could really dwarf every other thing that OMB has done in this area. What it is is a governmental effort, from my point of view, that would straightjacket health and safety risk assessment. Built on a single chemical specific model, it would apply to an industry-wide assessment of the threat posed by terrorist attacks on chemical plants or an assessment of what increased reliance on nuclear power would mean for public health and safety.

So whatever its elements, this would be the first time that in 26 pages we set forth rules for this wide variety of assessments. And it's worth noting that the National Academy of Sciences, which has put out three, maybe four depending on how you count them, reports on risk assessment, starting with the Red Book in 1983, has gone out of its way to emphasize that it is not possible to impose a one size fits all straightjacket on risk assessment, that there are some principles and some ideas that should be incorporated, but that setting a basic rule for risk assessments is really not scientifically sound.

Ironically though—and this is worth pointing out—the Risk Assessment Bulletin does not apply to registrations of pesticides, individual nuclear plant facility licensing proceedings, or testing done for the purpose of approving new drugs. It's worth noting that all of those risk assessments are done primarily by industry-regulated industry, and the double standard is certainly curious. Maybe Don can enlighten us on why that choice was made.

Now, we've talked a lot about the Information Quality Act. I do want to remind us of its history. We are lucky to have Jim here because he was there first. The Information Quality Act was born out of the tobacco industry's frustration with the passive smoking study that EPA had done. And the tobacco industry is a model for what Professor Tom McGarity calls the corpuscularization of science; that is, looking at each piece of scientific evidence very critically, deconstructing every study, questioning each individual piece as opposed to viewing all the scientific evidence together and making a scientific judgment on what the weight of the evidence tells us.

The Information Quality Act is the way that people seek to isolate pieces of scientific evidence. And although it has fallen on hard times, to be sure as Bill mentioned, we have little doubt that we'll be revisiting this issue on Capitol Hill, probably not in the middle of the night as an appropriations rider, no matter how good the reporting was by various isolated committees, instead in the context of a full-fledged debate, which will, among other things, have to consider what will happen to the 800-odd federal judges who are already overwhelmed by their criminal docket if the gates are opened and any industry aggrieved by any single piece of government information can go to the courts and challenge it under the peer review guidance or under the risk assessment guidance should it become final.

So it's certainly true, to sum up the what and the "so what," that the Data Quality Act or the Information Quality Act, the corpuscularization of science will occur with or without it. But should judicial review be granted and even if it is not, the hooks that are provided in the proposed Risk Assessment Bulletin for corpuscularizing and challenging science will enrich these debates and make them proliferate greatly. And I take little comfort—again, this is a reality check—with the argument that so far we haven't had too many of these things. It's true that there haven't been that many. Some of them have been very, very significant, for example, the challenge that some people here were involved with to the SIPs for the northeastern states—the State Implementation Plans—because they included state rules on controlling paint. That one never officially turned into any challenge to the states, but behind the scenes there is good evidence that the states were subject to another round of browbeating about how they should really have a conversation with the paint industry and try and straighten out their differences. And the ozone attainment in the northeast is not a small matter. And that was just one Information Quality Act request.

The two key problems with the risk assessments guidelines, again, the one size fits all. The best explanation of that is that the guidance says that whenever possible, central risk shall be estimated. If you have a single chemical—take perchlorate, mercury, atrazene, arsenic—and you have the National Academy of Science's panel—multidisciplinary panel, which will now include presumably observers from OMB at least watching it, much less supervising how agencies use those reports—what you would see is an effort to take all the models—all the pieces of information—and somehow

come up with a weighted average, some kind of mathematical calculation that will express central risk.

And as difficult as it is for anyone who has been involved in one of these things to get their minds around how we would do this for a single chemical, shift the focus to the other extreme where we're trying to do an industry-wide assessment of the nuclear industry or an industry-wide assessment of chemical plants. And imagine how all the inputs, all the models, all the individual studies, the outcomes, which may or may not be in numerical terms, will be combined into a central risk estimate—not a range, although the bulletin does require the presentation of ranges. But it is absolutely emphatic on the development of a central estimate, and it just makes very little sense from a scientific perspective, I would submit. And I would be very interested to see what the scientist on the panel—what Al thinks of that.

Finally, the second problem with the bulletin is its conflation of assessment and management. In order to comply with the bulletin, agencies must flash forward to the end of the rulemaking and develop an assessment of all the risk reduction measures that might be available and what the cost—what the implications are of those risk reduction measures. And they must then compare it to a baseline risk. Now, I'm not going to sit up here in front of you and be naíve and silly enough to suggest to you that, again, risk assessment is a matter of pure science. Obviously science policy judgments come heavily into play.

But what that requirement would essentially mean, as the academy was told by Colonel Dan Rogers, the point person on perchlorate for the Department of Defense, that before the academy could finish its perchlorate risk assessment, it would have to consider the impact on training and the national security. Rogers told them that there is no room for reliance on science policy precaution. For its own sake, every layer of science policy precaution inhibits our ability to train, putting our combat forces and ultimately our nation at risk. This is a very heavy burden for a group of scientists who are not trying to make the ultimate decision about what to do about a risk but are merely trying to come up with some kind of qualitative assessment of it so that that assessment can be handed to the decision makers who make the final calls.

Now, I still have when, where, and how, so let's make short shrift of those. Not much has been happening in the rulemaking or standard setting word. All of this is about what will happen in the future, and we all have different ideas about how close that future might be. Watching the Hill would be a very important point. There was a letter yesterday that was sent by Congressmen Dingle, Waxman, Oberstar, and Gordon to the academy, asking them how they plan to carry out their charge on the bulletin and expressing concerns about it. Also we can expect to see a bill up on the Hill, as he has told us, trying to make sure that the Information Quality Act is judicially reviewable.

There is tremendous pressure in this election year both not to do anything and to institutionalize all of these tools for making sure that the future does not get out of control if and when power shifts in Washington. "How" would clearly depend on what the Academy says about the bulletin, what the Congress says—and there will be

probably many committees involved, especially the judiciary committees—and ultimately what OMB does in its effort to modify it in response to public comments and the energy it is willing to put into enforcing it.

So, how did I do on time?

Mr. COPELAND. Perfect.

Ms. STEINZOR. Okay.

UNKNOWN SPEAKER. I thought you were doing a filibuster.

Ms. STEINZOR. You did? Where is my phonebook?

[Applause.]

Mr. COPELAND. Thank you all very much for your presentations. We certainly have a range of opinions here and certainly plenty of grist for questions and answers. Laura has agreed to be the walk around person with the mike for this session—I'm going to do it later—so I would ask three things. One is wait for the mike if you have a question so that the transcription service can capture your question on the tapes. Secondly, identify yourself and, if you want to, your affiliation. And then finally, state to whom you would like to address the questions, whether it's to all the panel members or a particular one. There should be plenty of things here. If the discussion lags, I have my own questions, but I will hold those off. If any of the panel members have a question, they can let me know that they would like to pose to another—their fellow panel members. I'll throw it out to this point. Yes, right here.

Question: My name is David Frost. I work for the general counsel's office at the Department of Homeland Security. My question is, well, for anyone, I suppose. It's on the copuscularization of science. And I should say my science background is almost nil. I was really so traumatized by grade school math that I became a lawyer in a fit of despair. But I'm just wondering—this idea that you could challenge a piece of a scientific study or an aspect of the research—you suggest that, Ms. Steinzor, as if that were a bad thing. And yet it seems to me that if a piece of the research on which someone has proposed a policy is shown to be defective, then presumably everything that's built on it would also be. So is it really such a bad thing?

[Cross talk.]

Ms. STEINZOR. Well, in another shameless pitch for our book, let me just say that Professor McGarity, who has also written an article about it—and I can give you the citation for it—explains why corpuscularization is so damaging. But let me try quickly to compare it to the way scientists usually make decisions, which is on the basis on the weight of the evidence. Like every human endeavor, there is no individual piece of science that is free from flaws. Even a simple rat bioassay in a lab—there can be decisions made about the doses given to the rats, how often they are fed, whether they have genetic weaknesses. And that's a simple example.

There is also—a more complex example would be an epidemiological study where the population is selected in a certain way, where we have questions about what the level of exposure was, where we question whether we followed the illness for long enough. And all of those individual flaws—generally what scientists do is study the evidence very carefully, take it as a body—that's what meant by the weight of the evidence—and make a judgment about how to off-

set one study against another and how to take into consideration the flaws of the studies.

To take each study individually and say, it has a flaw and we are going to make a court case out of it—almost literally—and knock it off the table, ends up in the end meaning that you have nothing left to make a decision on, even in the best of all possible worlds, even with the best of all possible science. Tom, is that fair? He's speaking today so he's -

Mr. KOVACS. Let me see if I could also respond. I think your question really hit the nail on the head. But before I address that, first I want to say, you know, Rena, when you work for the U.S. Chamber and you promote the free enterprise system, there's not such thing as a shameless pitch. So go for it.

[Laughter.]

Ms. STEINZOR. You're going for it now?

Mr. KOVACS. Oh, we'll always buy your book and read it. Are you kidding me? Absolutely, you got one copy sold.

Ms. STEINZOR. Oh, good. You can get more than one copy maybe.

[Laughter.]

Mr. KOVACS. And we might, but we believe in reading all opinions, not just one set of them.

Ms. STEINZOR. I'm an avid fan of your reports.

Mr. KOVACS. Oh good, thank you. We agree on something.

[Laughter.]

Mr. KOVACS. You know, we actually thought about your question as we were filing our petitions, and it was really something that goes to the heart and soul of the act. And I think we came to several conclusions. One is there may be pieces of evidence or of information, or there may be assumptions that are so influential, and that's the whole purpose of qualifying some information as influential—that it really needs to be challenged.

But when you go to put one of these data quality petitions together, whether it be the 16 databases or the salt, it takes an enormous amount—I mean, we spent seven months between my in-house scientist plus the outside scientist at Cambridge Environmental to put this together and to look at the database. We literally had to go and find every single chemical that EPA regulated and then do a printout so that we could see on the 16 databases where the differences were. And the fact that all of that information had to be done first before we could even get there—but some of the things that came up—and then in the Salt litigation, there was an example where the data was really troubling. And all we wanted to do was get the data so that we could—so that we could run an analysis to see if we can come close to, you know, getting the same results.

But what was so interesting is, when EPA finally, you know, denied our claim and then we appealed, some of the things that EPA said—and I think you really need to understand how valuable EPA sees these databases. They have a disclaimer on databases, which makes you see the disclaimers actually look funny. The software and the accompanying files are provided as is and without warranties, whether expressed or implied. The user assumes the entire risk of using this program. Yet these programs are pushed on to the public through many regulatory programs. On another in-

stance, they said, well, we no longer own the database anymore. We've given them back to Syracuse Research so, you know, they're really responsible. And in some instances where they said there was complete and total peer review, we actually went back and found that there was no peer review. And in some instances we asked, well, let's take specific data—just as you were talking about—and actually go back to the original studies and see if the data that was collected in the original studies is the same entered into the database. And in many instances, that data was wrong.

So when you sit here and you see all of that, we're not really sure what the process is at the Chamber. We only have the resources to take on the big issues, where it's influential—salt or the databases. But there are instances where the data may be so important or the assumption may be so important that it really—you have to take it apart in order to understand the situation.

Mr. COPELAND. Lisa?

Question: Yeah, I have a question for Don. I just wanted to pick up on Rena's point about the risk assessment guidelines not being applicable to pesticides registration, nuclear licensing, and Food and Drug Administration (FDA) approvals. And a person who is cynical might look at those categories and think, those are actually categories in which industry would want a prompt risk assessment, not to be weighed down with risk assessment guidelines, because those are cases where the statutory scheme makes a risk assessment necessary before business can get under way. And so I'm just curious—I know there must be more to it than that. So I'm just curious why those things were exempted from the risk assessment guidelines.

Mr. ARBUCKLE. The intention behind that provision had nothing to do with the concern that Rena expressed. In the executive order—Executive Order 12866, I believe, in I.Q. and in the risk assessment, OMB generally tries to stay away from particular adjudications, from licensing, from cases where there is not, as our favorite Administrative Procedure Act (APA) expresses it, cases of general applicability and future effect. It's general applicability, the regulating as a general—provisions that affect more than one individual, one person, one company, one chemical, where the specifics of that individual case are what would guide the decision, not a broader policymaking provision. So that's why that provision is common to a number of other documents.

Question: [Off mike.]

Mr. ARBUCKLE. There's many other aspects of the government that also you could say that about, just about everything we do. It's still an individual adjudication, an individual decision, and we try to stay away from those.

Ms. STEINZOR. But, Don, that would mean, just to clarify, Vioxx and DDT, right?

Mr. ARBUCKLE. If it's an individual licensing or decision-making.

Mr. COPELAND. Okay, thanks.

Identify yourself.

Question: Yes, I'm Don Elliot from Willkie, Farr & Gallagher, and I also teach at Yale and Georgetown. While we're in the shameless self-promotion department, I was glad that my friend Rita Steinzor identified by case for the—under the Data Quality

Act for the paint manufacturers as the most successful or, in her view, nefarious use of the Data Quality Act so far on behalf of industry. Let me tell you just a little bit about the underlying facts and then ask you why you would regard that as a negative episode, rather than a positive one.

Assume with me hypothetically—which I believe to be the case and was the basis for the Data Quality Act petition—that the regulation of ozone in the northeastern states was base on a single scientific study and that it could be demonstrated that some of the data in the scientific study had been misread. In other words, in some instances where there were certain levels, they actually reduced—they actually resulted in lower ozone levels so that the study had been completely misinterpreted in the regulations.

The issue was raised in notice and comment rulemaking and was given short shrift. It was raised in multiple court cases, and it was given short shrift—just dismissed. It was raised under the Data Quality Act, and, at least by your hypothesis, that resulted in bringing the states and the industry to the table to work out a negotiated solution. From my standpoint, that's a great success story. That illustrates, I think, how the Data Quality Act fulfills a need that is not being adequately addressed by the notice and comment process, not being adequately addressed by judicial review. So it seems to me that rather than being some nefarious episode in which the states are sort of overridden, it results in getting industry and the regulators together to discuss correcting a scientific error.

Ms. STEINZOR. Again, it's different views of reality. The piece of information that was at issue was not a scientific study on health effects, as your petition indicated. It was a calculation done on how much certain reductions in the composition of paint would reduce the OCs. If you decreased certain solvents, would you decrease the OC off gassing?

I've spent many hours looking into the genesis of this, and I'm told by state regulators that their problem was that they could not get adequate information from the paint industry to make calculations that the industry would be satisfied with and that this piece of data on how much reductions you would accomplish was something that they used in their rulemakings. There were numerous opportunities—this is New York, Pennsylvania, Delaware, Maryland, New Jersey—numerous opportunities for the paint industry to introduce different data about reductions. Never happened. The single piece of information was in the state rulemaking docket. The states issued their rules. The rules were challenged in court. Some of the challenges were—they were very thorough. One of them was that, because there was an exemption for small manufacturers, the state rules violated the large manufacturers' right to equal protection, as just one example. That was in New York.

All of the rules were upheld, and then the paint manufacturers petitioned EPA to reject the SIPs because there was a piece of data in the underlying state rulemaking dockets that they didn't like. And that is taking the Data Quality Act to great extremes since it says nothing about state rulemakings. And the idea that EPA has the resources to go read state rulemaking dockets is pretty fanciful.

In any case, as I understand it, the states rejected Jeff Homestead through the regional office's request that they sit down with the paint manufacturers again. They've all gone through with their rules. I was talking to the guy in Maryland, I think, about a month ago, and it's my understanding that New York has done the same. So I'm sure you have another side of the story yet again, but that was an example of a long, intractable dispute that almost had yet another chapter but didn't because the states were frustrated.

Mr. COPELAND. Thanks.

Question: Yes. My question is for Bill Kovacs.

Mr. COPELAND. Identify yourself.

Mr. PASCUAL PASKY. I work with U.S. EPA, and I work with a lot of models. And I suspect that you and I probably agree quite a bit about the need for transparency, and where I think you and I might differ would be with the implication that perhaps transparency leads to the single verifiable truth. As I'm sure you know, one of the first instances where the Data Quality Act was used was against EPA to take down one of its climate change models because of the work that Patrick Michaels at the University of Virginia had done contradicting some of the results of the model.

Now, would not greater transparency be accomplished if the model were allowed to stay and allow Patrick Michaels or whoever else present an alternative hypothesis—an alternative model, put that up on the web, and then let the discussion proceed—competing models as opposed to thinking that there is a single hypothesis that transparency leads to, to the exclusion of all other alternatives? Would that not be a better example of transparency.

Mr. KOVACS. Well, first of all, I'm really thrilled that you asked that question because that really is a really significant point. First of all, you should know that we were the ones who urged literally from the beginning CEI to abandon the lawsuit. We thought it was one that you shouldn't—that there was four or five, $6 billion worth of data that was collected in climate change, and we didn't really see how a Data Quality Act—that really would be parsing the pieces, and we thought that it should stay, not only that it should stay, that it should be subject to open review. So we probably agree with you on that. It should have stayed up. You should have opened it up to peer review, and we should have brought in everyone. And eventually, I think, two gentlemen from—from Australia or Canada—McIntyre (phonetic)—McIntyre, and there was one other one, who actually did go and look at Mann's (phonetic) work and did do an open review on the web. And it was really pretty fascinating.

But we would agree with you. Yeah, it should have stayed. We had that position all along, and we publicly urged CEI to abandon the suit.

Mr. ARBUCKLE. Curtis, can I make a comment?

Mr. COPELAND. Sure.

Mr. ARBUCKLE. The Information Quality Act has been soundly trounced here by Bill for one set of reasons and by Rena for another. Let me just give you the point of view basically for the career part of OIRA. We think that it's working quite well. That is, it doesn't give people an easy avenue to criticize government work, but it does give them an avenue with an appeal process. It was—

the Act was or our guidance on the Act—set it up very much—very much on purpose with a burden of proof on the petitioner so that the argument that could be had was based on information—that is, information and data—not on arguments about policy decisions.

We did not want it to become another avenue for having policy debates that may have already been decided. So there is a hefty data burden of proof on the petitioner. And then to pick up, the Act established guidance, not rules, and asked OMB to issue guidance and the agency to issue guidance, so it is more of an internal government quality control exercise than a regulation or a law that is challengeable through the judicial branch. We think that's the way it was set up on purpose.

Mr. COPELAND. So OMB would not support judicial review for the Information Quality Act?

Mr. ARBUCKLE. Nice try, Curtis.

[Laughter.]

Mr. COPELAND. I thought it was worth a shot. In the back. Oh, I'm sorry.

[Cross talk.]

Question: Kevin Bromberg, U.S. Small Business Administration, Office of Advocacy. This is a question for—for Al.

[Cross talk.]

Question: Is this better?

UNKNOWN SPEAKER. That's better.

Question: Kevin Bromberg, Small Business Administration—sorry, Office of Advocacy. This is for Al. The scientist question, you know, what's the need for additional peer review? You know, what's the problem? As someone who has spent over 25 years working on—I have the honor of reviewing EPA rules, but we can say this about other federal agencies. There is and was a great need for peer review of scientific materials coming out of, in my case, EPA. I can cite many war stories. And one real quick one is relatively current.

The Toxic Release Inventory lead rule, almost notorious, that came out in 2001 after a great controversy—there was a number of people who asked for peer review of that rule before it came out. We were among them, a lot of people from Congress, a lot of trade associates. The EPA said no. And the peer review that we've now obtained by the Science Advisory Board (SAB) after the fact, low and behold, said that the scientific basis for the lead rule, you know, was not correct. We were not surprised by that outcome.

There are many examples I found in my history. You know, they are not published in The Washington Post. You don't read about this, and that's part of the problem. But from people who are inside, you know, playing inside baseball—inside OIRA, inside the federal agencies—it was clear to me that having the peer review in advance would have had a different result on that rule.

Mr. TEICH. Was there a question in there?

Question: The question is, are you not—are you aware of the fact that there is a need for peer review at federal agencies. You suggested that you didn't think so.

[Cross talk.]

Mr. COPELAND. In back.

Question: Pat Casano, General Electric, Corporate Environmental Programs. I have a comment and then a question. I would encourage people to read the Fourth Circuit's opinion in the Salt case because in my view it doesn't definitively answer the question of whether judicial review is available. The key question in the case really was whether the agency's denial of the request for correction under the IQA was final agency action under the Administrative Procedure Act. And the Fourth Circuit didn't address that question. That is—that's the same problem with the earlier decision—I forget from which district court—that basically said in less than a page that judicial review is not available under the IQA. So people can certainly, you know, read the Fourth Circuit opinion and make their own judgments, but I really think it fails to address the key question and therefore doesn't definitively resolve that issue.

The question/comment is I think the discussion this morning points out why there is a need for the Risk Assessment Bulletin, which to me goes to the objectivity prong of the information quality guidelines. The science that the agencies do is very hard. It's not sticking a celery stalk in a glass of water with some food coloring in it and waiting to see if the celery turns blue. It's very difficult. There are lots of opportunities for mistakes. There are lots of opportunities where assumptions and defaults come into play. And so it's critical that it be an objective process, and everybody has a bias. Everybody has a perspective.

I think that the bulletin gets to that, in part at least, by the requirement for weight of the evidence. But one of the problems with that is that, as I understand it, there's no standard definition for what weight of evidence means or how you demonstrate that you've done a weight of evidence assessment. I was at an SAB ecorisk workshop recently and Glenn Suter from EPA said there are at least four different definitions of weight of the evidence. So I was pleased to hear Ms. Steinzor refer to that as what scientists generally do, but I'm curious as to whether there is a standard definition and what it is.

Mr. COPELAND. Is there a standard definition of weight of the evidence?

Mr. TEICH. Is there a standard definition of the weight of the evidence. I think it's—a little, you know, is what they say about pornography. You know it when you see it. It's difficult to define, but you know it when you see it. We have in sort of a common everyday culture a sense that there are always two sides to an argument. In science, there may well be two sides to an argument, but they don't necessarily carry the same weight, and they don't necessarily deserve the same degree of respect.

Scientists try to keep an open mind. Nothing is ever really final beyond being open to question. Science progresses by challenging existing findings and existing hypotheses and theories, but there are some things that would appear to be sufficiently well established they're not easily challenged. And those are the things that are supported by what we would call the weight of the evidence. It's an accumulation of studies over a period of time that's accepted by a large majority of the relevant scientific community. That's kind of the best I can do on that.

Mr. COPELAND. Okay, one last question.

Question: Thank you. Mark Powell with the Department of Agriculture. I have a question for Mr. Arbuckle. Thanks. The scope of the risk—proposed Risk Assessment Bulletin defines risk assessment strictly in terms of human health, safety, and the environment. Are there administrative reasons or legal reasons for defining the scope of the Risk Assessment Bulletin to that? There are, for example, federal insurance programs. There are influential assessments on risks to the built environment that aren't related directly to human health, safety, the environment, for example, the electricity grid—those sorts of things. Would those fall under the purview of other circulars or OMB administrative guidance?

Mr. ARBUCKLE. [Off mike.]

Mr. COPELAND. Why is the scope of the Risk Assessment Bulletin limited to health, safety, and environment?

Mr. ARBUCKLE. The answer to that is that, as you point out, there are very different types of risk assessment that exist across the spectrum of human study—insurance industry, financial institutions, and so on. And we felt that they were different enough than risk assessments in general that apply to health, safety, and environmental regulation that it would be not possible or particularly useful to try to incorporate all of these together. Now, one of Rena's point was the argument that we have straightjacketed, one size fits all guidelines within this area, and that is certainly not our intent. And we would expect the NAS to tell us so if they thought that was the case. But the idea is to try to provide a general set of best practice guidelines that can be used with the appropriate flexibility across this important spectrum of federal programs.

Ms. STEINZOR. Can I just add very, very -

Mr. ARBUCKLE. Also since we now have Bill and Rena after us, we didn't want to have the entire insurance industry and all the engineers of the world against us too.

Ms. STEINZOR. If the federal government is a family, then my answer to your question would be EPA is the bad child, and OMB is quite preoccupied with its activities and has been for many years. So that's—you'd agree to some of that, right?

Mr. ARBUCKLE. It's our favorite child.

[Laughter.]

Mr. ARBUCKLE. Tough love.

Ms. STEINZOR. I think it would like a little less attention.

Mr. COPELAND. We do have—we're trying to stay to—close to a schedule. If you have a question, you can pose it to them. These folks will be around, or some of them will be around for the day. Last thing—we'll take a 10-minute break. We'll be back at 10:45. Please thank this panel.

[Applause.]