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NEWS & ANALYSIS

Learning to Live With the Data Quality Act

by Paul Noe, Frederick R. Anderson, Sidney A. Shapiro, James Tozzi, David Hawkins,
and Wendy E. Wagner (moderator)

MS. WAGNER: Welcome to Learning to Live With the Data Quality Act. I am Wendy Wagner, a professor at the University of Texas Law School.

In the year 2001, the U.S. Congress passed the Data Quality Act (DQA) as a rider to an appropriations bill. There was no legislative history indicating what Congress meant when it required agencies to establish processes to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. Instead, Congress directed the Office of Management and Budget (OMB), and ultimately the Office of Information and Regulatory Affairs (OIRA) at OMB, to provide guidance on what this one-sentence, legislative requirement means.

OIRA came out with final guidelines last winter. Now the agencies are promulgating their own guidelines, also required under the Act, to describe the processes they've established to make sure that the information they disseminate is of high quality.

Our panelists today are going to talk about the OMB guidelines, the agencies' guidelines, and other recent DQA developments. The panelists will also offer their views about ways agencies should proceed in the future. For example, some of the panelists may suggest ways agencies could go even further to comply with the process requirements of the DQA, while other panelists may suggest ways that agencies could avoid or at least minimize the requirements of the Act. I suspect we'll probably see some strong differences of opinion today on which is the better course.

To kick off the panel, we will start with the appointed guardian of the DQA requirements—OIRA.

John Graham, who is the Administrator of OIRA, was originally scheduled to present today. Unfortunately, he couldn't make it, but fortunately for us, he sent Paul Noe. Mr. Noe is the counselor to John Graham at OIRA, and he

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works closely with Dr. Graham on the DQA issues, as well as a number of other issues, including the OMB's annual cost-benefit reports.

Before joining OIRA, Paul worked as Senior Counsel to Sen. Fred Thompson (R-Tenn.) at the Government Affairs Committee in the Senate.

MR. NOE: Thank you, Wendy. It's a pleasure to be here to engage in a dialogue with old friends, colleagues, and leaders in the field of administrative law.

I'd like to discuss our ongoing efforts, and those of the agencies, to improve the quality of information disseminated to the public. A recent law provides the framework for these efforts.

Our story begins late in the year 2000, when Rep. Joanne Emerson (D-Mo.) sponsored an amendment to OMB's appropriations bill. This amendment required OMB to establish governmentwide standards for ensuring and maximizing the quality of information disseminated to the public.

The Clinton Administration apparently raised a concern with the original proposal. The word "regulation" was changed to "guidelines," and the law was enacted as §515 of the Treasury and General Government Appropriations Act.

We at OMB call the DQA the Information Quality Act (IQA). As Wendy mentioned, there were no hearings for this law, there was no extensive legislative history, and there certainly was no fanfare when it was signed into law. But in our view, this law provides a very important opportunity to raise the quality of information disseminated to the public.

Undoubtedly, long before the Internet, technologies such as the telegraph dramatically increased the volume, speed, and accessibility of information. But the digital revolution has brought predictions that the volume of information traversing our airwaves and our wires will increase a million-fold to a billion-fold in our lifetimes.

In the information age, information is a vast source of power, freedom, and protection—if it is of sufficient quality. Government relies more than ever on disseminating information to accomplish its business and its policy objectives. And the public is ever more dependent on the reliability of this information.

Sometimes information tools are used in the context of recognizable regulatory programs, but in many instances, extremely important government disseminations are done outside of the traditional procedural safeguards of the venerable Administrative Procedure Act (APA). Regulation by information is becoming the norm. Against this backdrop, the IQA tells us that the time has come for a systemic effort to ensure the quality of information disseminated to the public.

There is plenty of evidence that the quality of information advanced by government decisionmakers needs to be im-

proved. In the scholarly literature on science policy, there are entire books of case studies demonstrating technical problems with information collected, used, and disseminated by federal agencies.

The IQA now establishes a kind of performance-oriented information quality system that spans across the government. This should help us build quality into the system from the very beginning and lead to evolutionary progress. It also, I think, could have a network effect, with cross-fertilization between agencies, within agencies, and between government and the public.

Interagency dialogue should flourish, as agencies implement their own guidelines, and OMB's government-wide guidelines. As mentioned in a recent October 4, 2002, memorandum to the president's Management Council, OMB would like to foster these kinds of inter-agency discussions.

This network effect, as I mentioned, also could be felt at the intraagency level. One example could be the U.S. Environmental Protection Agency's (EPA's) three-judge panel for deciding appeals of EPA information quality decisions. This panel will consist of three of the assistant administrators at EPA: from the Office of Environmental Information; the Office of Research and Development; and the Office of Policy, Economics, and Innovation. This could lead to a healthy interchange between the science, information, and economics components of the Agency.

With that overview, I would now like to walk you through the three phases of our information quality efforts. First, I will discuss OMB's general governmentwide guidelines; second, the agency guidelines; and finally, on the horizon, implementation.

OMB's governmentwide guidelines were issued in interim form on September 28, 2001, and in final form, on February 22, 2002. To implement the statute, OMB directed the agencies in three essential ways.

First, they must embrace a basic standard of quality as a performance goal as embodied in OMB's guidelines, and they also must develop predissemination review procedures to carry out this responsibility. In information collections by agencies under the Paperwork Reduction Act, the agency and OMB can consider whether the quality of subsequent disseminations would meet these applicable performance standards.

Second, agencies are to report annually to OMB on the number and nature of complaints, and how such complaints were handled by the agencies.

Finally, agencies established a petition process, allowing affected parties to request that the agency correct information that does not comply with the OMB or agency guidelines. OMB made clear that the burden of proof is squarely on the shoulders of the petitioner. It must demonstrate that a specific dissemination does not meet the applicable quality standards. The opportunity for public complaints and appeals went into effect October 1, 2002.

Government and the public have a shared interest in ensuring the quality of government information. The petition process not only will inform agencies about how they are affecting the public, but also it will increase sunshine over agency disseminations. That transparency could counter the ability of particular interest groups to capture the agenda of the agencies. Ultimately, it could help increase the accountability of government to the public.

While Wendy asked us to focus today on the health and environmental agencies, I would be remiss if I did not mention that the scope of the IQA is much broader than these regulatory agencies. It spans information related to regulatory, statistical, research, and benefits programs. It covers all federal agencies subject to the Paperwork Reduction Act, including the independent regulatory commissions engaged in economic regulation.

The guidelines also have a broad definition of "information." That is, any communication or representation of knowledge, such as facts or data, in any medium. And this is why we at OMB call this law the IQA, as opposed to the DQA. It covers much more than just quantitative data.

The guidelines also make clear that dissemination of third-party information "initiated" or "sponsored" by the agency is covered. That is, carried out in a manner that reasonably suggests that the agency endorses or relies upon that information.

OMB provided a variety of exemptions to protect privacy and commercial interests and to facilitate press releases, third-party submissions, public filings, archival records, personal articles by agency employees, testimony, subpoenas, and adjudicative processes.

For proceedings with established notice-and-comment procedures, such as rulemakings, OMB allowed agencies to meld their complaint response process with their preexisting procedures. We also provided agencies ample discretion to reject complaints that are groundless or made in bad faith, or that simply boil down to a difference of opinion.

OMB's guidelines also explain that quality encompasses "utility"—in other words the usefulness of the information for its intended uses, "integrity," and the security of the information, as well as its "objectivity." And objectivity means that the information is accurate, reliable, and unbiased—both as a matter of presentation and substance.

OMB recognized that information quality can be costly, and accordingly, we encouraged agencies to consider the social value of better information in different contexts. Ordinary information is distinguished from "influential" information. Influential information is scientific, financial, or statistical information with a clear and substantial impact on important public policies or private sector decisions.

Influential information is held to a higher standard of quality than ordinary information. With some exceptions and qualifications, influential information should be reproducible by qualified third parties. We see reproducibility as an essential feature of competent and accountable government. Show what data, analyses, and calculations you used, and how you arrived at your conclusions.

OMB's guidelines also promote the general objectivity principles for risk assessments that Congress adopted in the Safe Drinking Water Act [(SDWA)] of 1996. For influential scientific information regarding analysis of environmental health and safety risks, OMB directed agencies to adopt or adapt those principles in their own guidelines as fitting for their particular programs. Many agencies adapted these principles, including the Food and Drug Administration, EPA, the [U.S.] Department of Labor [(DOL)], the [U.S.] Department of the Interior, the National Oceanic and Atmospheric Administration [(NOAA)], the [U.S.] Department of Transportation, the Consumer Product Safety Commission, and the [U.S.] Department of Energy [(DOE)].

Phase two of our effort has been agency-specific guidelines, and OMB review of those guidelines. To facilitate development of agency guidelines, OMB arranged for three workshops conducted by the National Academies in spring 2002. These workshops were of high quality, and were widely attended by hundreds of agency employees, as well as many interested members of the public. They served as a springboard to foster the exchange of ideas in the development of the agency draft guidelines.

OMB's review of these guidelines began when they released their proposals for public comment in May. Based on a preliminary review, the OIRA administrator, Dr. John Graham, issued a memorandum to the president's Management Council highlighting some particularly noteworthy provisions of agency guidelines for consideration by other agencies. He also asked for more uniformity in a couple of areas. Similarly, on September 5, 2002, as OMB was completing its review of the draft final agency guidelines, Dr. Graham sent a follow-up memorandum to the president's Management Council, encouraging uniformity in a few key areas.

In the context of lengthy notice-and-comment procedures, agencies were asked to consider an information quality complaint before the end of those procedures, if the agency determined that it would not unduly delay their business, and that the complainant had shown a reasonable likelihood of suffering actual harm without a prompt resolution.

By October 1, OMB had completed its review of the agency guidelines for over 65 federal departments and agencies and 45 components. I applaud the hard work of the many professional agency staff who were involved in this effort. They're far too numerous to mention, but they worked very diligently on this, and added a great deal of creative thought to improve the guidelines.

I also want to thank my boss, John Graham, as well as OIRA's outstanding professional staff, particularly Jeff Hill, who devoted many long hours and creativity to this enterprise.

Finally, we are at phase three, the implementation stage. Having developed information quality guidelines, the agencies and OMB have to turn to the equally challenging task of implementing them. Agencies must ensure that the procedures and criteria are integrated into their day-to-day activities.

On October 4, Dr. Graham sent a third memorandum to the president's Management Council, outlining OMB's current plans for providing continuing guidance to the agencies in applying OMB's governmentwide guidelines, as well as monitoring complaints filed by the public. In that memo, OMB established two basic oversight measures. First, we provided some initial guidance to the agencies on the preparation of their annual reports, including descriptions of the kinds of complaints received and their resolution, so that we and the public can understand better how this law is working.

Second, to help OMB gauge the public interest in information quality issues and the agencies' responses, we requested that each agency provide us initially with copies of their complaints and related information regarding several key issues:

(1) Complaints involving major policy questions of interest to two or more federal agencies;

(2) Influential disseminations involving violations of OMB's governmentwide guidelines;

(3) Novel procedural, technical or policy issues, and

(4) Disseminations occurring during a public comment process, where the agency determines the complainant has shown a reasonable likelihood of suffering actual harm if the agency does not promptly consider the complaint, and doing so would not unduly delay the agency's essential business.

Agencies that post their complaints and responses on their websites are not required to forward these materials to OMB.

Thank you.

MS. WAGNER: Thanks so much, Paul. That was very helpful. Our next speaker is Fred Anderson. He is a partner at Cadwalader, Wickersham & Taft in the Washington office, where he practices primarily in the area of environmental law, although his practice covers a wide range of issues at all levels of the legal system; legislation, regulation, and litigation.

Fred has had many fascinating lives inside the legal world, but for our purposes, the one that is most relevant is his expertise under the DQA. He became a respected expert on the statute soon after it was enacted. In fact, he published an article on the DQA on October 14, 2002, in the *National Law Journal*. As Paul mentioned, Fred also was a presenter at, and actually one of the initiators of, two excellent workshops sponsored by the National Academy of Sciences [(NAS)] on the DQA. Fred is also on the [NAS] Standing Panel on Science, Technology, and Law, which has put on a lot of interesting programs on science and law.

MR. ANDERSON: Thank you, Wendy. I'd like to talk informally about the DQA and provide a perspective which we can explore in the questions and answers that follow. Wendy is right. The statute's legislative history and background are incredibly brief. As Tallulah Bankhead once said: "There's less to this than meets the eye." But if we were to switch to the metaphor of a mortgage, then the recent high level of activity is a "balloon payment" of hundreds of pages of a hundred or more agencies' information quality guidelines that were put on the record as of the first of October.

This potential "October Revolution" in federal information quality reflects a wider societal information revolution that has occurred. Despite the statute's past, and its short length, it potentially packs quite a wallop, because of the implications of information today. Information is power.

There are some fascinating things in the guidelines. I imagine you have read them deeply and have admired the skill and draftsmen's expertise that went into them. I urge you to have a special look, for example, at EPA's 54 well-written pages.

The statute's legislative history is brief, but the widely accepted version is that industry got it through Congress surreptitiously and out of pique, because of indiscriminate Internet "datadumps" by agencies like EPA of corporate data that embarrassed companies into actions that they are not required by regulation to undertake but rather felt strong-armed to do by the presence of the data. From that,

the widely reported view is that industry will make frequent use of this statute and so therefore it is a “tool of industry.”

But I think a reading the guidelines and the statute will reveal that the “affected parties” include practically anyone. I believe nonprofit groups, university researchers, and a wide array of other “affected parties” will also use this statute to challenge data and address information quality issues with the federal government.

The OMB has encouraged the agencies to adopt a wide definition of the term “affected parties,” to the point that [DOE] simply invites petitioners to state how their interests are affected before proceeding with their petition. (We’ll leave for a little bit later questions about Article III standing.)

Fear exists that the statute is going to unleash a deluge of petitions that will clog the wheels of the federal bureaucracy. I’m not so sure. I would agree, had I not lived through a number of other episodes in the history of administrative law where dire predictions of deluges were made and not realized as recently, for example, as the Shelby Act. I’m tempted to ask for a show of hands as to how many people have even heard of the Shelby Act. But for awhile, people in the know spoke of little else than how the government was to be inundated by Shelby petitions. By the way, the Shelby Act bears a beautiful parallel to the DQA; it also was an appropriations act insert; it also is very brief. It simply requires that “all data produced” with federal funds be available to “any person.” OMB also wrote guidelines, and those guidelines also went through quite a bit of controversy. There were two generations of comments—indeed, thousands of comments. The [U.S.] Chamber of Commerce prepared several “ramp-up” letters getting ready to petition under Shelby. These involved the data for the Harvard particulate study, environmental justice guidance, and diesel pollution studies (notice the EPA theme here). But I checked, and there have been only a handful of Shelby petitions. I don’t know about yesterday, but the last time I checked, you could count on one or possibly two hands the Shelby petitions that have been filed for all the federal agencies.

On the other side of the ledger, no one predicted 32 years ago that the National Environmental Policy Act (NEPA) would result in any judicial review. Now thousands, yes, thousands of decisions later, the courts have assumed the pivotal role in NEPA implementation. So we just don’t know how important the statute that we’re addressing today may become. As the undertaker says: “Remains to be seen.”

Early in my career, I could not envision the day when the [NAS], with OMB involvement, would host a meeting to deal with OMB information quality guidance. It just was not something I could imagine 15 years ago. Or for that matter, 15 months ago. The OMB and agency guideline process was, give or take a few details, a model of notice-and-comment rulemaking. Certainly, if not purely and strictly APA rulemaking, it was a transparent and public process that deserves to be commended. From what I have heard about the back-and-forth between OMB and the agencies, it also was a much better interaction than has occurred before. My colleagues in federal agencies have largely, but not totally, endorsed that point of view.

OMB promulgated rules, and then agencies promulgated guidelines under these OMB rules. The guidelines are specific and detailed and define the “y” words: the standards of quality, objectivity, integrity, and utility that give the pro-

gram content via OMB and agency efforts to spell out their meaning. This has been a process of quasi-legislative policymaking, very reminiscent of any number of federal rulemakings.

The rulemaking process under the DQA has been very transparent, reflecting the new philosophy of OIRA. I find that remarkable in an office so close to the West Wing. We’ll see what the future holds, but in the zealot pursuit of transparency, the OMB is asking for the information quality process to be visible as if in a fish bowl, e.g., incentivizing transparency with the requirement that if agencies put challenges on their websites they need not further consult OMB.

Where are we now? The next or implementation phase is going to be very interesting. Of course, the threshold issue is how many petitions will be filed and what is going to happen as the information quality system swings into operation. If it’s going to be a war between stakeholders and government, it’s certainly a “twilight war” as of right now. I don’t know of any petitions under the statute worth mentioning. If you are from an agency, and you have received a petition, I’d love to meet you. Perhaps you can be known as the first recipient and can be given some sort of recognition.

One of the big questions is what the role of the courts will be in implementing the statute. A second question is what kind of oversight the OMB might engage in, either in the presence or absence of judicial review.

To take the second question first, clearly OMB is planning to be very involved in active oversight of statutory implementation by the agencies. For example, in its October 4 memorandum, OMB states that if challengers meet with the agency, OMB must be notified and invited to the meeting. The memorandum also says that if challenges have been placed on the agency’s website, there is no need to go through the OMB notification process Paul described.

A few words regarding judicial review. I am aware that some students of administrative law contend that judicial review is not available under the DQA. If this statute were like others that OMB administers, and if OMB standard operating procedure had not changed so radically, then I would agree that judicial review would not follow. But my view is that this statute is different. It sets out standards for federal information quality, provides for OMB guidelines and oversight, and, most importantly, creates a citizen challenge mechanism, to which by guideline OMB has added an appeals procedure. If the statute’s full promise as a “good government statute” is to be realized, it must be through judicial supervision. I’m not jaded as many critics are about the judicial oversight of statutes—nor of this one in particular. I think the courts will be neither inefficient nor dilatory and will add to rather than detract from its sound implementation.

The statute is judicially enforceable in no small part because of its express language. One may be tempted to gloss over the language that begins the operative language of the statute: “Pursuant to the Paperwork Reduction Act,” followed by two pinpoint cites to that legislation, i.e., §3516, which directs the OMB to write rules and regulations for information quality, and §3504(d)(1), which obliges the OMB to develop policies and guidance on information that bind the agencies. There’s another relevant section, §3506(a), which provides that each agency “shall be responsible . . . for complying with” OMB guidelines. The DQA is anchored in the Paperwork Reduction Act. It itself

is short, with plenty of mandatory, succinct language in it, but it also fits tongue-and-groove in a craftsman-like way with the Paperwork Reduction Act, which itself contains mandatory language and specifies processes as well as substantive standards.

OMB “filled in the legislative gaps” with its guidance. The agencies further filled in gaps with their regulations to implement these mandatory requirements. I’ve already said that the process that produced the OMB rules was a model of notice-and-comment rulemaking. I would be comfortable arguing to a federal judge that the hallmarks of notice-and-comment rulemaking were observed and that the challenge and appeals process further reinforces that the rules are binding and therefore entitle challengers to rely upon them.

If the DQA is a “good government” statute like the Federal Advisory Committee Act, the Freedom of Information Act, and NEPA, and if it is broadly applicable to the entire federal edifice, courts do police the implementation of such statutes. Note, too, that judicial review is not excluded by the statute. It commits nothing to agency discretion by law. There is “law to apply” under *Citizens to Preserve Overton Park, Inc. v. Volpe*.¹ A strong judicial presumption of the availability of judicial review exists in the absence of any indication that Congress intended to preclude review. Exhaustion of administrative remedies occurs through the challenge and appeals processes which render issues well defined and ripe for judicial review. It’s true that while some agencies have included language in their guidelines to try to excuse themselves from judicial review, courts tend to look past such language to the statute itself and its good government purposes. Agencies of course do not want to be second-guessed by courts, but Congress has said that the quality of their information needs improvement.

MS. WAGNER: Thanks, Fred. You gave us a lot to think about.

Our next panelist is Sid Shapiro. He is the Rounds Distinguished Professor at the University of Kansas. He is also the founder and a board member of a recently formed think tank called the Center for Progressive Regulation, which by the way is not located in Lawrence, Kansas, although Sid is.

Sid’s academic career has been dedicated almost exclusively to issues in regulatory and administrative law. He has published a number of important articles and books, including a book that has just hit the stands called *Risk Regulation at Risk*.

Sid is also an expert on the [DQA]. He was the author of the comments the Center for Progressive Regulation filed on a number of agency guidelines.

MR. SHAPIRO: Thank you, Wendy. I’m somewhat less sanguine about the prospect of the DQA than our previous speaker, at least as it applies to rulemaking.

I am not much of a fan of administrative reform by appropriations rider, and I don’t regard the DQA as Congress’ finest hour. It’s an ill-defined statute, as you heard. There is no definition of key terms and no legislative history, with the predictable result that institutions and interest groups are rushing to fill the void with their own idea of what the legislation could mean, which invites overreaching and litigation and diverts agencies from their regulatory missions.

My argument today is the application of the DQA to rulemaking is just one example, although a very important one, of such overreaching. OMB and industry—in fact, I think most people—seem to agree or assume that the DQA applies to rulemaking, but I am not so sure.

I believe common approaches to the interpretation of statutes support the conclusion that the DQA applies to reports and to information that agencies put on the web, but it does not apply to rulemaking, for two reasons: first, Congress’ requirement that agencies establish a new administrative mechanism to ensure compliance with guidelines indicates that rulemaking was not included; second, the courts should not apply the Act to rulemaking because the results are inconsistent with other statutes with which the DQA ought to be harmonized.

There are two key provisions to the Act. First, Congress required the OMB to issue guidelines regarding the dissemination of information. Second, Congress mandated that the OMB guidelines had to do two things: (1) to require agencies to issue their own guidelines; and (2) to establish administrative mechanisms to give people the opportunity to appeal, or complain at least, about information they believe is inconsistent with the agency guidelines.

OMB, in its definition of the scope of the Act, focuses on the word “disseminate,” and takes the position that disseminate means any agency-initiated or agency-sponsored distribution of information to the public, and if one accepts that definition, I can hardly quarrel with the fact that rulemaking is included. Surely, a notice of proposed rulemaking is an agency-initiated or agency-sponsored distribution of information.

My argument, however, is that the word “disseminated” has to be interpreted in light of the requirement that agencies establish an “administrative mechanism” to hear data quality complaints, and that those two requirements together have to be harmonized. When you harmonize those two requirements, you come to the conclusion that the word “disseminate” does not include notices of proposed rulemaking.

I start with the fact that the ordinary meaning of “administrative mechanism” would clearly include the rulemaking process. In other words, there is already a mechanism to vet data quality in rulemaking. So if there is already a mechanism—and I’ll come back to this—which is used to protect the quality of information, did Congress really mean that agencies had to establish yet another and different administrative mechanism?

This argument leads to one of two directions. One possibility is that Congress did not mean to include rulemaking with the scope of the DQA. That is, when Congress referred to information that is “disseminated,” it meant information that is not already subject to an administrative mechanism to correct data problems. Otherwise, the requirement that agencies establish an administrative mechanism is redundant in the context of rulemaking.

The other possibility, which I’ll also come back to in a minute, is that Congress was dissatisfied somehow with the adequacy of rulemaking in protecting or vetting the quality of data, and therefore, it truly did mean that agencies had to establish yet another and different administrative mechanism on top of rulemaking to protect the quality of data.

My argument that the word “disseminate” does not include rulemaking does not do great violence to the word. Dictionary definitions emphasize that dissemination in-

1. 401 U.S. 402, 1 ELR 20110 (1971).

volves efforts to engage in “widespread” distribution of information, which suggests that the DQA applies only when agencies are actively engaged in trying to bring information to the attention of the public, as in a report or website. It’s certainly possible to view a notice of proposed rulemaking as having a more technical and different purpose, namely, the linchpin to rulemaking.

Well, since rulemaking is available to vet data, what did Congress mean? Why did it require agencies to set up an administrative mechanism? I think the answer is clear. Congress acted because outside of the context of rulemaking, there was no generally established mechanism to vet data. Indeed, prior to the adoption of this Act, the policy debate was about the quality of information, dealing with reports and information produced on the web, not about rulemaking.

Interest in this topic started, as near as I can tell, with a so-called white paper which was authored by Mark Greenwood of Ropes & Gray, a law firm in Washington, which came out in May 1999. In that paper, Greenwood argued that there were insufficient protections for those who might be adversely affected when agencies produced information on the web and in reports.² There was nothing in the paper about rulemaking.

In April 2000, the American Bar Association (ABA) held a program on the Greenwood white paper in Williamsburg, Virginia, with the entire discussion at the program concerning reports and the web. In 2001, at the behest of this section, the ABA House of Delegates adopted a recommendation³ that agencies provide procedural protections for people concerning information contained on the web and in reports. There is no mention of rulemaking in the ABA resolution.

The counterargument would be that rulemaking is inadequate to vet data, and therefore, some additional or new process is needed on top of the rulemaking process, and if that were the case, that would explain the requirement of this additional mechanism. But I have two responses.

First, I do not see how you can argue with a straight face that the rulemaking process is inadequate in this regard, because everything that the DQA does in the context of information on the web, or information in reports, is already done in the rulemaking process.

Transparency: Since 1973, in the *Portland Cement Ass’n v. Ruckelshaus*⁴ case, there has been a court-enforced requirement that agencies have to identify scientific data, and the methodology used to obtain it, in a notice of proposed rulemaking.

Accountability: There is a court-enforced obligation under “hard look” review that agencies must respond to all significant comments or have the rule remanded for failure to adequately explain the agency’s justification of its rule, and I would take it that this obligation includes reconciling any significant or serious argument that the agency has relied on data which is somehow inadequate.⁵

In addition to all of that, we have OMB review of all significant rules, both before there is a notice of proposed rulemaking, and before a final rule is issued, at which time I would take it OMB has the opportunity to point out to an agency that somehow it is relying on bad data.

Second, I would not pretend for a moment that what agencies do is not controversial, or that there has not been a steady drumbeat of criticism of the regulatory output of agencies. But that criticism concerns policy issues, not the quality of data. Those criticisms concern the appropriate level of regulation in light of scientific uncertainty about risk. That is a policy issue, not a scientific one. If you look carefully at the evidence as Wendy Wagner has done in a forthcoming article, you would find little evidence that agencies rely on poor quality data in promulgating regulations.

Wagner comes to the following conclusion:

[I]n spite of the thousands of public health and safety regulations promulgated annually, there are surprisingly few instances where unreliable science has been used. . . . If one subtracts, from those studies where industry or independent contractors fabricated data in order to support their application for licenses under [the Toxic Substances Control Act], the [Federal Insecticide, Fungicide, and Rodenticide Act], or [the Food, Drug, and Cosmetics Act], then the examples of the regulatory bad science is winnowed down to a few, virtually all of which are contested.⁶

So my first argument is that one must interpret the DQA in light of the notion that Congress is requiring a new administrative mechanism, and once you look at that aspect of the statute it becomes clear that rulemaking is not included. Rulemaking already vets data and is adequate for that purpose. This means that the reference to administrative mechanism refers to situations in which such a mechanism does not exist, i.e., to reports and to postings on the web.

My second argument is that the courts should not apply the DQA to rulemaking because the result is inconsistent with other statutes with which the DQA ought to be harmonized. Here I disagree with Fred Anderson, who says he is agnostic about whether the DQA applies to rulemaking. I am not agnostic because if the DQA applies to rulemaking, agencies must provide a separate administrative mechanism to hear data complaints, which will cause disruption and ossification. Courts should avoid this result in order to harmonize the DQA with the agency’s substantive mandate. Again, I call your attention to the fact that the act very clearly requires an agency to establish a new and different administrative mechanism, which means that agencies cannot rely on the normal rulemaking procedures to vet data quality complaints. If the DQA applies to rulemaking, we will have two separate administrative mechanisms to review data. One is the common rulemaking process, which results in a final rule. The other is a complaint process, which must respond to data quality complaints outside of the context of the rulemaking process.

So we have the normal process, where the DQA does not apply, and complaints about rulemaking quality are handled in the normal disposition of rules, and we have a second pro-

2. See White Paper From Industry Coalition to U.S. EPA [About] Concerns Over Information Programs (May 4, 1994).

3. See ABA, *Resolution and Report* (2001), at <http://www.abanet.org/leadership/2001/107c.pdf>.

4. 486 F.2d 375, 3 ELR 20642 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974); see also *Lloyd Nolan Hosp. & Clinic v. Heckler*, 762 F.2d 1561 (11th Cir. 1985). See generally JEFFREY S. LUBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 195-99 (3d ed. 1988).

5. See Thomas O. McGarity, *The Courts and the “Ossification” of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV.

525, 527 (1997) (explaining the encompassing nature of hard look review).

6. Wendy Wagner, “Bad Science” Fiction: *The Imaginary Crisis in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. (forthcoming 2003).

cess which Fred Anderson just described. In this second process, you have a data complaint that comes in while the rulemaking is pending. Assume that the agency turns down the complaint. That is final agency action, there is a separate appeals process for that, and then there is judicial review. As a result, we have a collateral attack on the agency's information during the pendency of rulemaking, which is subject to a distinct and separate judicial review.

OMB recognized the possibility that this would happen, and they adopted a funny way of responding to this problem. First, OMB says agencies can use well-established procedural safeguards if they permit the resolution of complaints on a timely basis. This means that OMB accepts the rulemaking process as an acceptable mechanism to handle data quality complaints. Agencies, however, are obligated to respond to the complaint with[in] 60 days if there is a reasonable likelihood that dissemination of information will harm the entity making the complaint and if an agency's response to the complaint would not unduly delay the issuance of the rule.

Let me say four things about OMB's position. First, it seems to me this interpretation still has the potential for numerous lawsuits. If an agency says there is going to be undue delay in responding within 60 days to a complaint, someone could challenge that. If an agency says we do not think this harms you, someone could challenge that. If they just turn down the complaint, someone could challenge that. So it's not clear to me it solves the problem of creating a collateral mechanism to interrupt rulemaking with judicial review.

Second, since OMB admits that rulemaking is adequate to ensure the quality of data that goes into rules, the OMB position that agencies must separately respond to data complaints has nothing to do with protecting the quality of data used to support rules. What OMB seeks to do is to protect the reputation of companies during the pendency of rulemaking, which does not justify the Act. There is no need to protect corporations in this manner because they already receive sufficient protection. People who represent corporations know how to get into the process already. They are going to be present at the agency before the rule is issued. Moreover, they can go to OMB and there are hearings before scientific boards. Thus, I do not think that they need this protection. And anyway, if protecting corporations in this manner is really the goal of the DQA, that's simply unprecedented. As the U.S. Supreme Court said in the *Federal Trade Commission v. Standard Oil Co.*⁷ case, expense and annoyance at participating in agency process is part of the social burden of living under government.

So my conclusion is that the application to rulemaking is not a foregone conclusion. The common approaches to statutory interpretation lead to the determination that that it does not apply, and I do not believe the courts ought to award Congress in passing appropriation riders such as this by adopting an expansive interpretation. Thank you.

MS. WAGNER: Thanks, Sid.

Our fourth panelist is Dr. Jim Tozzi. Jim is on the Board of Advisors for a different center, the Center for Regulatory Effectiveness [(the Center)], and he is purported to be the drafter, or at least part of the inspiration for, the DQA. I

think there is no question that he is one of the top experts on the DQA.

In addition to his work there, he also represents clients on a variety of good government statutes before the agencies. Before joining the private sector and nonprofit sector, he was a major player inside government. From 1972 to 1983, he served in a variety of roles inside government, including assistant director and deputy administrator of the OMB.

MR. TOZZI: Thank you, Madam Chairman, distinguished members of the panel, ladies and gentlemen. I would also like to back up to what Paul Noe said. I think the fact that by October 2002, these guidelines were in final form is really a remarkable accomplishment by both the federal agencies and all of the participants in the development process. I had presumed that the October deadline would not be met, yet virtually all the agencies have done so.

I offer two comments, one prospective, the other retrospective.

The prospective observation is that the implementation phase is indeed a very important process. Up to now at the Center, all of our work has concentrated on enactment and on offering views to the agencies regarding the writing of their guidelines.

But now I think we have to emphasize how we make the DQA work, and how we make it work fairly and equitably. The best way to do this is to start addressing concerns forcibly. For example, a number of observers have said that while the goals of the Act are laudable, the "devil is in the details." It is the implementation phase that is critical to success of the legislation. And while up to now we could have put some details aside, now they have to be addressed on the front burner.

So with that, I would like to give the Center's view on one matter that I think should be examined right away. The articulated concern is that [the] statute and its resultant paperwork are going to clog the government. There are two approaches to this issue. One is what I call a "win in court" strategy, and the other I would term a "win at the agency" strategy. These quite different approaches lend themselves to quite different ways of dealing with petitions.

Take first the win in court strategy. If you assume that a petition denial is final agency action, and that such is judicially reviewable, most cases are indeed going to be reviewable. The issue is made more complex because of the presence of the standing requirement. But putting that aside, if you assume that eventually if you file a petition you are going to go to court, you will address, or there is a tendency for the petitioner to address, everything that is a credible argument in favor of that petition. These petitions could become extremely lengthy, and extremely detailed. Eventually, the argument goes, the record before the agency is in all probability going to be the record before the judge.

Now, let me give you an example of a case in point. A group came into the Center regarding a risk assessment out on the street, and inquired about the potential of filing a petition on the assessment. The assessment was on the health effects of a chemical. It had two portions, epidemiology and rodent data. There were some two dozen epidemiological studies referenced, and on top of the two dozen studies there was a meta-analysis.

If you're going to take what I call a win in court strategy, then what would you question in your petition? You would question the meta-analysis, and you could go through all 24

7. 449 U.S. 232, 244 (1980).

studies and look at them in some detail. Then on top of that, you could use the Shelby Amendment and get the cohort data, and if you had several million dollars you could write a treatise and put it upon the agency's doorstep. It would take the agency months, if not years, to go through that amount of data.

Such an approach would, of course, indeed clog the system.

But there is another option, the win at the agency strategy. Taking the same example, there was one key study that was extremely important out of the 24. So if I were adopting a win at the agency strategy, I would file a petition strictly concerning that one study.

Which approach is likely to predominate? Unfortunately, there's going to be a tendency for the petitions to take on what I call the win in court strategy. Yet there may be a way out.

The Center believes that the thrust of the DQA was aimed at a win at the agency strategy, to pick out bullet point pieces of information, and go to the agency to deal with those particular matters of concern. I'm not suggesting that I would want to argue there is no need for judicial review, because that keeps the system honest. But the process of bringing the matter to the agency should be simple, involving identification of the claimed deficiency and a statement of what you ask that the agency do to correct the problem. This is something that you don't need to be a regulatory analyst to do, you could be John Q. Public, you can be some nonprofit group that has no budget. In order to accomplish this, we think that the agency should request petitioners when they have multi-issue complaints to put them in priority order. For example, in the example of the risk assessment, if there are 24 studies I'm going to take on, and a meta-analysis, I rank them: study 2, study 8, study 12, and I put them in priority ranking. Second, when the agency reviews the list, if after "x" of these items short of the complete list, they think they have exhausted the thrust of this document, then they stop reviewing it. And what they do is, they notify the petitioner that we think we are determinative on the identified issues, and therefore, we request that you withdraw your petition. The petitioner then has the option of coming back and saying, I want you to exhaust all your reviews. Then the agencies can utilize the escape valve they have in their regulations, namely to do so in, not 60 days, but from 3 months to 3 years or 18 months.

MS. WAGNER: Thank you. Our final speaker is David Hawkins. He founded the Natural Resources Defense Council (NRDC) Clean Air Project in 1971, and except for a stint as Assistant Administrator of EPA under the Carter Administration, he has been at NRDC through most of his legal career. After leading NRDC's air and energy program for two decades, he has now taken on the role of Director of NRDC's Climate Center. Because of the potential significance of the DQA for environmental protective regulations, David, as well as some other public interest groups, including Public Citizen and OMB Watch, have been watching and participating in the evolution of the DQA.

MR. HAWKINS: Thanks, Wendy. The DQA is a good example of what happens when good ideas go bad. What is the good idea? It is that governmental information ought to be of high quality, whether it is used in a rulemaking or serves as the basis of a report. Now, who could argue with that? No-

body. But does that mean that you need a new law, a new bureaucracy, a new set of causes of action, a new opportunity for judicial review? In my view, the answer is no. That is where the good idea has, in the case of the DQA, gone bad. What we have ended up with are directives written in a manner that create opportunities for principally regulated private sector interests to use this idea as a weapon to delay the ability of agencies to put new safeguards in place, to address issues such as those affecting health, safety, and the environment. Those same interests are empowered to use the DQA to effectively suppress or impose prior restraint on the dissemination of information that is essential in a democracy to inform the public—information that is important in promoting discussion of controversial issues, issues that have a significant policy component and often cannot be reduced to a technical debate about the quality of the information. Given the comments that have been filed, mostly by private sector interests, on how the DQA should be implemented, I would agree with Sid that we do not have reason to be sanguine about the prospects of it will be implemented.

The DQA has been marketed as a "good government" act. But one of the first principles of good government is to ascertain whether new legislation is necessary. I do not think it is. In the rulemaking context, as Sid has pointed out, there are safeguards with respect to a rule relying on inadequate data, and the case law over the last 50 years under the APA has created the opportunity for affected interests to challenge rules that are based on inadequate data. No one, in my view, has made the case that we need to substantially overhaul that standard in order to address a real-world problem that is of public interest. Yes, some private sector interests would like to have additional protections for their interests, but those views need to be balanced against the public interest in having prompt decisionmaking by the government.

What about reports and website information? Well, again, there is case law that says when there really is commercial harm presented by information, parties can have access to the courts, and have remedies. What this law would do, as some would have it interpreted, is create an opportunity to suppress information without any showing of harm to an interest, simply based on kind of a check-box approach to whether certain criteria of excellence of data quality have, in fact, been achieved. That is a very problematic way of ignoring the competing interests that are involved when agencies are dealing with complicated issues of whether information proves conclusively that there is a risk that should be addressed. These are policy issues that ought to be debated in public view, not discussed in a behind closed doors process.

I do not agree with the characterization the DQA will promote transparency. OMB's instructions to the agency are that the agencies let OMB know when they get a complaint that meets certain criteria, not that they let the public know. So there is nothing in OMB's instructions that guarantee that this will be a transparent process. This could, instead, be a process whereby the agency, the complainant, and OMB sit down in a room, and in a very nontransparent process determine what to do about the challenged information. In my view, that would be a mistake.

Much has already been said about some of the issues involved with problems with judicial review. One thing has not been mentioned yet is the application of a provision in the SDWA with respect to the quality of data; it is a good example of how OMB has, in its guidelines to agencies, over-

reached. The legislative history shows that in the 104th and 105th Congresses, there was an effort to establish data quality, peer review, and best available evidence-type procedures on a comprehensive basis across federal regulatory agencies. The issue was debated extensively. Expansive language did not get through the Senate. It did get through the House, however, and was incorporated in a reconciliation bill that was subsequently vetoed. What did become law was, in effect, a trial version of the concept to be applied to one rulewriting exercise under the SDWA. Congress did not accept the idea of applying such a process generically to all environmental, health, safety, and rulemaking by the federal government. But what OMB has done is to, through its guidance, in effect create a presumption—one that be policed by OMB and by the private sector—that the SDWA test should be applied to all risk assessments associated with health, safety, and the environment. If Congress wants to apply that policy, Congress can take action to apply that policy. If Congress applies it in one place, and refuses to apply it across the government, it is quite inappropriate for OMB to come in and essentially do administratively what it was unable to have adopted in an open process in Congress.

The DQA debate is reflective of a tension between private interests in access to markets that might be impaired by an airing of concerns about the quality of products, the quality of chemical compounds. Those are legitimate interests. But they have to be balanced against the interest of the public in being able to have the government respond promptly to concerns. The federal government does not have a history of excessively rapid reaction to perceived environmental, health, and safety problems. Consider as one of many examples the case of lead in gasoline. In 1922, the U.S. Surgeon General was asked to examine whether lead in gasoline would pose a risk, and the burden of proof effectively was shouldered by the government to find that there were problems. As the then-existing data were not of adequate quality to allow the government to so find, the Surgeon General took no steps to halt marketing. It went on the market, and we had a legacy of 50 years of kids being poisoned with lead because the data was not deemed to be of adequate quality until the late 1970s. That is a legacy that we could have avoided. Another example is the Surgeon General's report on tobacco in 1966. If the DQA had been in effect then, and if it had been implemented the way some of the advocates want to have it implemented today, I think we may not have seen that document, as well. That would, of course, have been a considerable loss to the public. I hope we do not have such results now.

MS. WAGNER: Thanks so much to the panelists for excellent presentations. We have some time for question and answer.

VOICE FROM FLOOR: I am in the Internet business. I think we bear some responsibility for a phenomenon over the last four or five years which has been to make it very easy for agencies to put a lot of data in places that a lot of people get access to before the data is verified. I am referring, not to the context of rulemaking and formal proceedings, but rather regarding agencies' penchant for utilizing their websites for self-promotion, and for the general dissemination of information. To what extent do any of you believe that the Act applies to links to a third-party site or to another agency site, or to studies or other data that the agency

is either aware of or in custody of that simply is of interest. Is the DQA going to be a means of challenging an agency's pointing to third-party data?

MR. HAWKINS: Well, I would hope not. I think the Internet has been a tremendous empowering feature. I think that the response to that data is public discourse, and open discussion of it, not suppression of the information on a prior restraint basis.

MR. NOE: OMB's guidelines exclude the kind of thing you're talking about. They state that information that is covered by the Act does [include] agency information on its web page, but it does not include the agency's provision of hyperlinks to information that others disseminate.

MR. O'REILLY: Prof. Jim O'Reilly, from the University of Cincinnati. Sid, in what context do you think the courts will be addressing the issue of whether the DQA extends to rulemaking? Do you think it will come up sooner, rather than later, and do you think it will be in the context of a particular health, safety, and environmental rule, or in some other kind of rulemaking? And I would appreciate the views of others on the panel. Thank you.

MR. SHAPIRO: I do not know, but sooner or later it is going to come up. Certainly, it would have been nice if Congress had addressed this issue, and made itself clear, because we are going to spend a lot of time litigating this issue, perhaps in several circuits before it is resolved, and that is what I meant by the perils performed by legislating through appropriations rider. If it has to be resolved, it will be resolved one way or the other, but I think this is an unfortunate way to do it.

MR. ANDERSON: I think the OMB rule is rulemaking, but I do not believe that the agency and OMB guidelines apply to rulemaking in the way that Professor Shapiro observed. I do not believe that the DQA was intended to trump the APA or any other specific statutory mandates for rulemaking. The OMB guidance on the circumstances in which information that is used in agency rulemaking might be examined under the Act was carefully worded to permit challenge only when a party faces immediate harm and the challenge will not unduly delay agency action.

Let us reconceptualize this issue. Information is important. It is power. It comes first, then underpins rulemaking. It has to be developed first for all federal policymaking. The statute addresses how information is developed, processed, disseminated, endorsed, and then finally relied on by the federal government. Most of the time information is going to be disseminated well prior to rulemaking. The statute will apply to information disseminated in advance of, or without regard to, any immediate rulemaking or policymaking. It is worth thinking for a moment conceptually about "parallel universes"—the universe of policy and rulemaking and how strict a regulation is going to be, and the universe of the scientific and technical substrate of sound policymaking. The statute, and its entire process, are designed to address that latter universe. The quality of information is a phenomenon in and of itself. I hope no party seeks opportunities to litigate over whether the DQA trumps 55 years of APA-based rulemaking. But don't we want to take an early and hard

look at the quality of information used to make policy, rather than years later, after a rulemaking has run its course?

MS. STEINZER: Rena Steinzer from the University of Maryland. I think actually, Jim, you have the most information about what is likely to happen in the courts, because you brought a case about dioxin even before the DQA was passed. It seems to me that the litigation is an example of what courts are likely to do when a challenger goes in front of them and says there are 20 epidemiological studies, and a meta-study, and some rodent data, and our concern is with page 82(a).

MR. TOZZI: That's a good point.

MS. STEINZER: You lost, right?

MR. TOZZI: Well, it depends on who you talk to.

MS. STEINZER: Well, you lost. You got standing —

MR. TOZZI: I got reviewability and I got standing, and I lost on the merits.

MS. STEINZER: They deferred to the agency, right?

MR. TOZZI: Yes. But it is possible that the outcome might be different under the DQA, as it sets a standard for judicial review beyond "arbitrary and capricious."

MS. STEINZER: Well, I wouldn't take it, except on an hourly fee basis.

MR. TOZZI: Well, today I agree with you.

MR. ANDERSON: I think there will be judicial review, but I also believe with Jim Tozzi that there will be a very flat pyramid with a few law suits at the top and down at the bottom a large number of challenges resolved at the agency level. As with the Shelby Amendment, I am not sure how to shape an issue for judicial resolution involved with the quality of data under the arbitrary and capricious standard with the expertise on information and analysis of data that exists in the agency. But would a court take a well-defined issue for review? I think so.

MR. HAWKINS: I would only say that as Jim has just articulated the objective of a litigant will be to try to convince a court that the DQA creates a bunch of new hoops that the agency has to jump through.

MR. FUNK: Bill Funk of Lewis and Clark Law School. I have a comment and then a question. The comment is that I agree with Sid that rulemaking is not "dissemination." However, it is also clear that OMB could, under the Paperwork Reduction Act itself, or under an Executive Order, impose the particular procedural requirements that it proposes under the DQA, but with an implication that there would not be judicial review. That would be a difference. You could get the substantive action by the agency, but no judicial review on rulemaking.

The DQA has no substantive standards whatsoever. It is solely a procedural statute. So whatever judicial review ob-

tains, there would only be a procedural issue as to whether or not the agency, in fact, went through the procedures that it was required to do under OMB. Now, OMB's guidelines require agencies to adopt substantive standards. So now we get procedures that impose substantive standards, then can you then get substantive standard review? I would argue no. There is case law about when you have to follow your own procedures and when you do not, and I think a good argument can be made that this is still, at this point, management, rather than trying to aid any particular participants in a process. So I do not think you can get around procedural review of real dissemination, but if that's a NEPA analysis, without having to cross the threshold of what is a significant impact on the environment, I do not think there's a lot of hooks you can get on it. There will be some litigation in the beginning, but I think it will end up sort of like the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, which is [making] a mountain out of a mole hill.

MR. HAWKINS: I suspect that what you're going to see is people point to the language in the statute that talks about the affected persons having a correction mechanism, and that will be the basis on which they argue that there was an intention here to deal with particular persons. We will do our best to try to persuade the courts that is a bad policy and not required by the statute.

MR. ANDERSON: Have a look at, not just the OMB guidelines, but also EPA and other agency guidelines in terms of what they say substantively about information. They are worth looking at, because of the tone of, say, the EPA guidelines. It is another world of public process that we are getting into. Those guidelines, among others, reflect it.

MR. MCGARITY: Tom McGarity, University of Texas Law School. Two years ago,⁸ a proposal was made by Alan Raul for a regulatory *Daubert* [referring to the Supreme Court case *Daubert v. Merrell Dow Pharmaceuticals, Inc.*⁹]. Raul proposed that the *Daubert* analysis that courts use in determining whether expert testimony is admissible be applicable to regulations promulgated by agencies. That is, he would apply substantive criteria of correctness of data, substantive criteria such as like reproducibility, peer review, that sort of thing. Forgive me for being a little cynical here, but it seems to me as though what is going on with the DQA is setting up those people who would like to go to court now, and enabling them to basically make regulatory *Daubert* challenges to agency rules, to the substantive merit of those rules. Are there going to be regulatory *Daubert* challenges in the context of rulemaking, and if such challenges are made, what is the Administration's position going to be on the substantive applicability of judicial review of rulemaking?

MR. NOE: Tom, if you want me to answer, I am happy to. I think if we get these guidelines implemented well, there is not going to be a big need for lots of judicial review. As I think you know, if Jim or somebody else files a lawsuit, the Administration will take a position in that lawsuit, and that

8. See E. Donald Elliott et al., *Science, Agencies, and the Courts: Is There a Crowd?*, 31 ELR 10125 (Jan. 2001).

9. 509 U.S. 579, 23 ELR 20979 (1993).

is going to be the role not of OMB, but the [U.S. Department of Justice]. So you may have to wait to consult with them about what the Administration's position would be. I would like to respond to a couple of criticisms David raised. He said that OMB should not have been able to ask the agencies to adopt or adapt general principles for good risk assessment along the lines of the SDWA, and I have a few things to say about that.

One, without dispute, the executive branch has the authority to ask agencies to adopt procedures. This has been done for over 25 years, through Executive Orders, for cost-benefit analysis. There is even some language in the Clinton [Executive] Order that we operate under on risk. The statute covers risk assessments, so we felt we should address that issue. Also, these risk assessment principles are very general. They basically say the agencies ought to use the best science and data that is available. They ought to be clear and understandable when they communicate to the public about risks. And when they do a risk characterization in the case of a quantitative risk assessment they should, to the extent practicable, provide some key information about what populations are affected by the risk, appropriate upper or lower bound estimates, what the most plausible estimate of the risk might be, and what some of the key scientific uncertainties might be, and how the agency resolved them.

We did not ask the agencies to adopt this verbatim, we asked them to adopt or adapt it, and the agencies uniformly did go to work to adapt them. And I could go on at length about the ways in which they did so. Here are a couple of examples. Almost all the agencies distinguish between quantitative and qualitative risk assessments, and for qualitative risk assessments they have much more streamlined procedures. They do not have the risk characterization component, the third component of the SDWA language I mentioned.

EPA has about five key ways in which they adapted this language, just to name one agency. They have a very detailed explanation about why they chose the language that they chose. The same thing for the [DOL]. They adapted this language to conform to their statutory mandates, and also to conform with their practices they use for doing risk assessments for safety assessments, and then they have separate procedures for health assessments. I could go on. EPA and NOAA have particular language adapted for ecological risk assessments. EPA also mentioned that we are going to adjust the good science and data clause to clarify that we will use peer review data when it is available, but not in all instances, while the SDWA basically creates a presumption you will always use it.

That is just a couple of ways in which agencies adapted this language.

David also said that the DQA will serve as a prior restraint on agencies getting out information, and again, the Act covers agency disseminations. So the information is out. The Act does allow the public to file a petition to ask for correction of information if they think it is of poor quality, but it doesn't say unless you do "x" you can never disseminate information. If the information is wrong, the agency may have to go back and correct it later, but that does not mean that as soon as someone files a petition it has to be removed from the website, or that the agency never could have disseminated it to begin with. I think that's an important point about how the law works.

MR. HAWKINS: Just one comment. The first sentence in the OMB guidelines says:

These guidelines direct the agencies to develop management procedures for reviewing and substantiating information before it is disseminated.

MR. NOE: That is correct. We have asked the agencies to develop pre-dissemination information quality review procedures which, by the way, is already occurring all across the federal government. But that does not mean that there is some kind of prohibition on disseminating information, and I think that was the implication of the comment.

MR. ANDERSON: I wanted to comment on all this in terms of transparency, a word that has been used a few times today. The SDWA provisions were quoted verbatim in the OMB guidelines and agencies were urged to "adopt or adapt" them. But what I took the OMB's purpose to be could have been done without reference to the [SDWA] by paraphrasing the same ideas and never mentioning the Act. What I thought OMB was doing was setting out standards for analytic clarity and transparency in environmental, health, and safety risk assessments. To the extent they could be used and focused by adopting SDWA language, fine, but if not, by adapting it. The point I'm trying to make has to do with analytic clarity—a clear statement of populations at risk, and a clear statement of what the uncertainties are involved in risk analysis, and a clear statement of supporting and conflicting data. Even if they are clearly wrong, let them be wrong clearly. [The] SDWA was a source, not an authority. With respect to the opaque process of having OMB and the agencies work on data quality, I think what OMB was trying to do, the way I read the October 4 memo, was get the agencies to use their websites to have everything in view of everyone. I have heard that there was back-and-forth inside OMB about whether or not to mandate this transparency, but questions about privacy, individual protections, and commercial information complicated, mandating that every challenge of every kind be put on the web for all to see.

MR. TOZZI: What's wrong with that, Fred? I don't see anything wrong with that.

MR. ANDERSON: No, I don't either, but that's a process that apparently took place. OMB has never had to implement a statute with a citizens challenge provision. "Affected persons" have a role to play. The meaning of "affected person" and administrative and judicial standing will have to be defined. How the appeals process works will have to be sorted out. But the point is, the OMB now has a statute by the tail that's very different than any other statute that it has implemented before.

You may think OMB's history of secrecy is awful, but let's look to the future—that's all we've got left. Where did the Ford Foundation and Rockefeller Foundation money come from that supports nonprofit organizations? This history is not pure, no purer than that of the statute. Let us just take this thing—it is the law—and try to make the best of it. I think it has a chance of becoming a good government statute. Try to make it work.

MR. BUZBEE: Prof. Bill Buzbee from Emory Law School. My question has to do with the ability of citizens or citizen groups to petition, seeking regulatory action, and how this statute might be used. If someone uses public health data, which often is qualitative data, case studies, nothing that is statistical, but there are suggestions of a possible link, and someone petitions the agency, seeking to have the agency act and look at the data, perhaps seeking rulemaking, perhaps seeking a revision of current policies or understandings, and someone else finds the information attached to that petition to be objectionable, how should the statute be construed there? Should it be construed that because of the broad petition rights that are constitutionally protected there is absolutely no ability to squelch that information; or do agencies now have an affirmative obligation to correct, in the sense of actually going out and doing their own data or investigation, or perhaps expunging it in some sense from the public domain? I find that—

MR. ANDERSON: But it has not been disseminated.

MR. BUZBEE: Once they receive it, most agencies will respond, most agencies will put it in a publicly available file, but many agencies will put it in their correspondence. Many agencies in recent years have put such information on websites, where you know what actions have been submitted.

MR. ANDERSON: Well, the agency has been “inseminated.” But no “dissemination” occurred. The question is, whether the agency endorses, or makes its own further proposals, in which case there is an agency “laying on of hands” and “dissemination.”

MR. BUZBEE: So you read dissemination to mean endorsement by the agency.

MR. ANDERSON: The question of “third-party data” is a very big one, nevertheless, in this way: if the DQA requires disseminated information to be of high quality, then what about the information that it receives from consultants, the academic community, the business community, and non-profit organizations. If the agency is someday going then to rely on their information, should not they all meet the same standards? EPA now has out for public review a set of third-party data “assessment factors.” These assessment factors are potential criteria—barriers if you will—to the third-party data that stakeholders might submit. It is interesting to look at the EPA assessment factors proposal, because while EPA cites the DQA, the assessment factors aren’t the same as “y” words. I’m sure this will all be sorted out, and EPA has already asked the [NAS] to host a workshop on this, but the third-party data question is a big one.

MR. CONRAD: Jamie Conrad with the American Chemistry Council. Much of the discussion we’ve heard today has been about the potential for this Act and guidelines to tie up, delay, ossify, what have you, the regulatory process, and I suppose my initial reaction is sort of like Bill’s and Fred’s, and this is much akin to what was said about SBREFA and the Congressional Review Act, and the Unfunded Mandates Review Act, and all the other laws that basically had no effect at all. And if one reads the guidelines, it becomes hard to

see a lot of cases where you could say “that’s a violation.” David, do you really see no utility in this statute for nongovernmental organizations, or are you just sort of soft-pedaling that, so as not to water down the sort of moral fervor?

MR. HAWKINS: If I had a choice of having this law or not having it, it would be a very easy choice. I would not have it. I think the cost and benefits of this law operate against the public interest. There is a law of gravity that operates with the interaction of private entities and the government. It is much easier to use judicial challenges to stop government action, to preserve the status quo, than it is to move a program. If we seek judicial review of an inadequate rule, we always face the choice of, gee, maybe we should just take this rule, even though it is inadequate, rather than sending the agency back to the drawing board. So there is a win/lose proposition for us there, there is some tension. That’s typically not the case for many of these private sector challenges where the status quo is victory. For us, the status quo is not victory.

MR. PARKER: Richard Parker, University of Connecticut Law School. If agencies are confronted, as they often are, with different studies that yield different conclusions, and the science is unclear, they say the science is unclear, but we are going to apply the precautionary principle because there are serious risks. We are going to adopt conservative assumptions. Is that good policy or not? There is a very strong conservative argument that the precautionary principle is just a cover for bad analysis, and if that is the case, that really colors the way the DQA will be interpreted and litigated. With regard to transparency, I have heard arguments that putting all the submissions, complaints, and petitions on an agency’s website is going to greatly help transparency. But what about the chilling effect of pre-dissemination quality review to begin with? Agencies are notoriously hassle-averse, and if they see hassles associated with posting any studies that they can avoid posting that they are at all unsure about, they are likely just not to post the study, and the result will be that scholars, scientists, people who might have very good information to share that will actually improve the analysis will find it much harder, if not impossible, to actually see the data integrated at the time that it would be most helpful.

MR. HAWKINS: I share the latter concern. Every time you create a new set of check boxes before the agency can do something, you increase the risk of the agency not doing it.

MR. NOE: Just on that last point, I would just say that it is very important that everybody understand that the DQA does not require perfect information, or anything close. When we talk about the transparency the Act is leading to, I think it goes to the notion that the agency is supposed to set its own performance standards that are appropriate for the intended uses of the information. And these might even be fairly low standards. There is not a simple answer that this will chill agency disseminations, because in fact, under the systems the agencies are setting up, there may be a very low hurdle, and I think there will be for most of the information that they disseminate. We only ask in the case of the truly

important influential information that they have higher standards of quality.

MR. HAWKINS: But Paul, with respect, that ignores Richard's point, which is the very agency decision to select a low hurdle itself can be the subject of a dispute, and you created a mechanism for the agency, having its resources distracted, to have to deal with these kinds of contentions, and if the agency has the discretion to not get into it, you have created an incentive for them to not get into it, and to not share information that otherwise might be shared.

MR. TOZZI: I think that is true if the agency is dealing with some marginal information, but are we suggesting it is better to have bad information than no information? If it is half-cooked data, they ought to have some standards.

MR. HAWKINS: It is better to have imperfect information than no information.

MR. TOZZI: Well, it is not wrong having imperfect information. It is, however, when you take a very large amount of data and make a single point estimate with no uncertainty—that is when you violate the standards of the Act. But if you come up and say, hey, I have studied this and the range of impacts could be from within a specified range, you will satisfy the DQA. It is a question of when you push the data too far.

So my answer to your question is, if you want to get it out, get your data out, you could come around that hurdle very easy. Just put a wide range of uncertainty on your data. Say, this may be the central barrier, but it can range between this and that. The bar is rather low.

MR. NOE: I would like to quote my friend, Alan Morrison, from what he said at one of the [NAS] workshops to agency staff. He said: OMB is your friend on this score. It agrees with you. It recognizes the dangers of putting excessive burdens, and reserves for the few, not the many, the label of influential information.

Part of this rationale is because the added burdens that will be put on agencies if challenged when information is deemed to be influential.

MR. SHAPIRO: I thought the ABA resolution actually drew the line in a better place. What the ABA, the House of

Delegates, said was that as to significant information products, agencies ought to notify the public before they are disclosed or disseminated that we have this information, and we are going to put it up on the web or someplace, and we want to hear what you have to say about it. This is all beforehand, so everybody gets a chance to make input.

After information is disseminated, what the ABA said is that any kind of appeals mechanism ought to be limited to objective information. So if [the Occupational Safety and Health Administration (OSHA)] puts up, as it does, inspection statistics about employers, and it says there has been a violation at the plant in Bethlehem, and the employer calls up and says, "we do not own a plant in Bethlehem," then OSHA ought to correct that information. But as to these disputes over the policy inferences which one draws from information, those are policy arguments, and I think, as David Hawkins said, the way to battle those out is to battle them out in public, rather than to give corporations the opportunity to collaterally attack, perhaps in court.

MR. ANDERSON: One of the things that emerged at the [NAS] panels is the idea that a process specifically to disseminate information for public vetting could be created. EPA already does this. Naturally, EPA had to come up with a special acronym for it that sounds like something from *Star Wars*—the [Notice of Data Availability (NODA)]. The NODA contains information that EPA knows already is going to be pivotal in connection with subsequent policy-making, probably a rule. The NODA enables a public vetting in that parallel universe that I was talking about.

MR. PARKER: Are NODAs exempt from this pre-quality dissemination requirement, or quality review?

MR. ANDERSON: I hope not. I do not see how they could be. Why?

MR. PARKER: Well, the whole purpose of the NODA is to improve your information by disseminating it. The purpose of the dissemination is to improve the information, not to assert that this information is already there.

MR. ANDERSON: I see. You have a point.

MS. WAGNER: Thank you again for being such a terrific panel.