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EPA RULEMAKING: DO BAD ANALYSES LEAD TO IRRATIONAL RULES?

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

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EPA RULEMAKING: DO BAD ANALYSES LEAD TO IRRATIONAL RULES?

THURSDAY, NOVEMBER 8, 2001

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATORY REFORM
AND OVERSIGHT,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to call, at 10:25 a.m. in room 2361, Rayburn House Office Building, Hon. Mike Pence (chairman of the subcommittee) presiding.

Chairman PENCE. The Subcommittee on Regulatory Reform and Oversight will come to order on the topic of EPA Rulemaking: Do Bad Analyses Lead to Irrational Rules?

I would like to apologize to the gentleman from Illinois and also to the distinguished panel of witnesses that we have for my tardiness. Ironically, I was attending a briefing with EPA officials regarding the cleanup of my congressional office from an anthrax contamination, which suffice it to say that there are good things the EPA does. Today we may hear a different perspective from some of our witnesses, but I am grateful for my colleague's patience and for the patience of all of those attending.

On June 21, I convened a roundtable on regulation to hear more than 30 small business trade associations describe for this Chair the struggles that they and their membership face from the regulatory state. Despite the diversity of concerns raised at the roundtable, one constant theme was evident; the inadequacy of the regulatory analyses that agencies use to support rulemakings. One agency in particular that was singled out for its poor regulatory analyses was the Environmental Protection Agency. Today's hearing will attempt to address those flaws.

Small business owners are very familiar with burdens that federal regulations place on them. Many studies, including those sponsored by the Office of Advocacy of the United States Small Business Administration, have shown that small businesses face disproportionately higher costs to comply with federal regulations, including those issued by the EPA, than their larger business counterparts.

Thus, accurate estimates of cost, if derived from the experiences of large businesses, may paint a false picture of the economic impact of an EPA regulation on small businesses. If the EPA misjudges the economic impact, will it produce a rational rule if the vast majority of businesses in America cannot comply?

The polestar of the rulemaking process is that the regulations must be rational. When Congress passed the Administrative Procedure Act in 1946, it believed that the process of notice, comment and agency response to the public comment would be sufficient conditions to insure a rational outcome.

After the regulatory onslaught of the 1970s, which saw the creation of the EPA and the enactment of many statutes that EPA implements by rulemaking, Congress and the executive branch determined that further refinements were necessary. Congress imposed new analytical requirements to assess the impacts on small businesses and other small entities. Presidents Reagan, Bush and Clinton produced Executive Orders mandating analysis of costs and benefits beyond those required by the Administrative Procedure Act or specific statutes such as the Clean Water Act.

In 1980, Congress enacted the Regulatory Flexibility Act. The Act represents another tool in the decisional calculus designed to develop rational rules. The RFA requires federal agencies to consider whether their proposed or final regulations will have a significant economic impact on a substantial number of small businesses. If the regulations do have a sufficient impact, the agencies are required to consider whether less burdensome alternatives exist that achieve the same objective.

The authors of the RFA expected that if an agency had two equally effective alternatives to achieve its regulatory objective it would logically select the one that is less burdensome on small businesses. Of course, a critical element of this analytical filter is the agency's proper assessment of the impact of the regulation on small businesses.

If the agency's cost estimate is incorrect, then its assessment of the burdens on small business will not be accurate, and the agency will not seek more effective cost alternatives. Therefore, the analytical requirements of the Administrative Procedure Act and the Regulatory Flexibility Act are crucial. They have been supplemented by regulatory review mandates by each President since 1980.

While the details are somewhat different, each Executive Order requires federal agencies like the EPA to conduct cost-benefit analysis for significant regulations, usually those with more than $100 million impact on the economy. If the costs of the proposed or the final rule outweighs the benefits, then the regulatory action would be detrimental to the overall welfare of society, and the rational policy maker, barring statutory imperative to the contrary, would not seek to implement that particular regulation.

More importantly, regulatory analysis which demonstrates that the cost of a particular regulation outweigh the benefits should give policy makers greater pause. That should be a signal for them to seek other alternatives to meet their statutory objectives, but that do not impose unnecessary costs on society or commerce. Thus, inadequate and incorrect regulatory analyses, including the scientific underpinnings of the estimates of costs and benefits, are detrimental to rational rulemaking and that mandated by the Administrative Procedure Act.

Today's hearing focuses on a cross section of regulations from the EPA that highlight the problems that can arise from incorrectly constructed regulatory analyses. They often lead into a realm of ir-

rational rulemaking such as the proposed cross media electronic reporting and record keeping rule, which would in essence require replacement of a substantial amount of existing information systems that currently keep track of more than 216 pages worth of EPA mandated record keeping. Proper application of the tools available to the EPA should eliminate such results.

I look forward to the recommendation of all of our witnesses today on the corrective actions that the EPA can take to avoid poor analyses and would now turn to the Ranking Minority Member who joins us today, the gentleman from Illinois, for any opening comments that he might have for this panel or on this topic.

Mr. PHELPS. I do not have any. I am just anxious before the vote to hear from this panel. Thank you.

Chairman PENCE.. Thank you very much.

With that, I will introduce Randall Lutter or Lutter?

Mr. LUTTER. Lutter.

Chairman PENCE. Lutter, thank you, is a resident scholar at the American Enterprise Institute and a fellow at the AEI-Brookings Joint Center for Regulatory Studies. He previously served as senior economist for the environment and regulation on the President's Council of Economic Advisors and as staff economist for regulatory affairs at the OMB.

Mr. Lutter is recognized for five minutes. We thank you for being with us today.

STATEMENT OF RANDALL LUTTER, RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE, AND FELLOW, AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

Mr. LUTTER. Thank you, Mr. Chairman. Thank you, Members of the Committee. I am pleased to appear before you to provide my views on how to improve regulatory analysis at the Environmental Protection Agency.

For more than ten years I have worked inside and outside government on regulations to reduce risks. I am now with the AEI-Brookings Joint Center for Regulatory Studies. A primary objective of the Center is to hold lawmakers and regulators accountable by providing thoughtful, objective analyses of existing regulatory programs and new regulatory proposals.

You have asked me for my views on whether EPA's benefit-cost analyses are adequate to support sound rulemaking. I would like to start by making a distinction between two separate purposes of these analyses. One is to inform decision makers at EPA and elsewhere in the Administration about the economic effects of regulation.

From the perspective of the decision makers who already control the resources and have the authority to get the quality of analyses that they want, these analyses may well be adequate. They have control of the resources, and they can get the answers to the questions that they are interested in learning the answers to.

A second purpose of EPA's regulatory analyses is to inform Congress and the public about the economic effects of its regulatory decisions. A significant number of EPA's analyses are inadequate for this purpose, primarily because the incentives for EPA to prepare high quality analyses are poor. As an institution, EPA faces incen-

tives to overstate the net benefits of its rules, particularly those rules that have very small or negative net benefits.

The biggest cause of poor economic analysis at EPA is the lack of incentives for more forthright research. The absence of independent review of EPA's benefit-cost analysis illustrates the lack of incentives. Courts rarely review EPA's benefit-cost studies because environmental laws generally authorize EPA to regulate without full consideration of the benefits and the costs.

No government body outside the executive branch assesses analytic quality. There are private sector critiques of EPA analyses, but these are often ineffective because they also comment on the regulations themselves. Independent observers tend to think that such comments on the regulations motivate the critiques of the analyses rather than the other way around.

I would like to make four specific recommendations on how EPA's regulatory analyses could be improved. First, Congress should create a separate Office of Policy Analysis within EPA and charge that office with doing all risk assessments and all benefit-cost analyses of significant regulations.

Currently, EPA program offices charged with administering particular programs oversee most of the economic analysis supporting these new regulations, but these offices suffer from a conflict of interest; tunnel vision, if you will. The air office naturally supports air regulations. This conflict of interest could be substantially mitigated if there were a separate office in charge of regulatory analyses within EPA.

Second, Congress should require that EPA's benefit-cost analyses adhere to established principles for high quality.

The Office of Management and Budget, where I used to work, has developed guidelines for doing sound regulatory analyses, yet it is clear from a careful review of EPA's economic analyses that the agency has not taken these guidelines seriously. To add political weight to the guidelines, Congress should adopt the kinds of principles contained in them and require that an agency such as OMB certify that EPA adheres to such principles.

Third, Congress should ask an agency other than EPA to conduct peer review of the economic analyses and of the risk assessments supporting EPA's significant rules.

Most of the economic analyses in the risk assessments supporting EPA's decisions do not go through any sort of outside peer review. Peer review may be no guarantee of absolute quality, but mandatory peer review of EPA's analyses of economically significant rules could provide an important new incentive for EPA to improve the quality of its analysis.

Fourth, Congress should fund regulatory analysis at the General Accounting Office in accordance with the Truth In Regulating Act of 2000.

It is important that there be a federal office outside the executive branch that is capable of assessing the analyses supporting federal regulations and the regulations themselves. The reason that the Truth In Regulation Act project is appropriate in discussing the improvement of regulatory analysis at EPA is that EPA is responsible for a very large share of all costs associated with new federal regulations. Congress could use the information generated by the Gen-

eral Accounting Office to improve regulation and the regulatory process.

In conclusion, a significant number of EPA's benefit-cost analyses, while technically very sophisticated, fail to comply with established principles for sound analysis. Improving the quality of the analysis requires establishing incentives for the agency to do high quality work.

There are four steps likely to be effective. Congress could create a separate policy office to conduct the analysis, it could mandate adherence to sound analytic principles in each of the benefit-cost analyses and risk assessments prepared by EPA, it could ask an agency other than EPA to conduct peer review of EPA's economic studies and the associated risk assessments, and it should fund the Truth In Regulating Act research at the General Accounting Office.

Thank you very much. I would be happy to take any questions.

[Mr. Lutter's statement may be found in the appendix.]

Chairman PENCE. Thank you, Mr. Lutter.

Now Fern Abrams, who is the director of environmental policy for IPC, which is the Association Connecting Electronics Industries, responsible for advocating a number of positions in the areas of environment, health and safety. Prior to joining IPC, she served as manager of environmental affairs at the American Trucking Association, where she focused in particular on Clean Air Act and hazardous water issues.

We thank you for being with us today. You are recognized for five minutes.

STATEMENT OF FERN ABRAMS, DIRECTOR OF ENVIRONMENTAL POLICY, IPC—THE ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES

Ms. ABRAMS. Good morning, Chairman Pence and Members of the Committee. My name is Fern Abrams. I represent IPC, the trade association for the electronic interconnection industry.

Our 2,800 members manufacture and assemble printed circuit boards, which are the backbone of the nation's high tech industries, including consumer, industrial and defense electronics. On behalf of our members, I would like to thank you and your staff for organizing this important hearing.

Ninety percent of IPC members that manufacture printed circuit boards are small businesses. As you know and stated in your opening, the cost of regulatory compliance often has a disproportionate impact on small businesses. Environmental regulations must be based on sound scientific and regulatory analysis so that they do not create unnecessary burdens while failing to achieve their goal of environmental protection.

IPC members, along with many other industries affected by the EPA's proposed effluent limit guidelines for industries that manufacture and maintain metal products, or more commonly known as MP&M, are deeply concerned that the agency has overestimated the benefits of the proposed regulation while significantly underestimating the economic impact.

The Clean Water Act requires that effluent limits be based on best available technology that is economically achievable, yet the agency has proposed limits that are neither affordable nor achiev-

able. A review of discharge monitoring data indicates that none of the facilities on which the proposed limits are based could meet the limits consistently. In fact, some of the proposed limits are so low that incoming drinking water would not meet them. These are not achievable limits.

The proposed limits also fail to credibly meet the requirement that they be economically achievable. The agency has significantly underestimated the cost of compliance. Their errors include faulty assumptions concerning technology capabilities, monitoring costs and facility space constraints, just to name a few out of dozens. For example, the agency has incorrectly assumed there will be no increase in monitoring costs when IPC member expected increases range from $1,000 to $350,000 per facility.

The agency's economic analysis also fails to meet common sense inspection by projecting that many firms will remain profitable despite facing compliance costs that are several times greater than their profit margins. This unreasonable analysis is made possible only because the agency's economic analysis assumes that compliance costs will be passed on to customers through a 90 percent increase in prices.

This assumption was apparently based on analysis of other unrelated industries conducted over five years ago in a vastly different economic climate. In reality, over 72 percent of our members have stated that they would not be able to raise their prices at all.

In addition, the rule's economic analysis assumes that 50 percent of printed circuit board facilities will be able to remain in business without being able to replace worn out equipment or modernize for 15 years. That is an astounding assumption, given that printed circuit board manufacturers must constantly invest in new equipment to meet customer demands for increasingly smaller electronics.

In addition to underestimating the cost of the proposed regulations, the agency has significantly overestimated its environmental benefits. Unlike previously effluent limitations rulemakings which use actual facility wastewater data to estimate the benefits of the proposed rule, the agency relied upon models to simplify the task of estimating costs and pollution benefits of this complex regulation covering 18 different industrial sectors under 200 SIC codes.

By using inadequately detailed models populated with data borrowed from unrelated industries, the agency has fabricated an environmental benefit that does not exist. Pollution removals calculated from actual facility data are 98 percent lower than those predicted by the agency's flawed models.

In conclusion, we believe that the agency has not demonstrated that the rule is cost effective. The agency has estimated the social costs of the proposed rule are $2.1 billion annually, while the total benefits that can be valued in dollar terms in categories traditionally analyzed for effluent guidelines are only in the range of $400 million to $1.1 billion annually.

The agency should not promulgate a rule with costs that exceed its benefits. The agency should follow the recommendations of the Small Business Regulatory Enforcement Fairness Act panel and remove from this rulemaking industries for which regulation is not cost effective.

Fortunately, the MP&M effluent limits have not yet been finalized. In fact, the agency has been working constructively with affected industries, including printed circuit boards, to try to improve the quality of its regulatory analysis prior to issuance of a final rule.

Going forward, the agency must make a better effort to get regulatory analysis right the first time around. It should not be standard practice to propose a rule based almost entirely on faulty analysis and poor assumptions and then depend on industry to try to uncover mistakes in the very short time for public comment. A more open regulatory process with regular data exchange between the agency and affected industries, combined with the early use of reality checks, would make both proposed and final rules more accurate and effective.

Thank you again for giving IPC the opportunity to express our concerns, and we welcome any questions.

[Ms. Abrams' statement may be found in the appendix.]

Chairman PENCE. Thank you very much, Ms. Abrams.

We have a journal vote on the Floor. What we will do is recess very briefly and do so now. That will permit me and the gentleman from Illinois to go and record our vote. The Chair will return. I know Mr. Phelps will return if his schedule permits, and we will continue with the testimony.

I thank you for your forbearance, and we will return quickly.

[Recess.]

Chairman PENCE. We will return to our testimony in this hearing of the Subcommittee on Regulatory Reform and Oversight.

Andrew Bopp has been the executive director of the Society of Glass & Ceramic Decorators since 2000. He previously served as SGCD's director of communications from 1995 forward. Mr. Bopp was also communications director for the Association of Incentive Marketing in Union, New Jersey, and is gratefully recognized for five minutes. Thank you for your patience.

STATEMENT OF ANDREW BOPP, EXECUTIVE DIRECTOR, SOCIETY OF GLASS & CERAMIC DECORATORS

Mr. BOPP. Thank you. Thank you for the opportunity to testify on the TRI lead rule today. As you said, my name is Andrew Bopp. I am the executive director of the Society of Glass & Ceramic Decorators. We are the trade association of companies that decorate glass and ceramic tableware, souvenir mugs and other items. This is a sample of what our members produce, this type of thing.

S.G.C.D. represents 650 companies and a manufacturing segment that is facing increasingly fierce competition from overseas production facilities, especially in China. Most SGCD members are small, often family owned companies that have more in common with the average local print shop than with a large industrial facility. Many of these companies are into their third generation of family ownership. SGCD has members in 37 states, including Indiana, Pennsylvania and Illinois.

The colors used by glass and ceramic printers contain various metal bearing borosilicates. Some colors cannot be produced without lead. When fired, they become chemically part of the glass or ceramic ware. Almost all of these lead bearing colors are used to

produce the product. Very little ends up as waste. SGCD and member companies work closely with FDA and other federal and state agencies to guarantee the safety of all wares.

I am testifying today to point out major flaws in EPA's economic analysis of changes to its toxic release inventory reporting threshold for lead and lead compounds. It is important to note that SGCD has made every attempt to work with EPA as it developed the rule. This included testimony at the agency's December 1999, hearing after the original TRI rule was issued. It is obvious, however, that the economic analysis was developed without any consideration of the rule's impact on glass and ceramic decorators.

I can understand why EPA would balk at evaluating every industry that might possibly be required to complete TRI reports under the new standard. However, EPA listed stone, clay, glass and concrete products, SIC 32, as being among the five largest lead reporting groups in the 1998 TRI reporting year at the 10,000 pound threshold.

Even after recognizing the significance of this industry group, Mr. Chairman, EPA chose to examine glass and ceramic decorators as part of a wide range of unrelated industries. This was done even though the other four top 1998 filers were evaluated separately. In so doing, EPA failed to consider the situation in the glass and ceramic industry where TRI reporting burdens and costs are dramatically greater for small companies than large companies.

It is possible that in some industries the differences in tracking lead usage may not be great between companies of varying sizes. However, the use of lead bearing colors in the glass and ceramic decorating industry is fairly unique. It is important to first note that every lead bearing color may contain a different quantity of lead. Every decorator must trace every lead bearing color used and make different calculations for that color.

You must also consider that large glass and tableware plants produce and decorate millions of matching plates, bowls, glasses and related items using a limited number of colors. These colors are likely to be used in large quantity, though. Some of these colors do contain lead, and the steps required to trace the lead used are confined to the numbers of colors used. Such tracking and reporting can be handled efficiently by a large decorator that employs an environmental compliance department.

On the other hand, the small contract glass and ceramic decorator fills orders that typically number in the dozens or hundreds of pieces. These small plants may use a greater variety of colors in a day than a large decorating facility will use in a month.

It is important also to note that none of these small businesses employ environmental compliance staff to handle such complicated burdens. There is no indication that EPA even considered the possibility of such a situation for small glass and ceramic decorators. As a result, EPA's estimate of the time necessary to compile and complete the TRI forms of 111 hours per year does not remotely correspond with reality for small glass and ceramic decorators. Remember, this is a rule that is supported by more than 500 pages of instructions and guidance.

As a further result, EPA's compliance cost estimates are correspondingly low. This directly affects the number of companies

that the agency believes will feel an impact beyond the one percent and three percent annual revenue thresholds that are used to determine the rule's small business impact.

To add insult to injury, EPA's economic analysis also includes the ridiculous assertion that there will be no first time filers in SIC 32 based on their research efforts such as they are. In reality, there are hundreds of small decorators that have never completed a TRI form for lead or any other TRI substance who must now comply.

Problems started when EPA failed to conduct small business outreach before first issuing the TRI proposal. From the appearance of the agency's economic analysis, it is obvious that SGCD's efforts to work with the agency after that point were ignored.

I also want to point out that the drastic reduction in the lead TRI threshold from 10,000 pounds to 100 pounds is based on a scientific premise that EPA has still not sent for independent peer review as it had promised. Given the massive effort and costs required to comply with the new TRI rule, one must ask what purpose do reports of this low threshold serve. There is no evidence whatsoever that glass and ceramic decorators present an environmental problem in their operations.

In conclusion, I urge the Committee to require federal agencies to meet with and learn from small businesses before regulatory proposals are issued. Early outreach will insure that federal agencies properly assess small business impacts and develop proposals that are tailored to meet agency objectives with the smallest business impact.

In terms of the TRI proposal, EPA's failure to conduct early small business outreach and the resulting inadequacy of its economic analysis deprived small businesses of the opportunity to have their unique situations considered. Due to these omissions and the large number of scientific uncertainties, I urge you to request the agency to reconsider the lead TRI rule to comply with the letter, as well as the spirit, of SBREFA while also conducting a prompt and thorough review of the scientific premise upon which the rule is based.

Thank you for the opportunity to testify before you today, and please ask if you have any questions.

[Mr. Bopp's statement may be found in the appendix.]

Chairman PENCE. Nicely done, Mr. Bopp. Thank you. We will have questions, I and my colleague, for each of you at the conclusion of the testimony.

James Conrad, Jr., is counsel with the American Chemistry Council, where he provides legal and policy advice to the regulatory and legal innovation team. Jamie leads the council's advocacy regarding environmental innovation, legislation programs, compliance and enforcement issues, governmental management of environmental information and the use of information as a regulatory or policy tool. He spent eight years in private practice with the Washington, D.C., office of Davis, Graham, Stubbs & Cleary where his practice encompassed regulatory advocacy counsel and litigation. He also developed and edits the Environmental Science Desk Book, which is published by West Group.

With gratitude, he is recognized for five minutes.

STATEMENT OF JAMES CONRAD, JR., COUNSEL, AMERICAN CHEMISTRY COUNCIL

Mr. CONRAD. Thank you, Mr. Chairman and Mr. Phelps. I am pleased to testify before you today regarding EPA's recently proposed Cross Media Electronic Reporting and Record keeping Rule or "CROMERRR".

While many American Chemistry Council members are Fortune 500 companies, we estimate that between a third and a half of our members—or between 60 and 90 percent—meet the SBA standards for a small business. Many of these members have only a single manufacturing plant. These smaller companies stand to benefit the most from the efficiencies made possible by information technologies. Most of these companies already keep records electronically.

Unfortunately, CROMERRR would do nothing to help that process. In fact, it would have the opposite effect, driving businesses back to using paper records. It would also cost $48 billion in initial costs—and that is based on EPA's own numbers.

What exactly is CROMERRR, and why is it so expensive? In a nutshell, the proposal imposes elaborate technical requirements on electronic information systems to guard against the remote prospect that data might be tampered with. For example, records must have secure, computer generated, time stamped audit trails that identify anyone who ever created or modified the record, when they did it and what changes they made. No off-the-shelf software does this now.

Mr. Chairman, the Food and Drug Administration imposed essentially the same regulation on drug companies in 1997. Most of them are still struggling, four years later, to comply with it. The average cost of compliance with this rule for drug companies is over $100 million apiece.

E.P.A. and authorized states regulate a lot more entities than the FDA does. In fact, EPA's own cost-benefit analysis estimates that about 1.2 million facilities file reports under EPA administered laws. These facilities keep a lot of records for EPA as well. What will it cost for these 1.2 million facilities, most of them small businesses, to comply with CROMERRR?

E.P.A.'s own analysis estimated that the up-front costs, on average, would be about $40,000, with annual costs thereafter of $17,000. $40,000 times 1.2 million facilities is $48 billion up front. That is almost seven times EPA's annual budget. $17,000 times 1.2 million is $20 billion in annual costs. That is over four times what the OSHA ergonomics rule would have cost annually.

Now, EPA's cost-benefit analysis does not contain these $48 billion or $20 billion figures because EPA contends that CROMERRR is entirely voluntary. In fact, their cost-benefit analysis assumes that very few companies would even adopt these requirements because of the great cost. The problem, though, is that most people would have no choice but to comply.

We are not accusing EPA of dishonesty. They just did not analyze their own regulation well enough to understand how it would work. Here is how it would work. Under CROMERRR, as long as a piece of information has ever passed through a computer, at any time in its life, it is an electronic record.

Next, the proposal says that any electronic record has to meet all the technical requirements of CROMERRR or else that record no longer satisfies the obligation to keep records. You are basically in violation of your record keeping obligation. You either comply with CROMERRR, or you switch to paper. What an ironic result: an EPA rule designed to implement the Government Paperwork Elimination Act driving people to using paper record keeping.

What is worse, if a regulation is generated by a computer in the first instance, then it is an electronic record from the get go, and printing it out on a piece of paper does no good.

For example, one of our smallest members has only 100 employees in two plants. In one of those plants they monitor the pressure on a pump in their air pollution control equipment. That data is generated by an electronic sensor, and it goes directly into the company's distributed process control system. Under CROMERRR, that data is an electronic record from the moment it is created, and paper is not an option to comply. That company would potentially have to redo its entire electronic control system.

Mr. Chairman, we agree that EPA has some legitimate concerns about protecting the integrity of data, but insuring integrity has an impact, and how much impact depends upon how secure the system needs to be. That is why OMB's guidance for implementing the Government Paperwork Elimination Act calls for agencies to do a risk analysis to decide how much security is appropriate. That guidance specifically says not to adopt a one-size-fits-all approach. EPA never completed that analysis, and they ended up instead adopting a single, high-security approach.

It may be too late for the drug companies that are spending hundreds of millions of dollars to comply with another rule that was also supposed to be voluntary. Let's not make the same mistake twice. We encourage EPA to withdraw CROMERRR immediately so that they can sit down with regulated entities large and small and learn about how these entities keep records and what sort of a problem there is, if one at all, in this case. The American Chemistry Council is ready and willing to engage in that discussion.

Thanks very much. I would be happy to answer any questions.

[Mr. Conrad's statement may be found in the appendix.]

Chairman PENCE. Thank you, Mr. Conrad.

Our final witness is the vice-president of environmental activities at the American Bakers Association, Dr. Anne——

Ms. GIESECKE. Giesecke.

Chairman PENCE [continuing]. Giesecke. Thank you for your assistance.

As vice-president of environmental activities with the American Bakers Association, Dr. Giesecke has been in charge of identifying and managing environmental issues and projects related to the baking industry. Dr. Giesecke is on the governing boards of the American Society of Baking and Baking Industry Sanitation Standards Committee. Her career focus on environmental issues began in 1980 with the Department of the Interior and continued with the U.S. Environmental Protection Agency as an environmental specialist from 1986 to 1991. She is the author of more than 60 articles related to resource management published in a variety of law

reviews and environmental journals and is gratefully recognized for five minutes.

STATEMENT OF ANNE G. GIESECKE, VICE-PRESIDENT, ENVIRONMENTAL ACTIVITIES, AMERICAN BAKERS ASSOCIATION, AND CO-CHAIR, CLEAN WATER INDUSTRY COALITION

Ms. GIESECKE. Thank you, Mr. Chairman and Mr. Phelps. On behalf of the Clean Water Industry Coalition chaired by myself and Meg Hunt of Edison Electric—we call it CWIC—we would like to thank you for this opportunity.

CWIC is made up of more than 250 companies and associations representing the nation's major manufacturing and service industries. CWIC is pleased that this Subcommittee is exploring the quality of EPA regulatory analyses and whether those analyses are adequate to support rational rulemaking.

At the onset, it is important to remind everyone that millions of people working to make our economy function share basic American environmental, health and safety values and want them applied to their workplaces, their homes and their communities. We certainly support strong environmental and health rules that are founded on sound science and developed in a deliberative and public process that includes working with the states and the regulated community so that the requirements achieve the rules' goals and are both effective and cost conscious.

The members of CWIC, and I would like to acknowledge the National Association of Manufacturers for their help with this testimony, believe that last year's rulemaking pursuant to the Clean Water Act to revise the total maximum daily load, TMDL, regulations was hastily issued and seriously underestimated the available science and the economic impacts on state and local governments and the regulated community.

Among the rule's many problems, it did little to address serious concerns with current 303(d) lists of impaired waters arising out of poor or nonexistent available water quality data, thereby establishing a potential for a gross misallocation of scarce resources. The Clean Water Act requires each state to identify waters that are not meeting water quality standards after the application of technology controls on point source dischargers. The resulting list is often referred to as the state's 303(d) list, and states are required to establish total maximum daily loads, TMDLs, for all waters on this list.

Establishing a TMDL requires a state to determine how much reduction each point and non-point source of pollution on the water body must make for water quality standards to be met. It is a complex, difficult and expensive calculation that needs science based monitoring data to be effective and presents a resource management issue for the federal government, the states and the regulated community.

We believe, therefore, that the process should be targeted toward those waters clearly established as impaired based on good data and upon sound scientific analysis. Manufacturers, particularly those of us in the food sector, need a clean, abundant and affordable water supply.

CWIC has supported many state and local concerns expressed during this rule writing process. For example, the Association of

State and Interstate Water Pollution Control Administrators, ASIWPCA, the national professional organization of state and interstate water quality program officials, stated in their June 20, 2000, comments to EPA that, "State TMDL development and implementation to date clearly demonstrates that the cost estimates developed by EPA are inadequate, incomplete and misleading. Far more will be required to develop a TMDL than the $25,000 the EPA envisions."

ASIWPCA members testifying before Congress have estimated the costs to states of preparing nearly 40,000 TMDLs over 15 years, as presently required, to be between $1 billion and $2 billion annually. Moreover, in a recent draft cost report mandated by Congress, the National Cost of the TMDL Program, the EPA estimates that the average annual cost for developing TMDLs will be $63 million to $69 million.

In a recent General Accounting Office study, only six states responded that they have a majority of the data needed to fully assess all their waters. Forty-five states reported a lack of resources, and several states pointed out that they are operating under state imposed staffing restrictions. Others said that they are limited in how many samples they can analyze because of the shortage of laboratory funding. EPA staff admitted that fewer resources are being devoted to monitoring and assessment at the state level than ever before.

In addition to these program costs are the costs that will be incurred by the regulated community to participate in TMDL development and even more significant costs of compliance. The capital and annual operating and maintenance cost for companies is staggering. The Advent Group, a wastewater consulting company, estimates the cost of the TMDL regulations on the regulated community to be between $20 billion and $80 billion over a ten year period.

Was the TMDL rule the result of bad analysis? In a recent National Academy of Sciences National Resource Council study, the NRC listed numerous errors, the lack of sufficient data and unscientific rationale for proposing the rule. These issues must be addressed in any revision of the TMDL promulgated in July, 2000.

We are hopeful that during the next 18 months steps can be taken to revise the rule and to establish a framework that is technically, scientifically and programmatically sound.

We applaud you for holding this hearing, and I would be glad to answer any questions. Thank you.

[Ms. Giesecke's statement may be found in the appendix.]

Chairman PENCE. I am going to break protocol and recognize the patient gentleman from Illinois who awaited the Chair for the initial round of questions. The Chair will reserve the opportunity to question the panel after Mr. Phelps is done.

Mr. PHELPS. Thank you, Mr. Chairman. No apologies necessary. It is a tough schedule sometimes, so we appreciate your indulgence.

Mr. Conrad, first, industry groups have a paramount job of record keeping standards, strict standards that should be met. Why should EPA not have specific requirements for measuring or making sure that your records are legally kept and legally I guess would be tested in some way, but an alternative?

Mr. CONRAD. You are absolutely right. Our members have legal obligations to retain records and to preserve them and not change them, and they do that. They are at the risk of criminal prosecution, certainly, if they monkey with them intentionally.

It is also appropriate, I think, in the area of electronic records to have some degree of security so that the records are not immediately accessible by anybody, but in fact our members have some sorts of security procedures in place now. The computers where these data are kept are not accessible to just about anybody. They have PIN numbers and other kinds of access restrictions.

They have been doing all this for years, and there is, to our knowledge, no evidence that any of this is insufficient. We are not aware of any cases where electronic data have been manipulated or, perhaps more to the point, where the government has had any difficulty in prosecuting any of these kinds of cases, so I guess our plea is that we sit down with EPA—and apparently the Justice Department as well—and sort of talk through how we keep these records and what the concerns are, what would be a cost effective approach to guaranteeing their security.

Mr. PHELPS. Are you satisfied with the opportunities that groups were given to participate in public comment meetings, written comments, on the regulations about electronic record keeping? If so, what concerns were raised by your group at any of the meetings?

Mr. CONRAD. Well, the ironic thing is that this rule actually was developed in a fairly open fashion, and the EPA did have a couple of public meetings in the summer of 2000 to lay out what was going on. Folks actually spoke up.

I happen to have a reliable paper copy of the handout of that meeting and my notes from it, and I wrote up at the top 16 months ago with a star next to it, "People are freaked about not being able to print out computer documents and sign them. Few people have or can afford all the electronic audit trail stuff to ensure no changes."

People were raising these concerns at the meeting. I mean, I knew nothing about this issue until I went to this meeting. I gathered from what I heard over the course of that day that people had tremendous heartburn about what this could mean from the record keeping.

We assumed that, having heard that, the agency would take those concerns into account, and yet the proposal is essentially exactly the same as they talked about back then.

Mr. PHELPS. So what was the agency's response when these concerns were raised at the meeting?

Mr. CONRAD. They sort of just took notes. I mean, it was sort of a one-way thing. People explained how they felt, and they wrote them down, but there was never really a give and take.

Mr. PHELPS. Kind of one of those things the doctor puts down when you are getting diagnosed. Hmmm. Kind of like that?

Mr. CONRAD. Maybe they couldn't read their own handwriting.

Mr. PHELPS. Dr. Lutter, you have been an outspoken critic of the cost-benefit analysis obviously. Would you think it would be most efficient in some cases for an agency to do an economic analysis even knowing that data gaps exist and make corrections based upon public comment?

Mr. LUTTER. I am not sure I understand your question. Currently the agencies prepare economic analyses of regulations, publish them at the proposal stage and solicit comments on that analysis along with comments on the rule at the proposal stage. I think that is an appropriate procedure.

Mr. PHELPS. Well, what I am getting at is when a rule is trying to be substantiated, the expenditures can be compared with the final projected benefits. The question is would it be just as cost effective to proceed with publishing the rule and allowing the industry to fill in the gaps?

Mr. LUTTER. Sir, to fill in the gaps in the analysis? No. I think that is a role for the government to undertake, provided that there is adequate opportunity for the public and the affected industries to comment on the appropriateness of the analytic procedure the agency is following.

Mr. PHELPS. So adequate reliability you think could be achieved. I think it has been noted that you have established that it cannot be achieved by peer review, adequate reliability, to replicate agency analysis, but by systematic, independent efforts to replicate agency analyses.

Do you believe that the taxpayer is best served using replicating agency analyses, or is this a theory based on resources and time?

Mr. LUTTER. I would like to focus attention on the key and often neglected purpose of the economic analysis, which is to inform Members of Congress and the public about the merit of the regulatory decisions. I think that the existing institutional incentives that the agency faces do not really promote forthright and neutral analysis from the agency.

The question is how does one improve those incentives? There are several procedures. One would be peer review. Surely that is worth doing. Currently there is no adequate independent peer review of EPA's regulatory analysis. A separate one in addition to that—these are complementary approaches—would be for Congress to fund the Truth In Regulating Act project at the General Accounting Office. I think that that office could, as part of its work, seek to verify whether or not agency estimates are replicable.

My inspiration for that comment is largely based on longstanding work in the community of academic economics. Even peer reviewed articles are not always replicable in the sense that other researchers trying to ask whether identical methods applied to identical data lead to identical answers discover that they do not.

It is for that purpose that I think it would be very useful to have a TIRA project at GAO seek to ascertain the replicability of analyses by regulatory agencies.

Mr. PHELPS. Thank you.

Ms. Abrams, representing a large rural district—I have the largest geographic district east of the Mississippi, a lot of small counties with 4,000 or 5,000 in the whole county—one of the greatest challenges I have had as a state legislator, as well as a congressman now, is to try to work with those people, you know, at whatever degree or level of wastewater treatment plants they have.

It is a Catch-22 in trying to attract industry to small areas that need jobs that do not have the tax base for other mandates and obligates for the people to get industry to come in. One of the first

things they are looking at is what kind of, of course, infrastructure totally, but water and sewer and waste treatment plants.

In Illinois, most of the small communities, to be able to access government grants it is based on a matching system like an 80/20 for local, for state, federal flow through money to the economic commerce agencies, or sometimes 70/30, 90/10.

These small communities, you know, by the mere nature of the cost of wastewater treatment and those infrastructure needs cannot attract or do not do a very good job—I should not say cannot—by their own limitations industry, and yet where industry does exist the question is when we get into your industry, the metal products and machinery, do you think your industry avoids passing along the cost to the townspeople of treating the waste?

Ms. ABRAMS. The industry is already 100 percent regulated by pre-treatment standards under the existing 413 metal finishing and 433 standards, so I think to the extent that the EPA has seen fit, the industry is already pre-treating and covering the large cost of treatment pursuant and resultant from their processes.

I think it is important to note in the case of this proposed rule that it is a re-regulation of industries already fully regulated and that it is opposed by the trade associations representing the publicly owned treatment works because they feel that it imposes a large cost completely underestimated by EPA on the POTWs to implement a federal effluent limit guideline. They feel that existing effluent limit guidelines fully protect them and allow them to do the job that they need to protect the community's water sources.

They also already have fully delegated authority to impose local limits that are higher when they see fit to protect either environmental quality or their own economic viability, so they feel that these standards are wholly unneeded and in fact present a burden, not a benefit for them and for the communities that you are speaking of.

Mr. PHELPS. Is that a major concern, though, for your industry, the wastewater treatment cost, or is it just pretty much accepted?

Ms. ABRAMS. Right now it is the cost of doing business. Those regulations have been around for over a decade. I am not sure there is a company out there that could tell me off the top of their head what percentage of their environmental compliance costs it represents. It is a significant cost, but it is part of being a corporate citizen in America that you need to treat your wastewater.

The issue at hand is that the proposed regulation has no environmental benefit and would increase costs to the extent that we fully believe over 50 percent of the domestic printed circuit board industry would be unable to compete globally and that there would never be a new circuit board plant constructed in this country.

Mr. PHELPS. Thank you very much. I may have questions later.

Chairman PENCE. The Chair would also like to thank the panel for some very provocative and thoughtful presentations.

A few questions starting with Dr. Lutter; not to put you on the spot after that good exchange. What agency do you think should be charged with selecting peer reviewers for EPA's regulatory analyses?

Mr. LUTTER. The simple answer is not EPA.

Chairman PENCE. Okay.

Mr. LUTTER. The more complete and truthful answer and much more informative answer is much harder. In discussions with other people, NAS or NRC has come to mind, but it is not clear what would be the perfect answer to that question.

I think what one can say is that it should not be EPA because the process of picking peer reviewers, and the process of managing the questions given to the peer reviewers is one that can be controlled in such a way as to make analysis look like it is blessed when in fact people continue to have serious reservations about its credibility. This suggests that some non-EPA agency would be more apt to do that job well.

Chairman PENCE. Ms. Abrams, I have the impression that you believe the EPA did not perform an effective outreach in developing and seeking comments on the proposed MP&M rule. What should EPA have done to improve the outreach in specific recommendations?

Ms. ABRAMS. I think that the EPA made a good effort to outreach. They convened a SBREFA panel, which they do not do for every proposed rule. They also held public hearings.

I think with respect to the SBREFA panel that there was just not enough data presented to the SBREFA panel for them to make adequate review and assessment, and even after the rule had been published in the Federal Register a good bit of the background data and analysis was not available in the public record for several months after that, resulting in an extension of the rulemaking period.

Chairman PENCE. Mr. Bopp, I found some of your testimony really breathtaking.

Mr. BOPP. So do our members.

Chairman PENCE. The estimate of 111 hours per year to make their way through 500 pages of instruction.

I guess my question is you essentially are saying the EPA failed to assess the impact specifically on ceramic and glass decorators, not understanding the nature of the industry essentially as a subset of the regulated class.

Do you have any recommendations about if the EPA did identify your industry in particular how we would insure that they would develop regulatory analyses based on the correct data and a correct understanding?

Mr. BOPP. That is a good question because the correct data was there. I mean, the rule was first announced and then pulled back, and then several of our members, small members, testified before a panel, so it was not a question of them being unaware of us. One way or the other, it just was not considered, or if it was considered it did not come out in the research at all.

I guess it would get down to better peer review of the research. Again, I mean, to come out with something like this, as flawed as it is. And in the end it was a very, very rushed rule. It was pushed through officially finally January 17 of this year. There were a lot of rules that went through that way, and I think not enough care was given at that point for whatever reasons.

It was not a question of them not getting the information from us. It was a question of for one reason or another it did not enter into their economic reports. Therefore, it did not enter into consid-

eration. I guess better peer review, like some others have mentioned, would really help that and, again, someone other than EPA reviewing their research.

Chairman PENCE. Thank you.

Dr. Giesecke, the EPA originally estimated that the total incremental cost of TMDL was going to be about $220 million, and then one year later in a draft economic report the cost estimate was raised to a minimum of $10 billion over ten years.

With your background in this area, how do you account for that kind of almost logarithmic difference in estimates?

Ms. GIESECKE. They had taken advantage of a regulatory interpretation and determined that they did not have to fully account for expenses that might be incurred by the states because this was a delegated authority in most cases, so they simply used a number limited to what EPA headquarters and regional offices might be expected to incur and not consider what the delegated states and certainly not even in the next estimate what the regulated community would be subject to in terms of costs.

Chairman PENCE. Thank you.

Mr. Conrad, did the EPA recognize in the CROMERRR circumstances any substantial differences between the chemical industry and the pharmaceutical industry? In your testimony you indicated that 60 to 90 percent of the businesses in your association are small businesses.

I do not have testimony or information about the nature of the pharmaceutical industry, but it seems to me there are very few companies that can survive in that industry that would qualify for any of this Committee's jurisdiction.

Mr. CONRAD. Right. Of course, CROMERRR does not just affect us. I mean, essentially it affects anybody who is required to keep records under any EPA requirement under any statute, so Clean Air, Clean Water, RCRA.

I mean, you have all kinds of regulated entities down to the size of gas stations, as well as all of the consultants and analytical labs and so on who work for them whose computers have to mesh with them and who are all affected, so it is a much wider range of facilities.

I am not really familiar with the size distribution of businesses in the drug industry, but certainly my experience kind of off the cuff is that drug companies tend to be pretty big, and that they are gobbling each other up and have a lot more capacity to absorb a regulation like that.

Frankly, the things they are regulating, I mean, these are things people eat, as opposed to materials which certainly people have the potential to be exposed to, but it is a much more attenuated chain from a regulated facility under EPA to a person than in the case of drugs.

Chairman PENCE. Thank you.

Having conferred with the gentleman from Illinois, my colleague, that he does not have any additional questions, we will move to adjourning this hearing with a word of gratitude to each one of you for greatly illuminating our understanding of the challenges in the area of the analyses the EPA uses.

I particularly appreciate Dr. Lutter's comment with regard to using established principles for sound analysis, which will be very much of a lodestar.

Mr. PHELPS. I would also like to thank the panelists for their very well designed testimony. Thank you.

Chairman PENCE. With that, again my gratitude for your patience with my schedule today. Enjoy your lunch.

[Whereupon, at 11:45 a.m. the subcommittee was adjourned.]

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CHAIRMAN

NYDIA M. VELÁZQUEZ, NEW YORK

Congress of the United States
House of Representatives
107th Congress
Committee on Small Business
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Statement of Mike Pence
Chairman
Subcommittee on Regulatory Reform and Oversight
Committee on Small Business
United States House of Representatives
Washington, DC
November 8, 2001

On June 21, 2001, I convened a roundtable on regulation to hear from more than 30 small business trade associations. Despite the diversity of concerns raised at the roundtable, one constant theme was evident – the inadequacy of the regulatory analyses that agencies use to support their rulemakings. One agency in particular was singled out for its poor regulatory analyses – the Environmental Protection Agency. Today's hearing will address those flaws.

Small business owners are very familiar with burdens that Federal regulations place on them. Many studies, including those sponsored by the Office of Advocacy of the United States Small Business Administration, have shown that small businesses face disproportionately higher costs to comply with federal regulations, including those issued by the EPA, than their larger business counterparts. Thus, accurate estimates of costs, if derived from the experiences of large businesses, may paint a false picture of the economic impact of an EPA regulation on small businesses. And if the EPA misjudges the economic impact will it produce a rational rule if the vast majority of businesses in America cannot comply?

The polestar of the rulemaking process is that the regulations must be rational. When Congress passed the Administrative Procedure Act in 1946, it believed that the process of notice, comment, and agency response to the public comment would be sufficient conditions to ensure a rational outcome. After the regulatory onslaught of the 1970s, which saw the creation of the EPA and the enactment of many statutes that EPA implements by rulemaking, Congress and the Executive Branch determined that further refinements were necessary. Congress imposed new analytical requirements to assess the impacts on small businesses and other small entities. Presidents Reagan, Bush, and Clinton produced executive orders mandating analysis of costs and benefits beyond those required by the Administrative Procedure Act or specific statutes, such as the Clean Water Act.

In 1980, Congress enacted the Regulatory Flexibility Act (RFA). The RFA represents another tool in the decisional calculus designed to develop rational rules. The RFA requires federal agencies to consider whether their proposed or final regulations will have a significant economic impact on a substantial number of small businesses. If the regulations do have a sufficient impact, the agencies are required to consider whether less burdensome alternatives exist that achieve the same objective. The authors of the RFA expected that if an agency had two equally effective alternatives to achieve its regulatory objective it would logically select the one that is less burdensome on small businesses. Of course, the critical element in this analytical filter is the agencies proper assessment of the impact of the regulation on small businesses. If the agency's cost estimate is incorrect, then its assessment of the burdens on small business will be inaccurate and the agency will not seek more cost-effective alternatives.

The analytical requirements of the Administrative Procedure Act and the RFA have been supplemented by regulatory review mandates from each President since 1980. While the details are somewhat different, each executive order requires federal agencies, such as the EPA, to conduct cost-benefit analyses for significant regulations, usually those with more than $100 million impact on the economy. If the costs of the proposed or final rule outweigh the benefits, then the regulatory action would be detrimental to the overall welfare of society and the rational policymaker, barring statutory imperatives to the contrary, would not seek to implement that particular regulation. More importantly, a regulatory analysis which demonstrates that the costs of a particular regulation outweigh the benefits should give policymakers great pause. That should be a signal for them to seek other alternatives that meet their statutory objectives but do not impose unnecessary costs on society. Thus, inadequate or incorrect regulatory analyses (including the scientific underpinnings of the estimates of the costs and benefits) are detrimental to rational rulemaking mandated by the Administrative Procedure Act.

Today's hearing focuses on a cross-section of regulations from the EPA that highlight the problems that can arise from incorrectly constructed regulatory analyses. They often lead into the realm of irrational rulemaking, such as the proposed Cross-Media Electronic Reporting and Recordkeeping Rule which would, in essence, require replacement of a substantial amount of existing information systems that currently keep track of more than 216 pages worth of EPA mandated recordkeeping. Proper application of the tools available to EPA should eliminate such results. I look forward to the recommendations of the witnesses on the corrective actions that EPA can take to avoid poor analyses.

I will now turn to the ranking member of the Subcommittee, the gentleman from Pennsylvania, Mr. Brady for his opening remarks.

Improving Regulatory Analysis at the Environmental Protection Agency

Randall Lutter

1. Introduction

I am pleased to appear before you to provide my views on how to improve regulatory analysis at the Environmental Protection Agency (EPA). For more than 10 years, I have worked inside and outside the government on regulations to reduce risks, especially risks to the environment and human health. Since 1998, I have conducted research on a variety of health, safety, and environmental topics at the AEI-Brookings Joint Center for Regulatory Studies, a cooperative effort between the American Enterprise Institute and the Brookings Institution.

A primary objective of the center is to hold lawmakers and regulators accountable by providing thoughtful, objective analysis of existing regulatory programs and new regulatory proposals. The Joint Center has been at the forefront of outlining principles for improving environmental and safety regulation, enhancing economic welfare, and promoting regulatory accountability.[1]

You have asked for my views on whether the EPA's benefit-cost analyses are adequate to support rational rulemaking and what changes can be made to improve those analyses. In this testimony I offer comments on whether EPA's analyses are adequate for their intended purposes and then make recommendations to improve these analyses.[2]

2. Are EPA's Analyses Adequate To Support Sound Rulemaking?

In judging the adequacy of EPA's benefit-cost analyses it is useful to distinguish between two separate purposes. One purpose is to inform decision-makers at EPA and elsewhere in the Administration about the economic effects of regulations. From the perspective of Administration decision-makers who control the resources and have the authority to get the quality of economic analysis they want, EPA's analyses may be adequate for this purpose. Yet a significant number of EPA's benefit-cost analysis is

[1] Please see www.aei.brookings.org for publications of the Joint Center.

deficient for sound decision-making because of inadequate attention to alternatives, inappropriate baselines, improper treatment of future regulatory effects, as well as other deficiencies.[3]

A second purpose of EPA's benefit-cost analyses is to inform Congress and the public about the economic effects of its regulatory decisions.[4] A significant number of EPA's analyses are inadequate for this purpose primarily because the incentives for EPA to prepare high-quality analysis are poor. As an institution, EPA faces incentives to overstate the net benefits of its rules, particularly those rules that have very small or negative net benefits.[5]

The biggest cause of poor benefit-cost analysis at EPA is the lack of incentives for more forthright research. The absence of independent review of EPA's benefit-cost analysis illustrates the lack of incentives.

- Courts rarely review EPA's benefit-cost studies because environmental laws generally authorize EPA to regulate without full consideration of benefits and costs. For example, errors in EPA's estimate of the costs of its 1997 air quality standard for ozone were irrelevant during judicial review because the Clean Air Act prohibits EPA from considering costs in setting standards.[6]
- No government body outside the executive branch assesses analytic quality. Private sector critiques of EPA's analyses are often ineffective because they also comment on EPA's regulations, and independent observers believe that such comments motivate the critiques of EPA's analyses, rather than vice-versa.

In addition, the same EPA office that drafts a rule also supervises the benefit-cost analysis. The lack of proper incentives has implications for efforts to improve EPA's analysis.

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[2] See Hahn and Lutter (2001) for related testimony.
[3] See Hahn et al., (2000). See also Lutter (1999b) and Lutter (2001) for more detailed analyses of particular rules.
[4] I ignore benefit-cost analysis that EPA sometimes conducts for a third purpose --to show that its regulations comply with rare Congressional directives to regulate efficiently.
[5] See Hahn (1996).

3. Improving EPA's Economic Analysis

EPA's benefit-cost analyses will not improve without new incentives for better analysis. Several reforms could generate significant improvement.

Recommendation 1: Congress should create a separate Office of Policy Analysis within EPA and charge that office with doing all risk assessments and all benefit-cost analyses of significant regulations.[7]

Discussion: Currently, EPA program offices charged with administering particular programs oversee most of the economic analysis supporting new regulations. These offices suffer from a conflict of interest. The air office, for example, naturally has an incentive to support air regulations. The problem is one of "tunnel vision," as Justice Breyer noted in his insightful 1993 book *Breaking the Vicious Circle.*[8] Rather than allowing program offices to prepare economic analysis of proposed regulations, EPA should have a separate Office of Policy Analysis charged with providing independent, high-quality analysis for the EPA Administrator. This policy office would have both authority and responsibility for ensuring that EPA's benefit-cost analyses meet the highest possible standards.

Recommendation 2: Congress should require that EPA's benefit-cost analyses adhere to established principles.

Discussion: The Office of Management and Budget (OMB) has developed guidelines for doing sound regulatory analyses.[9] It is clear from a careful review of EPA's economic

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[6] See Lutter (1999b).
[7] President Clinton's Executive Order 12866 defines as "significant" any regulation likely to result in a rule that will either annually affect the U.S. economy by $100,000,000 or adversely and materially affect the U.S. economy, productivity, environment, or public health, or any entity of the non-federal government. See Clinton (1993), Section 3(f)(1).
[8] See Breyer (1993).
[9] See Daniels (2001), Lew (2000), and Office of Management and Budget (1996).

analysis that the agency has not taken these guidelines seriously.[10] To add political weight to OMB's guidelines, Congress should adopt the kinds of principles contained in the guidelines. It should also require that an agency such as OMB certify that EPA's analyses adhere to such principles.

Recommendation 3: Congress should ask an agency other than EPA to conduct peer-review of the benefit-cost analyses and the risk assessments supporting EPA's significant rules.

Discussion: Most of the benefit-cost studies and the risk assessments supporting EPA's significant rules do not go through any outside peer-review.[11] Peer-review is admittedly no guarantee of quality, at least as measured by independent replicability.[12] Yet mandatory peer-review of EPA's analyses of economically significant rules could provide an important new incentive for EPA to improve the quality of its analysis.

In addition, EPA-managed peer-review of scientific and economic analyses when it has occurred has lacked the independence necessary to be effective. The Administrator makes appointments to the expert scientific committees. Many of the experts are heavily dependent on EPA for funding. The committees often focus only on the questions brought to them by agency staff, and not necessarily on broader, more important questions related to the regulation.[13] Independent analysts have given virtually no credibility to at least one major study reviewed by the EPA's Science Advisory Board.[14] Peer-review of EPA's analyses would be more effective if an agency independent of EPA had responsibility for committee appointments and staffing.

Recommendation 4: Congress should fund regulatory analysis at the General Accounting Office in accordance with the Truth In Regulating Act of 2000.

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[10] See Hahn et al., (2000). For more detailed assessments of individual EPA analyses, see Lutter (1999b) and Lutter (2001).

[11] Of course there are exceptions. For example, EPA's Clean Air Act Compliance Assessment Committee reviewed the risk assessment underlying EPA's 1997 air quality standards. See Lutter and Gruenspecht (2001) for a critical perspective on this review. EPA's Science Advisory Board also reviewed the benefit-cost study underlying EPA's 2000 residential lead hazard standards.

[12] See Dewald et al., (1986).

[13] See Lutter and Belzer (2000).

Discussion: Regulatory analysis conducted outside of EPA may provide valuable new incentives for improved benefit-cost analysis at EPA. The 2000 Truth in Regulating Act established a pilot project at the General Accounting Office to promote review of agency regulations and their supporting analyses.[15] This project is worthwhile because it would establish the first federal regulatory oversight office independent of the executive branch. However, the viability of this project is in doubt because Congress has not yet delivered the $5 million in annual funding authorized by the Act.

An agency outside the executive branch should provide an assessment of the analysis supporting new environmental regulations because such independent review would provide valuable incentives for EPA to verify that its analysis is replicable and consistent with the highest standards.[16] In addition, Congress could use information generated by such an agency to improve regulation and the regulatory process. Since EPA accounts for a large portion of the rules in the current review process, funding the Truth in Regulating Act is integral to improving analysis at EPA.

4. Conclusions

A significant number of EPA's benefit-cost analyses, while technically very sophisticated, fail to comply with established principles for sound analysis. Improving the quality of the analysis requires establishing incentives for the agency to do high-quality work. Four steps likely to be effective are having a separate policy office conduct the analysis, mandating adherence to sound analytic practices, asking an agency other than EPA to conduct peer-review of EPA's benefit-cost studies and associated risk assessments, and funding the Truth In Regulating Act research at the General Accounting Office.

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[14] See Lutter and Belzer (2000).
[15] See Cavanagh et al, (2001, p. 17).
[16] See Lutter (1999a).

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Good morning Chairman Spence, Ranking Member Brady and members of the Committee. My name is Fern Abrams and I am the Director of Environmental Policy for the IPC, the trade association for the electronic interconnection industry. IPC's 2,800 members manufacture and assemble printed circuit boards, the backbone of our nation's high tech industries, including consumer, industrial, and defense electronics. On behalf of the IPC, I'd like to thank you and your staff for organizing this important hearing.

Ninety percent of IPC members that manufacture printed circuit boards are small businesses. As you know, the cost of regulatory compliance often has a disproportionate impact on small businesses. Environmental regulations must be based upon sound scientific and regulatory analysis so that they do not create unnecessary burdens while failing to achieve their goal of environmental protection.

IPC members, along with many other industries affected by the Environmental Protection Agency's (Agency) proposed Effluent Limitations for industries that manufacture and maintain Metal Products (MP&M)[1], are deeply concerned that the Agency has overestimated the benefits of the proposed regulation, while significantly underestimating the economic impact.

The Proposed Effluent Limitations are not Achievable

The Clean Water Act requires that effluent limits be based on Best Achievable Technology (BAT). Simply put, Best Achievable Technology is the best treatment that is economically achievable. Yet the Agency has proposed limits that are neither affordable nor achievable. A review of discharge monitoring data indicates that none of the facilities on which the proposed limits are based can meet them consistently. In fact, some of the discharge limits proposed by the Agency are so low that incoming drinking water would not meet them. These are not limits based on best achievable technology.

[1] Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Metal Products and Machinery Point Source Category (66 FR 423).

The Economic Impact of the Proposed Rule has Been Significantly Underestimated
The proposed limits also fail to credibly meet the requirement that they be economically achievable. To begin with, the Agency has significantly underestimated the cost of compliance. Errors include faulty assumptions concerning technology capabilities, monitoring costs, and facility space constraints, just to name a few. For example, the Agency has incorrectly assumed there will be no increase in monitoring costs when expected increases at IPC member facilities range from $1,000 to $350,000 per year.

The Agency's economic analysis also fails to meet common sense inspection by projecting that many firms will remain profitable despite facing compliance costs that are several times greater than their profit margins. For example, the Agency's analysis projects that a facility facing a compliance cost burden that is equal to 31% of its revenues will remain open. This unreasonable assumption is made possible only because the Agency's economic analysis assumes that compliance costs will be passed on to customers through price increases of over 90 percent. This assumption apparently was based on analysis of other, unrelated MP&M industries conducted over five years ago in a vastly different economic climate. In reality, over 72 percent of IPC members have stated that they would be unable to increase customer prices.

In addition, the rule's economic analysis assumes that 50% of printed circuit board facilities will be able to remain in business without being able to replace worn out equipment or to modernize for 15 years. This is an astounding assumption given that printed circuit board manufacturers must constantly invest in new equipment to meet customer demands for increasingly smaller electronics.

The Environmental Benefits of the Proposed Rule have been Significantly Overestimated
In addition to underestimating the cost of the proposed regulation, the Agency has also significantly overestimated the environmental benefits of the proposed regulation. The proposed effluent standards arguably are among the most complex ever undertaken by the Agency, covering 18 different industrial sectors under more than 200 SIC codes. Unlike previous effluent limitations rulemakings, which used actual facility wastewater data to estimate the environmental benefits of proposed rules, the Agency relied upon models to simplify the task of estimating

costs and pollution benefits of the MP&M effluent limitations. Unfortunately, models are effective only when working with uniform processes and only when inputting highly reliable data, neither of which is true in this case. By using inadequately detailed models populated with data borrowed from unrelated industries, the Agency has fabricated an environmental benefit that doesn't exist. Pollution removals calculated from actual facility data are 98 percent lower than those predicted by the Agency's flawed models.

The Agency has Failed to Demonstrate the Cost Effectiveness of the Proposed Rule

In conclusion, we believe that the Agency has not demonstrated that the proposed rule is cost-effective. The Agency has estimated that the social costs of the proposed rule are $2.1 billion annually, while the "total benefits that can be valued in dollar terms in the categories traditionally analyzed for effluent guidelines" are only in the range of $0.4 billion to $1.1 billion annually." The Agency should not promulgate a rule with costs that exceed the benefits. The Agency should follow the recommendations of the Small Business Regulatory Enforcement Fairness Act panel and remove from this rulemaking industries for which regulation is not cost-effective.

Fortunately, unlike many of the rules discussed today, the MP&M Effluent Limitations have not yet been finalized. In fact, the Agency has been working constructively with affected industries, including my own, to try to improve the quality of its regulatory analysis prior to issuance of a final rule.

Going forward, the Agency needs to make a better effort to get regulatory analysis right the first time around. It should not be standard practice to propose a rule based almost entirely on faulty analysis and poor assumptions and then depend on industry to uncover mistakes in the very short time frame afforded for public comments. A more open regulatory process, with regular data exchange between the Agency and affected industries, combined with the early use of reality checks would make both proposed and final rules more accurate and effective.

Thank you again, Mr. Chairman for giving IPC the opportunity to express our concerns and I welcome any questions.

Presentation of Society of Glass and Ceramic Decorators
by Andrew Bopp, Executive Director
October 25, 2001

Summary:

EPA's economic analysis of its new Toxic Release Inventory (TRI) lead rule which lowered the reporting threshold from 10,000 to 100 pounds was critically flawed in its review of the rule's effects on small businesses. This was nowhere more true than for the glass and ceramic decorating industry. The agency failed to conduct any specific analysis of the glass and ceramic decorating industry (part of SIC 32) which it lists as one of the five largest TRI reporters in 1998 for lead and lead compounds under the old 10,000 pound threshold, a threshold that should have triggered a thorough evaluation of impacts. This failure meant EPA never considered the converse variance in the glass and ceramic decorating industry under which TRI reporting burdens and costs will be dramatically greater for small companies than large companies in the industry. The agency compounded this error by reporting that there will be no new TRI filers in the glass and ceramic decorating industry (part of SIC 32) which is ridiculous. From all of these flawed assertions, EPA determined that no companies in SIC 32 would have compliance costs greater than 1 percent or 3 percent cost/sales thresholds used to predict the small business impacts. As a result, EPA certainly underestimated the small business impact in our industry.

SGCD urges EPA to reconsider its economic analysis as to the impact on small businesses and to conduct a prompt and thorough review of the scientific premise upon which the agency has based this rule.

Thank you for the opportunity to testify before you today. I am the Executive Director of the Society of Glass and Ceramic Decorators, which is the trade association of companies that decorate glass and ceramic tableware, collectibles, promotional wares and other items. SGCD represents 650 companies in a manufacturing segment that is facing increasingly fierce competition from overseas production facilities .. especially in China.

Many SGCD members are companies with familiar household names that produce the plates and drinking glasses that we use in our homes everyday. However, the majority of SGCD member companies are small operations that have more in common with the average local print shop than with a large industrial facility. Many of these companies are family-owned with several generations represented in the enterprise. SGCD has members in 37 states including Indiana and Pennsylvania.

Instead of printing on paper .. these companies use screen printing and other techniques to print on glass and ceramicware. They generally purchase blank glass or ceramic mugs or tumblers and they add company logos, prom or party descriptions or souvenir imprints.

The colors that these glass and ceramic printers use contain various metal-bearing borosilicates .. and some colors cannot be produced without lead. When fired .. the colors vitrify – or become chemically part of – the glass or ceramic body upon which they are applied. This explains why glass or ceramic decorations do not chip or peel as household paints will do over time.

SGCD and member companies work closely with the U.S. FDA, other federal agencies and various state agencies to guarantee the safety of all wares that are produced. There are very specific tests that determine exact leaching levels for any piece of ware, and if the ware does not meet these standards .. it may not be sold in the United States. The tests are fairly simple for a testing lab to perform .. and they are extremely reliable. In the shop, the lead-bearing colors are applied to ware and fired with excess color stored for reuse. There is no appreciable waste generated in this process, and companies reporting at the 100 pound threshold are likely to record zero emissions after spending many hundreds of hours to confirm that fact.

I am testifying today to point out flaws in EPA's economic analysis that resulted from the agency's failure to conduct small business outreach prior to the issuance of its proposal to lower the Toxic Release Inventory (TRI) reporting threshold for lead and lead compounds. Although EPA did hold public hearings in response to Congressional questions concerning the TRI proposal, and a panel of SGCD members did testify at those hearings in December 1999 .. it is evident from EPA's economic analysis and a GAO report that reviewed that analysis that the agency did not consider all the costs that small businesses in the glass and ceramic decorating industry will be forced to bear to comply with this rule. In addition, the Small Business Administration (SBA) Office of Advocacy has notified EPA of many other flaws in the development of the rule that I do not have time to review today.

I want to emphasize that the rule-making process was flawed from the start when EPA failed to ask for input from small business associations such as SGCD before issuing its proposal. In spite of Congressional intervention, which forced EPA to conduct hearings after the proposal was issued, such hearings cannot substitute for pre-proposal meetings with affected industry groups. The Small Business Regulatory Enforcement Fairness Act (SBREFA) recognizes that the post-proposal period provides insufficient opportunity for small businesses to have the necessary impact on the regulatory process. After a proposal is issued, it is very difficult to convince an agency that another approach may achieve its goal in a less burdensome way. In any event, EPA has still not accurately analyzed the impact on small glass and ceramic businesses of this new rule.

A critical failure of EPA's economic analysis as it relates to small glass and ceramic decorators is illustrated in the GAO's Report on Implementation of the Proposed Lead

Rule of September 2000. The report notes that "it (EPA) did not examine whether the rule would have different impacts on the different types of manufacturers that were expected to comprise the bulk of new filers." (page 23, section on estimating company revenues)

It is possible that for some industries .. the differences in tracking lead usage may not be great between companies of varying size. However, the use of lead-bearing colors in the glass and ceramic decorating industry is fairly unique .. and the tracking and reporting requirements will be much more complicated for smaller companies than for large companies.

Not only did EPA fail to take such differences into consideration .. but the GAO report notes that the agency amazingly made contrary assertions implying a smaller tracking and reporting burden for smaller companies. The GAO report notes that EPA "said that first year compliance costs in a small company could reasonably be expected to be less than the cost of reporting at a larger facility" for a variety of reasons. (page 27, section on EPA Office of Prevention, Pesticides and Toxic Substances, Revised its Estimates on Rules Impact) The agency relied on this assumption to state that first-year compliance costs for small firms could be well below their original estimate that was used to estimate the impacts on affected small entities.

In the glass and ceramic decorating industry, this assertion is demonstrably wrong. To understand why this is so .. one must understand the nature of the glass and ceramic decorating business. It is important to note first that every lead-bearing color may contain a different quantity of lead; therefore, every decorator must trace every lead-bearing color used and make different calculations for that color.

You must also consider that large glass and ceramic tableware plants produce and decorate many thousands and even millions of matching plates, bowls, drinking glasses and related patterns using a limited number of colors – although these colors will obviously be used in large quantities. Some of these colors may contain lead .. and tracking that lead through the plant may be difficult; however, the steps required to trace the lead used for each color are confined to the number of colors used. Such tracking and reporting can be handled efficiently by a large decorator that employs an environmental compliance department to handle such reporting.

On the other hand .. the small contract glass and ceramic decorator fills orders that typically number in the dozens of pieces with 144 being a fairly standard promotional mug or glass order. These small plants may use a greater variety of colors in a day than a large decorating facility will use in a month. It should also be noted that almost none of these companies have ever been required to file any TRI report, and they do not have environmental compliance staff to handle such a complicated burden. Again .. think of

the quick printer when thinking about these companies. There is no indication that EPA even considered the possibility of such a converse variance for the glass and ceramic decorating industry in their economic analysis.

Once EPA failed to account for such variances, its economic analysis naturally reflected these flaws when attempting to quantify the rule's effects on small businesses. EPA's estimates of the time necessary to compile and complete the TRI forms (111 hours/year for a rule that is supported by more than 500 pages of instructions and guidance) do not remotely correspond with reality for small glass and ceramic decorators. They reflect the agency's failure to differentiate reporting circumstances in varied manufacturing SIC codes. As a result, EPA's cost estimates are correspondingly low .. which directly affects the number of companies that the agency believes will have an impact beyond the 1 percent and 3 percent thresholds used to predict small business impacts. As a result EPA certainly underestimated the small business impact in our industry.

I can understand why the agency would balk at evaluating every industry that might possibly be required to complete Form R TRI reports under the new standard. However, the agency listed Stone, clay, glass and concrete products (SIC 32) as being among the five largest reporting groups in the 1998 TRI reporting year for lead and lead compounds. (S.4, Estimated Reporting Activity, Economic Analysis, October 2000). These reports were obviously filed in the glass and ceramic industry primarily by very large decorating operations that met the previous 10,000 pound threshold for reporting.

In a surprising lapse after listing SIC 32 as a top reporting category in 1998, EPA's estimated reporting activity summary in its economic analysis on the next page of the report addresses SIC 32 as part of a wide range of SIC industries (20-39, "Other manufacturing or industrial combustion.") (Table S-1Estimated Number of Additional Reports for Lead and Lead Compounds, page S-5). The other four top 1998 lead filers are evaluated separately (SIC 33, primary metal industries, SIC 36, electronic and other electrical equipment and components; SIC 10, metal mining; and SIC 4953, refuse systems.) Glass and ceramic decorating, however, was never analyzed.

It would seem to be a basic requirement of economic impact analysis at least to attempt to ascertain whether one of the largest likely reporting categories should be evaluated separately in an attempt to understand the use of lead and lead compounds in that industry. If EPA had approached our association or any other group representing related industries in the development stages of this rule, we could have indicated how small decorators would be impacted. It is obvious that our attempts to work with the agency after the rule was first issued did not have an effect on its economic considerations.

In another flawed assertion likely emanating from the failure to understand the glass and ceramic decorating industry, EPA reported that there would be 0 first-time filers in SIC 32 based on their research efforts (Table 3-2, Numbers of Facilities and Additional Reports Associated with Lead and Lead Compounds by Industry Group, Economic

Analysis of the Final TRI Rule, October 2000). This assertion is ridiculous, as there will be hundreds of small decorators that have never completed a TRI form for lead or lead compounds or any other TRI substance.

Early outreach with my industry may have produced a completely different proposal. It should be noted that in addition to the many flaws in the agency's economic analysis, the drastic reduction in the lead TRI threshold from 10,000 pounds to 100 pounds is based on a scientific premise that the Agency has still not fulfilled its promise to send for independent peer review.

In conclusion .. I urge the Committee to require federal agencies to meet with and learn from small businesses before regulatory proposals are issued. Early outreach will ensure that federal agencies properly assess small business impacts and develop proposals that are narrowly crafted to meet agency objectives with the smallest possible business impact.

In terms of the lead TRI proposal, EPA's failure to conduct early small business outreach and the resulting inadequacy of its economic analysis .. certainly as it relates to glass and ceramic decorators .. deprived small businesses of the opportunity to influence the proposal in ways that would have minimized its small business impact. Due to these omissions and the large number of scientific uncertainties related to this rule, I urge you to request the agency to reconsider the lead TRI rule to comply with the letter as well as the spirit of SBREFA while also conducting a prompt and thorough review of the scientific premise upon which the rule is based.

Thank you for the opportunity to testify before you today on this very important issue.

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STATEMENT OF

JAMES W. CONRAD, JR.
COUNSEL

on behalf of the

AMERICAN CHEMISTRY COUNCIL

before the

HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT

EPA RULEMAKING: DO BAD ANALYSES LEAD TO IRRATIONAL RULES? – EPA'S PROPOSED RULE ON ELECTRONIC REPORTING AND ELECTRONIC RECORDS

October 25, 2001

Introduction

Good Morning, Mr. Chairman and members of the Subcommittee. My name is Jamie Conrad. I'm Counsel with the American Chemistry Council. The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make our lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and extensive health and environmental research and product testing. The business of chemistry is a $460 billion-a-year enterprise and a key element of our nation's economy. It is the nation's #1 exporting sector, accounting for 10 cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other industry.

While many Council members are Fortune 500 companies, many more are small businesses. In fact, we estimate that between 35-50% of our approximately 180 members meet the relevant SBA size standard for a small business. Many of these members have only a single manufacturing plant. As you might imagine, the substantial regulatory burden imposed by agencies like EPA is particularly challenging for companies of this size. At the same time, these smaller companies stand to benefit most from the efficiencies made possible by innovative information technologies.

Mr. Chairman, I am pleased to testify before you today regarding EPA's recent proposed rule on electronic reporting and electronic records, conventionally known as "CROMERRR."[1] While well intended, the rule as proposed would offer few, if any efficiency gains to businesses, small or large, that are regulated by EPA or delegated states. In fact, the regulation would have the opposite effect, imposing astronomical costs and, paradoxically, driving businesses away from electronic ways of managing information. This result seems to stem not so much from bad analysis as from ignoring the cost/benefit analysis that was done and not doing the risk analysis that OMB requires.

Summary

Everyone supports the voluntary use of electronic systems to replace paper ones where that's appropriate. Information technology enables processes to be expedited, simplified, and streamlined. This potential benefit is especially critical for small businesses, which have proportionately greater paperwork burdens and fewer resources than large businesses. That's why there was such broad support for the Government Paperwork Elimination Act of 1998.[2] CROMERRR ostensibly implements that law. But it actually conflicts with the law and will frustrate its goals.

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[1] "Establishment of Electronic Reporting; Electronic Records," 66 Fed. Reg. 46162 (Aug. 31, 2001). Until recently EPA called this the "Cross-Media Electronic Reporting and Records Rule" or "CROMERRR," a label which has stuck.

[2] Pub. L. No. 105-277, 44 U.S.C. § 3504 note.

CROMERRR addresses two topics: electronic reporting and electronic recordkeeping. At this point, the Council is reserving judgment on the reporting provisions – they may well be fine, although we are beginning to hear rumblings of inconsistencies with pilot projects that other parts of EPA have developed with states and with regulated entities. However, we have not had much time to focus on the reporting side of the proposal because we have been so alarmed by what the recordkeeping side would require of companies.

There are two fundamental problems with the recordkeeping aspect of the proposal:

- The first is its mandatory nature. While CROMERRR claims to be entirely voluntary, as a practical matter it is not. It employs an incredibly expansive definition of "electronic record," covering essentially any data that ever pass through a computer. CROMERRR further provides that *any electronic record has to meet its demanding technical requirements, or else the record will no longer satisfy the underlying recordkeeping requirement.* Since many facilities now maintain required records electronically, CROMERRR will require them to upgrade their systems or, where possible, switch to paper.
- The second problem is how enormously burdensome it would be for businesses to meet CROMERRR's technical requirements, which impose elaborate safeguards to prevent the remote prospect that data might be tampered with. No commercially-available off-the-shelf software has these capabilities. Compliance will require wholesale overhaul of computer systems -- Y2K all over again, possibly worse.

CROMERRR is "intended to be consistent" with, and is closely modeled on, an FDA rule issued about four years ago that was also described as voluntary and cost-saving.[3] Instead, the FDA rule has turned out to be mandatory for anyone who maintains data electronically. It has also turned out to be horrendously complicated and expensive to comply with. Four years later, pharmaceutical companies are still struggling to comply. Fundamental principles of administrative law suggest that where one federal agency interprets a given set of words in a particular way, another agency adopting the same language is going to be held to the first agency's interpretation, at least until the second agency can offer good reasons for a different interpretation.

Increasingly, policymakers are calling for more and better information about environmental quality and the performance of individual facilities. It is ironic that EPA's Office of Environmental Information has proposed a rule that will force regulated entities to spend their limited information resources on procedures that generate no new information, but only guard against risks that have not been adequately characterized.

EPA's own cost/benefit analysis concluded that the costs of implementing CROMERRR exceed the benefits. Very few companies would implement it voluntarily. This result does not comport with EPA's stated intention to "reduce the burden of compliance."[4]

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[3] 66 Fed. Reg. 46170.
[4] 66 Fed. Reg. 46163.

As explained below, CROMERRR is "significant" within the meaning of Executive Order 12866 not only because it involves "novel legal or policy issues," as recognized by EPA, but also because it is likely to have an annual effect on the economy of $100 million or more. More important to this Committee, CROMERRR clearly would trigger the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act. EPA has not complied with any of these authorities, however, because it has taken the unsustainable position that CROMERRR is voluntary and would actually save companies money. But it won't. The balance of this testimony will explain (i) why CROMERRR is not voluntary, (ii) why it would be so costly to comply with, and (iii) why EPA should withdraw at least the recordkeeping provisions of CROMERRR. The American Chemistry Council is prepared to work with EPA to improve them.

CROMERRR is mandatory, as a practical matter, and would apply to most records at most EPA-regulated facilities

The scope of CROMERRR is so vast that it would apply to essentially all organizations subject to federal environmental laws. About 1.2 million entities file reports under EPA regulations, either directly or via delegated state programs. Virtually all of these entities are required by some EPA rule to keep records. I am attaching to my testimony a very recent compilation, prepared by the American Chemistry Council, of EPA recordkeeping requirements. As you can see, there is an astonishing multitude of them. Even this document, 208 pages long, omits many - for example, the pesticide law called FIFRA.[5]

Even where rules don't require records to be kept, the possibility of enforcement makes it necessary. Many EPA rules don't apply to facilities or operations if they fall below certain thresholds for releases, inventories, etc. Needless to say, these exemptions are vital to small businesses - in general, they reflect EPA's judgment that the costs of compliance are not justified by the small environmental effects involved. Most of these exemptions operate on the honor system - if you determine that a rule doesn't apply, you don't have to report that conclusion to EPA or the state. But if one of those authorities challenges your determination, you had better have some records to document how you made your decision. We can envision facilities being challenged if those records don't satisfy CROMERRR.

So almost every facility regulated by our environmental laws has to maintain some records. CROMERRR would govern most of them. While it applies nominally to "electronic records," these are defined as "any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."[6] In other words, so long as a piece of information passes through a computer at any stage in its life cycle - from generation to archiving and retrieving - it is an electronic record.

[5] The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y.
[6] Proposed 40 C.F.R. § 3.3, 66 Fed. Reg. 46189.

This definition is taken virtually word for word from the FDA's electronic records rule, and that's how the FDA has interpreted it.[7]

Unfortunately, right now, much if not most of the information that facilities maintain to comply with EPA rules passes through a computer at some point, and hence meets this definition of an electronic record. By and large, regulated entities do not operate in a purely paper world. In fact, much regulatory information is generated by computers in the first instance, and can *only* be electronic. Some significant examples include:

- continuous emissions monitors;
- hand-held fugitive emissions data loggers;
- gas chromatograph/mass spectrometers and other analytical equipment; and
- temperature and flow meters.

Even very small chemical companies run their machinery by distributed control systems, complex integrated systems for collecting, analyzing and presenting information on operating parameters of equipment and processes. For many companies, the outputs of these systems serve as the basis for much of their reporting on emissions, releases, etc. Other companies have developed customized software for special purposes, such as:

- screening export orders for reporting obligations under Section 12(b) of TSCA;[8] and
- recording hazardous waste generation and management data (used to prepare RCRA biennial reports, annual Toxic Release Inventory reports and other filings)
- entering, analyzing data from toxicological and epidemiological studies.

All of these systems would generate "electronic records." Under CROMERRR, these records would satisfy the recordkeeping requirements of EPA rules *only* if they satisfied all the requirements of CROMERRR.[9] If a particular record doesn't meet CROMERRR, then the facility is in violation of the underlying recordkeeping requirement.

Simply printing out a record does not seem to be an adequate solution. For one thing, the data will have existed for some period of time in electronic form. If that electronic system does not meet CROMERRR requirements, then theoretically it could have been tampered with before it was printed. But even if you could avoid CROMERRR by printing out data as soon as it was generated, that would hardly be a helpful solution. In that case, a rule designed to "remove . . . obstacles to electronic . . . recordkeeping"[10] would be forcing facilities to print out all their records onto paper – including records they are now keeping electronically. This would be an ironic result, clearly inconsistent with a statute entitled the Government *Paperwork Elimination* Act.

Again, the foregoing is not paranoid speculation -- the FDA has interpreted its functionally identical rule to mean that if data ever pass through a computer, that

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[7] *See* 62 Fed. Reg. 13437 (Mar. 20, 1997), discussing 21 C.F.R. Part 11.
[8] The Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692.
[9] *See* proposed 40 C.F.R. § 3.100(a), 66 Fed. Reg. 46190.
[10] 66 Fed. Reg. 46163.

computer must comply with the FDA rule, even if the data are printed out. EPA intends CROMERRR to be consistent with the FDA rule. And complying with CROMERRR, like complying with the FDA rule, would be a major nightmare.

CROMERRR's requirements are very demanding and very expensive

As mentioned before, electronic reporting and recordkeeping have already demonstrated great savings and convenience in the commercial world. Why, then, would anyone be concerned about switching from paper to electronic records? The answer, in a word, is fraud. Paper records have an inherent connotation of authenticity, even though forgery is as old as handwriting. In the electronic world, though, data are simply miniscule electrical charges that can vanish – or be changed – with a keystroke. Any organization that relies on electronic data has some legitimate concern about preserving the integrity of that data -- about ensuring that unauthorized people can't make changes to data, and that authorized people can't make improper changes without detection.

But ensuring integrity has an impact on the scope and effectiveness of the system. The extent of this impact depends on how secure the system needs to be. That's why OMB's implementing guidance for the Government Paperwork Elimination Act calls for agencies to do a risk analysis for each type of recordkeeping requirement to assess:

- how likely is it that fraud will occur?
- how bad are the consequences if it does?
- how much will differing degrees of security cost?[11]

OMB's guidance instructs agencies to adopt the appropriate level of protection, based on this analysis. It specifically admonishes them not to adopt a one-size-fits-all approach.[12]

We have been unable to find any evidence that EPA ever performed this analysis – not in the preamble to CROMERRR, not in the Agency's cost-benefit analysis, or anywhere else. It appears that EPA simply took the highest degree of security – the one used by FDA -- and imposed many aspects of this far-reaching system on *all* EPA recordkeeping. The elements of this level of security are substantial:

- *Audit trails*. Records must have secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator key entries and actions that create, modify or delete electronic records.
- *Archiving*. The records must be stored in such a way that completely preserve the context in which the document was prepared, the associated metadata (i.e., information about the data) and the audit trail.
- *Migration*. If a facility ever migrates an electronic record from one medium or format to another, EPA expects each record, plus all of its metadata, to be transferred from the original to the new format so that the entire body of

[11] *See* "OMB Procedures and Guidance on Implementing the Government Paperwork Elimination Act," Part II, § 3, 65 Fed. Reg. 25514 (May 2, 2000).
[12] *Id.* at 25510. The guidance also admonishes agencies to continually assess the risks to their own computer systems and to maintain adequate security. *Id.*

information is moved without modification. Error checking functionality would be required to verify that this occurred.

- *Ready onsite availability*. The record, and all of its meta data, must be "readily available" at any time for onsite inspection and offsite review.

The net, intended result of these requirements is an essentially tamper-proof system, in which any attempt to compromise data will leave indelible traces for prosecutors. EPA also requested comment on a range of other security features of the FDA rule (e.g., validation, training, operational and authority checks) that would only further increase the burden of CROMERRR.[13]

Moreover, CROMERRR requires facilities to comply with these requirements for the life of record, which is defined by the underlying recordkeeping requirement. While some of these are only 3-5 years, many are much longer. For example:

- The operating log maintained by a hazardous waste treatment, storage or disposal facility must be kept for the life of the facility, which could be decades.[14] When you consider that a hazardous waste incinerator may be required to monitor air emissions every six minutes, and that these monitoring data must go into the operating log, you can see the daunting challenge of CROMERRR.
- Data supporting a pesticide registration must be kept for the life of the registration, which again can be decades. These supporting data -- primarily involving toxicology studies – are also exceedingly voluminous.

Meeting CROMERRR requirements would often mean complete overhauls of computer systems, at huge costs. No commercially available, off-the-shelf software package meets these requirements. While some vendors claim they have patches to make popular software compliant, these patches are generally still in beta form, and not available off-the-shelf. Companies are not going to want to stake their legal liabilities (and reputations) on these products. Questions have also been raised about the extent to which the licenses under which regulated entities use software would allow them, or their contractors, to modify that software. Many and perhaps most corporate information systems are already customized to the company or facility to the point where they may not be "patchable." Such systems might have to be completely redeveloped from ground up.

Software evolves rapidly. The costs and technical challenges of migrating enormous, CROMERRR-compliant data sets to new formats and systems so that they retain the required functionality will often be prohibitive. Companies may be compelled to leave those data on old, "legacy" systems that might have no other function but to maintain old electronic records. It would be extremely costly to maintain such old systems, and very difficult to retain information technology staff willing to work on such a dead-end career path.

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[13] *See* 66 Fed. Reg. 46171-72.
[14] *See, e.g*, 40 C.F.R. §§ 264.347(d), 264.73(d).

The lessons learned from the FDA rule should not be forgotten. As noted above, the FDA adopted essentially the same rule as CROMERRR in 1997.[15] Four years later, the Food & Drug Law Institute notes that "many [companies] are still struggling to understand and implement it" and have been forced to "develop a compliance plan" with the FDA to come into compliance years after the effective date.[16] Many drug companies are spending in excess of $100 million *each* to comply. The FDA, like EPA, advertised its rule as voluntary and cost-saving.[17] It has turned out to be dramatically otherwise. Let's not make the same mistake twice.

The theme of this hearing is whether bad analyses lead to irrational rules. In a very vital respect, EPA has *done* an analysis, but then ignored it. The preamble to CROMERRR mixes reporting and recordkeeping together and declares that, combined, they will save the regulated community over $300 million/year.[18] But combining the two obscures the findings of EPA's own cost/benefit analysis, which looked separately at reporting and recordkeeping. It assumes that *only one half of one percent* of the 1.2 million facilities that file reports under EPA administered laws would implement the recordkeeping provisions, due to their "very significant" costs.[19] EPA's estimated costs include first-year implementation costs of $40,000, and $17,000 annual operating costs, per facility.[20] Compared to the costs that these 6,000 facilities would otherwise have incurred for recordkeeping, the analysis concludes that these facilities would incur additional net costs for every year of CROMERRR implementation. In the second year, the cost for just these 6,000 facilities would be $14.69 million.[21] So electronic recordkeeping will not reduce costs.

But even this analysis assumes that facilities have a choice, which is an incorrect assumption. CROMERRR is likely to apply to most, if not all, of the 1.2 million facilities reporting under EPA-administered laws, and possibly others who don't report but who keep records documenting that they don't have to report. In that event, the costs identified in the cost-benefit report would be staggering – in the tens of billions of dollars annually. Even small businesses are going to face major costs from CROMERRR; there can be no question that the rule would produce a significant impact on a substantial number of small entities. EPA's claim to the contrary is wrong, and it will need to comply with the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act if it proceeds.

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[15] 62 Fed. Reg. 13430 (Mar. 20, 1997).

[16] See www.fdli.org/pubs/audio/electronic.html. The FDA was forced to issue enforcement guidance recognizing that firms would need "a reasonable timetable for promptly modifying any systems not in compliance (including legacy systems) to make them Part 11 compliant," and deferring enforcement where firms could "demonstrate progress in implementing their timetable." 64 Fed. Reg. 39147 (July 21, 1999).

[17] *See* 62 Fed. Reg. 13431, 13434.

[18] 66 Fed. Reg. 46186.

[19] Logistics Management Institute, "Cross-Media Electronic Reporting and Records Rule; Cost-Benefit Analysis" (March 2001), at 3-7.

[20] *Id.* The preamble to the proposed rule repeats the $40,000 implementation cost, but claims facilities would save $23, 080 annually in operating costs. 66 Fed. Reg. 476178. We cannot see where EPA derived that number, which conflicts with its own cost-benefit analysis.

[21] *Id.* at 3-8.

Solutions

Mr. Chairman, it is important to remember that CROMERRR is intended to implement the Government Paperwork Elimination Act. That law says only two things about recordkeeping:

- Agencies must "provide . . . for the option of the electronic maintenance . . . of information, when practicable as a substitute for paper";[22] and
- Electronic records . . . maintained in accordance with procedures developed under this [law] shall not be denied legal effect, validity or enforceability because such records are in electronic form."[23]

Regulated entities already have the option of keeping records electronically. They have been doing so for years. In our experience, no one in federal or state government has attempted to deny the legal effect, validity or enforceability of these records. In fact, many EPA rules expect records to be kept electronically. For example, the Hazardous Waste Combustor MACT standard - issued two years ago - specifically authorizes facilities to use data compression, a concept that only makes sense when one is talking about electronic data.[24]

By its terms, then, the GPEA doesn't really require EPA to do *anything* regarding electronic recordkeeping. But if CROMERRR goes final, it will have the paradoxical effect of current electronic records being denied legal effect, unless companies (i) spend huge sums of money to comply or (ii) go back to paper, where that's possible. This result conflicts with and frustrates Congressional intent. It is an irrational result.

We also note that GPEA provides agencies with no authorization to "improve the level of corporate individual responsibility and accountability . . . that currently exists in the paper environment," which is one of the asserted purposes of CROMERRR.[25] EPA's proposed requirements would greatly exceed reliability associated with paper records, rather than being "generally equivalent."[26]

Mr. Chairman, we appreciate and fully support the federal government's legitimate concerns about fraud occurring with electronic records. But the Office of Management & Budget, in its GPEA guidance, has dealt with this issue. As discussed above, the guidance instructs agencies to conduct a risk analysis, but EPA apparently has not done so. While it may be an open question whether bad analyses lead to irrational rules, this rulemaking demonstrates that doing *no* analysis surely does.

We urge EPA to conduct this analysis. We also urge them to note OMB's finding that the risk of fraud is highest in cases of one-time transactions between strangers involving

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[22] Section 1704(1), codified at 44 U.S.C. § 3504 note.
[23] Section 1707, *id.*
[24] *See* 64 Fed. Reg. 52961 (Sept. 30, 1999).
[25] *See* 66 Fed. Reg. 46166.
[26] *Id.*

large sums of money, and lowest in cases of ongoing regulator/regulated relationships – like those involved in this rule.[27] A cursory review of environmental false statement cases suggests fraud usually occurs at the outset, with wrong data entered in the first place, not after the data have already been reported. EPA also needs to consider that paper systems aren't fraud-proof. Without conducting the risk analysis called for by OMB, EPA cannot justify the enormous real costs of CROMERRR to protect against undocumented, hypothetical risk of fraud.

Finally, it is ironic that now, when everyone is calling for more and better information about environmental quality and the performance of individual facilities, EPA's Office of Environmental Information is mandating that regulated entities spend their limited information resources not on procedures that give us valuable new information, but on elaborate procedures to guard against unanalyzed risks.

While well intentioned, this proposal is ill-considered. In particular, it fails to give adequate notice regarding its mandatory effect and its massive costs. The only fair solution is to pull it back and start over. It may be acceptable for the reporting portion to proceed with through the rulemaking process, although we have heard some concerns about it. There also are questions about whether the reporting half of CROMERRR can stand without the recordkeeping half; i.e., whether electronic reports need some provisions regarding the integrity of documents. However, if those provisions are at the CROMERRR-level of cost and complexity, you can be sure that no one will volunteer for electronic reporting.

Mr. Chairman, the American Chemistry Council is ready and willing to engage with EPA and other stakeholders in a discussion about the right approach to electronic recordkeeping. But that process will take time, and will probably need face-to-face, real-time workshops involving technical people. It certainly cannot take place in the context of the current proposal.

Thank you for the opportunity to present this testimony. Please do not hesitate to contact me if you would like to pursue this important topic.

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[27] *See* 65 Fed. Reg. 25517.

TESTIMONY OF
Anne G. Giesecke, Ph.D.
Cochair of the **Clean Water Industry Coalition,**
Vice President
Environmental Activities
American Bakers Association

Before the Subcommittee on Regulatory Reform
And Oversight
House Committee on Small Business

November 2001

Mr. Chairman, members of the Subcommittee, on behalf of the Clean Water Industry Coalition (CWIC), an *ad hoc* group of more than 250 companies and associations representing the nation's major manufacturing and service industries, including automobile, chemical, food processing, glass, mining, oil, plastic, forest and paper, real estate, steel, surface finishing, textile, electric and water utilities, agribusiness, transportation and associated industries, I want to thank you for this opportunity to testify before you today.

WIC is pleased that this subcommittee is exploring the quality of Environmental Protection Agency's (EPA) regulatory analyses and whether those analyses are adequate to support rational rulemaking.

At the outset, it is important to remind everyone that the millions of people working to make our economy function share basic American environmental, health and safety values and want them applied in their workplaces, their homes and their communities. We certainly support strong environmental and health rules that are founded on sound science and developed in a deliberative and public process that includes working with the states and the regulated community so that the requirements to

achieve the rules' goals are both effective and cost conscious. A number of rules that were hurried through the promulgation process in the final days of the last Administration suffered from a demonstrable deficiency in these essential qualities of responsible rulemaking. The abuse of science and slanted cost-benefit analyses has been an endemic problem at the EPA. These tools should be an integral part of the regulatory analysis at the earliest stages and be used to understand and define policy choices, not defend policy choices after they've already been made.

The members of CWIC believe that last year's rulemaking pursuant to the Clean Water Act to revise Total Maximum Daily Load (TMDL) regulations was hastily issued and seriously understated the available science and the economic impacts on state and local governments and the regulated community. Among the rule's many problems, it did little to address serious concerns with current state 303(d) lists of impaired waters arising out of poor or nonexistent available water-quality data, thereby establishing a potential for a gross misallocation of scarce resources.

The Clean Water Act requires each state to identify waters that are not meeting water-quality standards after the application of technology controls on point source dischargers. The resulting list is often referred to as the state's 303(d) list, and states are required to establish total maximum daily loads – or TMDLs – for all waters on this list. Establishing a TMDL requires a state to determine how much reduction each point and non-point source of pollution on the waterbody must make for water-quality standards to be met. It is a complex, difficult and expensive calculation that needs science based monitoring data to be effective and presents a resource management issue for the federal government, the states and the regulated community. We believe, therefore, that the

process should be targeted towards those waters clearly established as impaired based on good data and upon sound scientific analysis.

The rule signed by Carol Browner on July 11, 2000, in the face of strong opposition by Congress, the states and many stakeholders did not cure many of the major substantive concerns raised by these opponents during the rulemaking and about which there was considerable consensus. It therefore remains controversial, and we are pleased that Administrator Whitman has just signed a final rule to delay the effective date of the TMDL rule until April 30, 2003, to allow for a review and revision of the rule. We are also pleased that the requirement for states to submit a new list of impaired waters in April 2002 has been delayed until October 2002. We hope that subsequent guidance to the states on how to develop those lists will result in a common-sense, reasonable prioritization of resources to those waters that are clearly impaired by pollutants and suitable for TMDL development as contemplated by the Clean Water Act.

Towards that end, the new guidance and any revision of the TMDL rule must establish a framework for the program that recognizes the finite resources available for the water program – especially given new priorities for state, federal and private resources arising out of the events of September 11. As discharge permittees, industry is concerned that insufficient funds and high costs will harm states' abilities to adequately manage their respective water programs. Manufacturers, particularly those of us in the food sector, need a clean, abundant and affordable water supply.

The Association of State and Interstate Water Pollution Control Administrators (ASIWPCA), the national professional organization of the state and interstate water-quality program officials, stated in their January 20, 2000, comments to the EPA that

"State TMDL development and implementation to date clearly demonstrates that the cost estimates developed by the EPA are inadequate, incomplete and misleading. Far more will be required to develop a TMDL than the $25,000 the EPA envisions." ASIWPCA members testifying before Congress have estimated the costs to states of preparing nearly 40,000 TMDLs over 15 years, as presently required, to be between $1 billion and $2 billion annually. Moreover, in a recent draft cost report mandated by Congress because of its dissatisfaction with EPA's earlier cost estimate ["The National Cost of the Total Maximum Daily Load Program"], the EPA estimates that the average annual cost for developing TMDLs will be $63 million to $69 million. This is significantly more than EPA's earlier estimate of $25,000 and it does not include the estimated funding needed to properly identify and list impaired waters and to undertake the activities essential for implementing and monitoring the success of a TMDL.

In a recent General Accounting Office (GAO) study, only six states responded that they have a majority of the data needed to fully assess all their waters. According to the same study, 45 states reported that a lack of resources was a key limitation to improving water quality. In addition, several states pointed out that they are operating under state-imposed staffing restrictions and others said that they are limited in how many samples they can analyze because of the shortage of laboratory funding. EPA staff admitted that fewer resources are being devoted to monitoring and assessment at the state level than ever before.

In addition to these program costs are the costs that will be incurred by the regulated community to participate in TMDL development and even more significant costs of compliance. The capital and annual operating and maintenance cost for

companies is staggering. The Advent Group, a wastewater consulting company, estimates that the cost of the TMDL regulations on the regulated community to be between $20 billion and $80 billion over a 10-year period. Furthermore, the EPA in its draft report estimates the costs to the regulated community to implement the TMDL program to be possibly as high as $1 billion to $4 billion per year, depending on the efficiency of the TMDL. These are preliminary numbers that do not take into account the many variables, such as contaminated sediment remediation; management of combined sewer overflows; measures to address biological impairments; industrial and commercial site costs for controls required by storm-water regulations; and data-collection and potential-litigation costs. We believe that these cost estimates are very conservative and are likely to be much higher for the private sector.

The TMDL process is primarily a measurement process directly related to the setting of water-quality standards. Appropriate standards linked to appropriate and effective analytical tools, coupled with realistic understanding of available resources, are critical. A framework that perpetuates and compounds problems in each of these areas leads to a flawed rule. A framework that fails to address or remedy problems in these areas is indicative of bad regulatory analysis that is unlikely to yield the environmental benefits we desire as a country and is most likely to squander tremendous resources in the process.

Was the TMDL rule the result of bad analysis? In a recent National Academies of Science (NAS) National Research Council (NRC) study ["Assessing the TMDL Approach to Water-Quality Management"], the NRC listed numerous errors, the lack of sufficient data and unscientific rationale for proposing the rule. The NRC stated that

"water-quality standards must be measurable by reasonably obtainable monitoring data. In many states, there is a fundamental discrepancy between the criteria that have been chosen to determine whether a waterbody is achieving its designated use and the frequency with which water-quality data are collected." Many waters on state 303(d) lists did not have the benefit of adequate water-quality standards, data or waterbody assessment. The report goes on to state "the EPA needs to develop a uniform, consistent approach to ambient monitoring and data collection across the states."

There is a concern in the regulated community that it is impossible to know the quality of the data from state to state. A uniform procedure ensures that there is legitimacy to the process. The committee also found that "although in many situations the science is sufficient to develop TMDLs to meet ambient water-quality goals, the programmatic issues substantially hinder the use of the best available science."

These issues must be addressed in any revision of the TMDL rule promulgated in July 2000. We are hopeful that, during the next 18 months, steps can be taken to revise the rule and to establish a framework that is technically, scientifically and programmatically sound and with the kind of transparent decision-making necessary for public support.

We applaud you for holding this hearing to focus on the need for EPA to use sound science and cost-benefit analyses to define the health and environmental problems and design the most cost-effective remedies, rather than to corrupt these analyses in order to defend policy decisions already made.

Thank you and I will be happy to answer any questions.

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November 5, 2001

The Honorable Mike Pence, Chairman
House Subcommittee on Regulatory Reform Oversight
2361 Rayburn House Office Building
Washington, DC 20515-6319

Dear Mr. Chairman:

The Subcommittee on Regulatory Reform Oversight is planning to hold a hearing on November 8, 2001 on the use of science in decision-making. The Annapolis Center for Science-Based Public Policy promotes policies based on sound science. We believe that Congress could go a long way to assure that regulations are based on science and not emotion by requiring that Federal agencies adopt the Center's Annapolis Accords on Risk Analysis, Cost-Benefit Analysis, and Toxicology. These basic principles assure that minimal standards are adhered in the use of science and cost-benefit analysis. These principles also set parameters about the use of Toxicology in decision-making.

I am also pleased to send you the Center's publication "*Epidemiology in Decision-Making*". While this publication does not describe "accords" or principles, it does discuss the role strengths and weaknesses of epidemiology in decision-making.

I request that our reports be included in the hearing record for this hearing.

Sincerely,

Harold M. Koenig, M.D.
Vice Admiral, Retired and
Former Surgeon General, United States Navy
Chair and President,
The Annapolis Center for Science-Based Public Policy

HMK/dmh
Enclosures
Cc: House Subcommittee on Regulatory Reform Oversight

THE ANNAPOLIS CENTER
The Annapolis Accords for Cost-benefit Analysis

Growing concern over the effect of environmental, health and safety policies on the economy has lead to increased consideration of the benefits and costs of such policies. Cost-benefit analysis has been used as a means of comparing the costs of positive benefits with the negative impacts, and can result in improved environmental, health and safety decision-making and prioritization.

Policy alternatives cannot be compared, and management decisions should not be made, unless the risks associated with a particular hazard are identified and the benefits and costs of regulating that hazard are quantified. The *Annapolis Accords For Cost-benefit Analysis* have been developed as a guide to understanding how risk assessment and cost-benefit analysis can be incorporated in the decision-making process for the development of legislation, regulations, or operational policy.

COST-BENEFIT ANALYSIS AS A DECISIONMAKING TOOL

Cost-benefit analysis should be an integral part of the decision-making process. Cost-benefit analysis should be used to provide information to decision-makers and the public on the benefits and costs of policies to protect public environmental, health and safety quality. Decision-makers should not be bound by a strict cost-benefit test, but they should be able to justify decisions where expected costs exceed expected benefits, or where costs are uncertain or in dispute.

Cost-benefit analysis should be used to identify the distributional consequences of a policy. As a decision-making tool, cost-benefit analysis allows decision-makers to consider the positive and negative impacts of a policy before it is implemented. The analysis should be used to compare the negative impacts of policy decisions, such as job losses or increased costs to an industry in a local economy, with the positive impacts, such as improved health.

Cost-benefit analysis should be used to design policy strategies that achieve a desired goal at the lowest possible cost. In the past, environmental, health and safety policies have relied on a "one-size-fits-all" or "command-and-control" approach. Cost-benefit analysis can highlight the extent to which cost savings can be achieved using alternative, more flexible approaches, such as performance standards and market-based approaches, that reward compliance at a lower overall cost to society.

Policymakers should attempt to incorporate cost-benefit analysis in the decision-making process at all levels of government. Decision-makers at all levels of government should be encouraged to consider the benefits and cost of proposed policies. The scale of the cost-benefit analysis should depend on the risks involved, the timeframe of the decision-making process, and the available scientific and economic information. Although a comprehensive cost-benefit analysis may not be warranted in all cases, a rough cost-benefit analysis can be useful in providing decision-makers with an estimate of the benefits and costs of a proposed policy.

Whenever possible, decision-makers should rely on more than one cost-benefit analysis to consider, and weigh, a variety of regulatory options. To increase the amount of information available to decision-makers, a variety of policy alternatives for achieving a desired goal should be considered. To accomplish this, more than one cost-benefit analysis should be performed so that the benefits and costs associated with various alternatives can be estimated and compared.

ASSESSMENTS OF BENEFITS AND COSTS

A quality cost-benefit analysis depends on the availability of a scientifically sound risk assessment. A scientifically sound risk assessment of a hazard should include all relevant peer-reviewed, up-to-date information which takes into consideration all potential consequences for human health, quality of life, and health of ecosystems. A risk assessment should clearly communicate sources, assumptions, limitations and uncertainties in the available scientific data.

Risks need to be estimated qualitatively and quantitatively before benefits and costs can be measured. Assessments of risk should use all relevant information necessary to characterize a potential health or environmental hazard. Both quantitative and qualitative estimates of risk should be based on clear definitions of hazards, types and amounts of exposures, the variability of response among affected populations, and effects over time. The benefits and costs of protecting the public from a hazard cannot be estimated until the risks of that hazard and the uncertainties are qualitatively and quantitatively identified.

All key assumptions should be spelled out clearly and, whenever possible; uncertainties should be identified and discussed. A core set of economic assumptions should be used in calculating the benefits and costs associated with environmental, health and safety regulations. Key assumptions include the social discount rate, the value of reducing risks and accidents and premature death, and the value associated with other improvements in health. If uncertainties exist in the available scientific and economic information, estimates based on this information should be clearly identified and discussed.

Benefits and costs should be quantified whenever possible. Not all impacts of a regulatory policy can be quantified, or expressed in monetary terms. The available information may imply ranges of possible values for estimating benefits and costs, and not single numbers, which makes quantification difficult. When this occurs, best estimates of the costs and benefits should be included along with a description of the uncertainties. This will prevent qualitative factors that are not easily quantified from being ignored in a cost-benefit analysis.

Peer review is a necessary part of a complete cost-benefit analysis. Given the uncertainties inherent in cost-benefit analysis, the results should be peer-reviewed by an outside panel of economic and scientific experts. Before a cost-benefit analysis is performed, guidelines should be established by an outside review body for agencies to follow in conducting cost-benefit analysis, and revised periodically on the basis of new scientific and economic information.

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THE ANNAPOLIS ACCORDS FOR RISK ANALYSIS:
A CITIZEN'S GUIDE FOR RISK-ASSESSMENT AND RISK-MANAGEMENT

RISK-ASSESSMENT ACCORDS

A risk assessment should be complete. A complete assessment of a hazard, using peer-reviewed, state-of-the-art information, includes consideration of potential consequences for human health, quality of life, health of ecosystems and economic well being.

All relevant information should be used in risk assessments. Assessments of risk should use all relevant information necessary to characterize a potential health or environmental hazard. If an assessment does not include all relevant information, there should be a clear explanation of the reasons for such an omission and explicit judgments about the quality and weight of the evidence.

Estimating risk should be based on clear definitions. Both quantitative and qualitative estimates of risk should be based on clear definitions of hazards, types and amount of exposures, the variability of response among affected populations, and effects over time.

Claims about scientific certainty should be spelled out and sources given. Risk assessment is an ongoing process that needs to carefully reflect the latest information. Claims about scientific truths and consensus should, therefore, be made with caution. Assessments should clearly communicate sources, assumptions, limitations and uncertainties in the available scientific data.

Risk considerations should be clearly communicated. Judgments of the seriousness of hazards should include quantitative estimates of risk and consideration of qualitative factors to enhance their understanding and use not only by scientists and policy-makers but also by the public.

Risk-Management Accords

Opportunities should exist for informed public contribution in risk-management decisions. Risk-management plans and policies should include early opportunities for participation by a variety of interests. Such participation should involve evaluating risk estimates and risk-reduction alternatives that are compatible with other significant societal goals. Risk-assessment information should be available and understood by all participants in the risk-management process.

Decision-makers should use risk assessments to prioritize public health and environmental-risk management. Risk-based priorities should be identified, using the best possible assessment to help assure that significant resources are allocated to addressing the largest and most important health and environmental threats. Risk-ranking techniques should be developed to compare the quality of assessments of natural and manmade risks.

Risk-management decisions should consider the benefits and costs of alternative policies. When risk-management policies are developed, policy-makers should insist on having information about what the expected benefits will be, who will incur gains or losses, and how much each alternative will cost and who will pay. When combined with the insight provided by risk assessments, such benefit and cost information can yield the fairest level of public health, environmental and economic protection.

Risk-management decisions should encourage the development and use of new knowledge and insight. Policies should be designed so that they provide incentives for new scientific knowledge and social, ethical and legal insight. Such incentives will continuously improve the quality of risk-based decisions.

Implementation strategies are a key element of risk management. Risk-management actions should consider a range of innovative and adaptive policies and administrative steps to achieve public health and environmental goals more rapidly and cost-effectively. These strategies should include non-regulatory approaches.

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promoting responsible environmental, health, and safety decision-making

Epidemiology In Decision-Making

The Role of Epidemiology in Decision-Making

Legislatures and administrative agencies considering environmental and public health issues frequently must evaluate methods, analyses, and conclusions of epidemiological (EPI) and other scientific evidence which provides a basis for expert opinion studies. To provide guidance for decision-makers, The Annapolis Center convened a workshop in June 1998 of thirteen scientists, doctors, and lawyers with extensive training and experience in epidemiology, toxicology, pharmacology, and forensic use of scientific evidence.

Recognizing that sufficient literature for specialists already exists, the workshop group agreed to produce a primer for non-scientists who seek to understand epidemiologic studies. In that spirit, the group debated and eventually arrived at a number of observations concerning epidemiological studies. Those observations include the following:

- Today, epidemiology is formally understood as the study of the distribution and determinants of diseases in humans.
- No two EPI studies are identical, and no given study can be replicated exactly.
- Absolute risk is a more useful measure for legislators and policy-makers than relative risk because it shows the foreseeable impact of exposure to the risk factor.
- Nevertheless, in some situations, relative risk is more useful to courts and those required to evaluate causation.
- To epidemiologists, *association* means only that a risk factor and the disease occur together. It does not necessarily mean the factor *causes* the disease. Co-incidence is not proof of cause.
- Even if it finds an association between a suspect factor and disease, a poorly designed study is of questionable value to decision-makers because chance, bias, and confounding cannot be excluded as explanations for the association. However, some design errors-may not be fatal, and the extent and direction of error can be estimated in some cases.
- In a well-designed study, the investigator will foresee the likely sources of bias and take steps to control them to the degree practicable.
- The meaning of *cause* in scientific inquiry often differs from the meaning of *cause* in legal proceedings. Accordingly, legal decision-makers must first determine that the evidentiary weight of relevant epidemiologic data is appropriate to the issues before them.
- Although EPI studies never prove causation, either generally or in a specific case, they can show cause to be more (or less) likely as a potential explanation for an observed association between risk factor and disease. Furthermore, EPI studies *per se* do not prove safety.

- **Determination of causation requires a weight-of-evidence approach that considers epidemiology, biologic mechanisms of action, relevant toxicology, and other factors.**

The group developed a series of cautions for users of EPI research. These cautions centered on:

- Scrutiny of investigator credentials whenever an EPI study is used in decision-making.
- Limitations in the applicability of EPI studies, given the parameters of design of a particular study.
- Reliance on databases and their reliability.
- Extrapolation of animal studies to the question of disease causation in humans.
- Reliance by EPI investigators upon research findings in other disciplines.
- Differing degrees of certainty in defining and measuring adverse effects following exposures of specified intensity and duration.
- Consistency of findings between and among studies.
- Expertise of peer reviewers and their ability to judge the quality of studies they review.
- Design of meta-analyses, especially the comprehensiveness of source information.

Lastly, the group developed the following suggestions for policy-makers, regulators, and courts for optimum use of EPI in legal proceedings:

- Consider the use of neutral, advisory experts in epidemiology and allied fields (*e.g.,* toxicology and statistics).
- Allow appropriately educated legislators and regulators to make final decisions on public-health policy that may have major economic impact. These decisions should be made only with explicit evaluation of the costs of such proposals measured against reduction of risk that may be achieved.
- Disclose the EPI and other evidence cited to justify proposed regulation, and consider application of Daubert to judicial review of the science upon which administrative agencies rely.
- Develop and apply uniform standards for the identification, characterization, and assessment of risks.
- Urge judges who function as "gate-keepers" of scientific evidence to make greater efforts to scrutinize the quality of research underlying an expert's opinion.

The Role of Epidemiology in Decision-Making

The Annapolis Center
1999

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Introduction

Epidemiology is the study of which groups of people get which diseases and why. EPI is increasingly a source of the scientific evidence that legislatures, administrative agencies, and courts consider when they have to decide whether a substance is toxic enough to cause illness or death.

This primer on epidemiology was created for these decision-makers and their professional staffs – counsel to Committees of Congress and of State legislatures, agency legal staffs, and judicial clerks in federal and state courts. It may also be useful to others without special training in science, such as journalists and the public, who may have to judge the relevance and reliability of scientific or media reports about the risks of specific foods, medicines, activities, occupations, or environments.

> Legislatures and administrative agencies considering environmental and public health issues frequently must evaluate methods, analyses, and conclusions of epidemiological (EPI) and other scientific evidence that provides a basis for expert opinions.

A typical case concerning the use of EPI data in litigation is the U.S. Supreme Court decision in General Electric Co. v. Joiner. In Joiner, a city electrician sued the manufacturer of the transformers he worked on, claiming that the polychlorinated biphenyls (PCBs) produced by the transformers caused his lung cancer. The trial court ruled that the opinions of Mr. Joiner's experts on causation were not admissible evidence because the EPI studies underlying these opinions were unreliable.

One of the studies, of cancer mortality among capacitor workers, involved a group of subjects too small to permit statistically significant estimates of risk. Another study of capacitor workers did show an increase in lung cancer deaths but did not examine PCB-exposure as a possible cause. A third study failed to rule out cigarette smoking as a possible cause.

The District Court granted summary judgment to General Electric, but the Court of Appeals disagreed with the lower court's assessment of the scientific evidence. General Electric appealed to the Supreme Court. In finding for General Electric, the Supreme Court relied on its own decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 597 (1993). In Daubert, the Court construed Federal Rule of Evidence 702 (dealing with expert witness testimony) to require that federal trial courts admit scientific evidence only after determining that it is both relevant and reliable.

The rules of evidence in many states are modeled on the Federal Rules of Evidence. Consequently, trial courts in those states that decide to follow Daubert also take on the role of "gatekeeper". Legislatures and administrative agencies considering environmental and public health issues already find themselves having to judge the methods, analyses, and conclusions of EPI and other scientific studies upon which expert witnesses base their opinions. Yet the professional staffs on which these decision-makers routinely rely seldom have scientific training

or skills, or even a working familiarity with the terms, concepts, methods, and reliability criteria of EPI research.

In light of these developments in the law, The Annapolis Center convened a workshop in June of 1998 of thirteen scientists, doctors, and lawyers with extensive training and experience in epidemiology, toxicology, pharmacology, and the forensic use of scientific evidence. Recognizing that sufficient literature for specialists already exists, the workshop group agreed to produce a primer for non-scientists who seek to understand epidemiologic studies. This primer explains what EPI evidence is composed of, what its strengths and limitations are, and how it can best be used by legal decision-makers.

What is Epidemiology and Who Uses It?

In the early 20th century, "epidemiology" meant almost exclusively the study of epidemics of diseases such as smallpox, malaria, and typhoid fever, which are spread through infection by bacteria or viruses. In the United States and other advanced countries, most of the epidemic diseases of that time have now been eradicated or controlled. Since mid-century, it is chronic, rather than infectious diseases that have been studied the most.

Today, epidemiology is formally understood as the study of the distribution and determinants of diseases in humans.

A single event, such as an insect bite or ingestion of an air- or food-borne virus, can start an infection. Chronic diseases, in contrast, develop over time, often years (*e.g.,* various cancers and respiratory disorders), and they typically involve repeated exposure. They may be caused or influenced by agents found in foods and medicines, the home and the work place, or even in the natural environment.

Today, epidemiology is formally understood as the study of the distribution and determinants of diseases in humans. The two main branches of the subject correspond to the two elements of this definition.

Descriptive epidemiology tries to identify which groups of people get which diseases. Descriptive studies simply report the actual distribution of disease in different *populations.* Children exposed to environmental lead, workers exposed to particular job-site chemicals (*e.g.,* benzene, PCBs, asbestos), and users or consumers of the same food, prescription drug, or municipal water supply are examples of *populations.* Epidemiologists doing descriptive studies use census data, demographic information, death certificates, health and autopsy records, and other sources in their efforts to identify patterns of disease distribution.

Analytical EPI attempts to identify the reasons why certain groups develop certain diseases. Often, the investigator has used descriptive studies as the basis for hypotheses about what causes a disease or makes its onset more likely. An analytical study seeks to identify the specific agents or events that may be associated with the development of disease, and to assess the degree of risk, if any, that may result from exposure to the suspected hazards.

The most direct way to identify hazards that may cause or contribute to disease would be an experiment in which a group exposed to the suspect agent or event is compared to another group that has not been exposed. Medical ethics, however, does not permit this kind of experiment with human beings. Consequently, the analytical epidemiologist must gather data not by experiment but by observation. The researcher selects for study a sample of people who have allowed themselves to be exposed to the suspect agent (*e.g.,* cigarette smoke) or who have been exposed to an agent unknowingly (*e.g.,* radon). By studying the health histories of persons in the sample, the researcher hopes to discover *risk factors* that make onset of disease more likely.

Among the important concerns of legislators, regulatory agencies, and courts are the risk factors associated with particular diseases. Consequently, analytical, rather than descriptive, EPI studies are typically of greater interest to these decision-makers.

How Epidemiological Research Is Done

The investigator in an EPI study usually begins with a hypothesis about potential risk factors associated with a disease. The researcher chooses a population having the relevant characteristics of age, race, sex, health history, social and economic status, geographical distribution, and exposure to the suspect agent or condition. Using standard statistical methods, the researcher selects a sample of this population. After the relevant data from this sample are collected (by interviews, written questionnaires, medical examinations, or telephone surveys), they are tabulated and interpreted.

> No two EPI studies are identical, and no given study can be replicated exactly.

Standards for interpreting data, judgments of relevance, and criteria of probative value may differ among investigators studying the same disease and risk factors. Standards, judgments, and criteria also may vary among different studies performed by the same investigator. Consequently, no two EPI studies are identical, and no given study can be replicated exactly. The uniqueness of each observational setting adds an element of complexity to assessment of the internal and external reliability of a study's conclusions.

Conventional science tests the reliability of conclusions by examining whether a number of different investigators doing the same experiment arrive at the same or similar findings. This kind of verification is not possible in epidemiology because its methods cannot include experiments that systematically expose people to suspected toxins. On the other hand, preventive measures, such as vaccines or new drugs, can be studied experimentally in *clinical trials,* where patients who are already ill are randomly assigned to receive either the treatment under study or a placebo (or the standard treatment, if any).

The Meaning of *Risk* in Epidemiology

Risk means likelihood and a *risk factor* is anything that increases the likelihood of disease. Since epidemiologists say that a person with a risk factor is *exposed* to the risk of developing the disease, risk factors are also called *exposures*. In a narrower sense, *exposure* means how great, how often, and how long was a person's contact with a risk factor (*e.g.,* cigarettes, asbestos, or lead).

> **A**bsolute risk often is a more useful measure for legislators and policy-makers than relative risk because it shows the foreseeable impact of exposure to the risk factor.

Assessment of the kind and magnitude of risk posed by a given exposure can be expressed as either an absolute or a relative risk. A statement of *absolute* risk indicates the percentage of the exposed population (*e.g.,* smokers) who will get the disease (*e.g.,* lung cancer). In public and private health decisions, absolute risk often is a more useful measure than relative risk because it shows the foreseeable impact, and therefore the probable health-care costs, of exposure to the risk factor.

> **R**elative risk is more useful to decision-makers who must evaluate causation.

Relative risk, on the other hand, is more useful to decision-makers who must evaluate causation. A statement of *relative* risk tells how much more or less likely it is that people with the risk factor (*e.g.,* smokers) or suspect characteristic will get the disease, when compared with those not having the risk factor (*e.g.,* non-smokers). For example, "smokers are ten times more likely to get lung cancer than are non-smokers" is a statement of relative risk.

When an EPI study finds an association between a suspect agent and a disease, the investigator typically expresses the magnitude of the association (*i.e.,* the relative risk) by a number (*e.g.,* 2.4). Depending on the kind of study, this number is called the standardized mortality ratio (SMR), odds ratio, or relative risk.

> **T**o epidemiologists, *association* means only that a risk factor and the disease occur together. It does not mean the factor *causes* the disease.

Thus, the relative risk number compares the occurrence of the disease in two groups: one group of people exposed to the suspect agent and another group of people not exposed. A relative risk ratio of 1.0 means that these two groups were found to develop the disease at the same rate. That is, the suspect factor has not been shown to be a true *risk factor,* which is to say it has a *null effect.*

By contrast, a relative risk ratio exceeding 1.0 suggests that exposure increases the risk of getting the disease, and the higher this number, the greater the risk. Relative risk ratios therefore show how strong the association is between risk factor and a disease.

> *Co-incidence is not proof of cause.*

To epidemiologists, *association* means only that a risk factor and the disease occur together. It does not mean the factor *causes* the disease. A relative risk ratio

exceeding 1.0 shows that the risk factor occurs with the frequency or at the rate the ratio indicates. But co-incidence is not proof of cause. For example, we do not cause the sun to rise by getting up at the same time it does.

Even if it finds an association between a suspect factor and disease, a poorly designed study is of questionable value to decision-makers because chance, bias, and confounding cannot be excluded as explanations for the association. Some design errors, however, may not be fatal, and the extent and direction of error can be estimated in some cases.

Epidemiologists attribute a demonstrated association to chance, bias, confounding, and/or causality. In a well-designed study, the investigator tries to reduce the influence of the first three, leaving cause as the most likely explanation of the demonstrated association. Even if it finds an association between a suspect factor and disease, a poorly designed study is of questionable value to decision-makers because chance, bias, and confounding cannot be excluded as explanations for the association. Some design errors, however, may not be fatal, and the extent and direction of error can be estimated in some cases.

Chance and "*p* Values"

Epidemiologists investigate groups, not individuals, and all EPI research uses samples selected from larger populations. Since no sample ever completely mirrors the whole of which it is a part, some of the observed differences between two samples can always be the chance effect of sampling. Consequently, epidemiologists use "standard" statistical tests to estimate how much uncertainty there could be in their findings due to sampling effect.

Statistical significance tests in epidemiology have been devised to assess the compatibility of a set of data with the null hypothesis (H_o) that a population exposed to agent "x" and a population not so exposed do not differ in the incidence or prevalence of condition "y" (implying that agent "x" does not cause condition "y"). In the process of "accepting" or "rejecting" H_o, investigators can make one of four different decisions based on the result of the statistical test. First, they can accept H_o when it is actually true. Second, they can accept H_o when it is actually false. Third, they can reject H_o when it is actually true. Fourth, they can reject H_o when it is actually false.

Rejection of H_o when it is in fact true is called a type I error, and the probability of making this error is called alpha. Acceptance of H_o when it is in fact false is called a type II error, and the probability of making this error is called beta. Investigators typically select a value for alpha, known as the *p*-value, prior to evaluating their data. By contrast, the value for beta depends on how much the true situation deviates from H_o. The greater the true hypothesis deviates from H_o, the smaller the value of beta. If beta is the probability of making an incorrect decision when H_o is false, then 1 minus (ß) is the probability of making a correct decision when H_o is false. This probability is called the power of a statistical test, and power increases the more the true hypothesis deviates from H_o. Importantly, the power of a statistical test is also a function of the chosen *p*-value, the variance involved, and the sample size. The concept of power is extremely important in the interpretation of statistical tests.

The interpretation of statistical tests typically begins when a statistic (e.g., *t*, chi-square, etc.) that summarizes the evidence against the null hypothesis (H_o) is calculated and compared to the distribution of such statistics if H_o is true. If the calculated statistic is judged to be too unlikely under H_o, then H_o is rejected. Otherwise, H_o is accepted at a stated level of significance known as the *p*-value.

Obtaining a statistically significant difference (say, $(p) < .05$, $p < .01$) between exposed and unexposed populations indicates that differences as large as, or larger than, those observed may occur with "too small" a probability under H_o to be reasonably attributed solely to chance. Conversely, obtaining a test result that indicates no statistically significant difference (say, $(p) > .05$, $p > .01$) between exposed and unexposed populations implies that differences as large as, or larger than, those observed may occur under H_o with "too large" a probability for the investigator to rule out the null hypothesis. Epidemiologists typically specify what they mean by "too small" or "too large" by selecting a particular *p*-value.

Consequently, a difference observed between the results of two populations that is judged to be statistically significant at $(p) < .05$ means that differences as large as, or larger than, that observed in the study would occur by chance alone less than 5% of the time. Conversely, a

difference observed between the results of two populations that is judged not to be statistically significant at $(p) > .05$ means that differences as large as, or larger than, that observed in the study would occur by chance alone more than 5% of the time.

A null hypothesis is neither proved nor disproved by any statistic evaluated at an arbitrarily chosen level of significance (p-value). "Acceptance" and "rejection" of H_o are merely terms that relate to specific probability statements computed under the hypothetical condition that exposure to substance "x" does not cause condition "y."

Finally, statistical significance is not equivalent to practical, clinical, or biological significance. Statistical significance pertains only to the existence of a difference, not its magnitude. To judge the practical significance of a finding, estimated magnitudes of differences must be considered in light of all accumulated evidence known to the investigator. Conversely, real and important differences may be missed even when data do not yield a statistically significant difference at a conventional level of significance (usually 0.05). The failure to obtain a statistically significant difference does not prove a real difference does not exist; it only shows that the observed difference easily could be explained by chance alone. Small sample sizes, large population variability, and small but real differences can all decrease the ability to use statistics to distinguish a real difference from random processes. If the EPI investigation had a very low power, for example, important, true differences between populations may not have been detectable.

Bias and Confounding

What epidemiologists mean by bias is a distortion of the real relationship between risk factor and disease. Bias can result from mistakes in selecting the study population, in choosing the people in the sample ("selection bias"), or in classifying them as sick or well, exposed or not exposed. Clerical error, omissions in data collection, and imperfect or poorly performed tests for disease or exposure are common causes of misclassification.

> In a well-designed study, the investigator will anticipate the likely sources of bias and will take steps to control them to the degree practicable.

Bias can also result from the recognized tendency of sick people to remember a non-existent exposure to the suspect agent ("recall bias") and from the tendency of investigators and interviewers to see what they want to see ("observer bias"). In a well-designed study, the investigator will anticipate the likely sources of bias and will take steps to control them to the degree practicable.

A "confounder" is another factor actually associated with both the putative risk factor and the disease, but not otherwise considered by the investigator. For example, we know that both smoking and workplace chemicals can be real or suspected causes of certain cancers. Suppose an investigator found a very strong association (risk ratio exceeding 3.0) between, say, PCBs and lung cancer, and the chosen p value was well under .05. Even if sources of bias in the study are well-controlled, the association would have little evidentiary value if the investigator failed to design the study to rule out smoking as a possible confounder. The trial court in Joiner found one of the studies cited by plaintiff's experts to have just such a defect.

Cause

Cause means something different in science from what it means in law. Different decision-makers have different standards for determining cause.

A variety of statistical, mathematical, and practical techniques are available to help epidemiologists minimize the effects of chance, bias, and confounding. When the investigator has used these techniques to the extent feasible, the most likely remaining explanation for a demonstrated association between risk factor and disease is cause. *Cause* means something different in science from what it means in law. Different decision-makers have different standards for determining cause.

Many scientists test conclusions by repeating experiments. When many different investigators make the same or similar findings, a conclusion is taken to have been proved true. The standard of proof is consensus of qualified opinions, verified by repeatable experiments.

Epidemiology is not an experimental science. Nor does it study individual cases in isolation. Its most meaningful results are statistical: the happening together of a suspect agent or event ("cause") and a known identifiable effect. Although EPI studies cannot prove causation, either generally or in a specific case, they can show cause to be more (or less) likely as a potential explanation for an observed association between risk factor and disease.

Epidemiology studies cannot prove causation, either generally or in a specific case, although they can show cause to be more (or less) likely as the explanation of a demonstrated association between risk factor and disease.

EPI studies cannot prove safety. Nevertheless, regulators and other legal policy-makers sometimes conclude from negative ("null effect"') studies and other evidence that a suspect agent does not really pose a significant risk. For example, epidemiologists cannot show that Bendectin will never cause birth defects, but the substantial body of studies that have been done has persuaded most people that very little risk exists. It was EPI studies combined with toxicological research that persuaded the Food and Drug Administration to remove sodium saccharin from its status as a suspected carcinogen.

Epidemiological studies cannot prove safety.

When an original, properly designed, and properly executed EPI study finds a strong association and lack of random effects, and animal studies show a positive correlation between dose and response, cause can be presumed as the most likely explanation. A detailed set of standards for assessing causation in individual studies can be found in a protocol known as the *Hill Criteria* (see bibliography). When several EPI studies find a strong association, and laboratory investigations support a known biological mechanism of action, or suggest a plausible one, the presumption is even stronger that the risk factor is a likely cause of the disease.

In the case of a single individual with the disease, one or the other of the two foregoing types of EPI evidence, a proven exposure, and the absence (or minimal effect) of any alternative cause

can, when taken together, provide sufficient evidence to satisfy tort law's *more probable than not* standard for proof of causation.

A thoughtful and useful examination of causality in all three of these contexts – the single study, the general case, and the individual plaintiff – can be found in Dr. Cole's article (see bibliography).

Cautions For Users of Epidemiological Research

Investigator Credentials Epidemiology is a recognized academic specialty, but epidemiologists are not examined, licensed, or certified by any government agency or professional organization. The user of an EPI study should consider the education and experience of the investigator, and compare these credentials to those with recognized expertise in the field. The American College of Epidemiology reviews contributions of epidemiologists and names as fellows of the College those with recognized accomplishments.

Study Design Epidemiology is observational, not experimental (exact replication of a given study is simply not possible) and the conclusions of a poorly designed study are of little value. Users of a particular study should scrutinize the research design, including use of (or failure to use) standard techniques for controlling the effects of chance, bias, and confounding. The criteria of data-interpretation also should be examined carefully.

Data Bases Some studies use published data bases, not all of which are equally reliable. Users of such studies should ask many of the same questions about these data bases that they ask about the study itself.

Animal Studies Even the most carefully performed animal studies cannot directly address either absolute or relative risk to human beings. Users should ask whether there are sufficient grounds for extrapolating from animals' doses and disease-responses to humans.

Allied Sciences An EPI study can be either corroborated or called into question by research in other sciences, especially toxicology, biochemistry, and pharmacology. Users should determine whether such research exists and if it does, consider its relevance to the epidemiological conclusions at issue.

Absolute Risk Legislatures, agencies, courts, and all other users of EPI research should always ask what is the absolute risk of harm, *i.e.,* how many exposed individuals became ill in a specified period of time versus how many of these individuals would have become ill if not exposed to the particular hazard. Where severity of harm varies with level of exposure, they should determine what degree of harm correlates with what dose-levels.

Consistently Strong Association In judging relative risk, the single most important factor is a consistently observed, strong association between risk factor and disease (relative risk exceeding 3.0). The inference of cause and effect is strengthened if the demonstrated statistical association is consistent with known or plausibly hypothesized biological mechanisms, and is observed in more than one study.

Peer Review Virtually all the EPI studies that legislators, regulatory agencies, and courts rely upon are published in peer-reviewed journals, but the mere fact of such

publication does not attest to a study's reliability in any major way. Peer review is essential to the research process and works well when a paper is personally reviewed by a specialist in the investigator's own field. However, time constraints for publication often cause the review to be done by someone less experienced or qualified, and the large number of journals increases the chances that a paper can get published somewhere eventually.

Meta-Analysis

Non-randomized observational studies (*i.e.,* those based on samples selected from exposed and unexposed populations) are sometimes aggregated for *meta-analysis*, a study of studies. If it discriminates the more and the less reliable among the underlying studies, and uses *sensitivity* analysis to identify the effects of one or a few studies with large samples but lower-quality research designs, a meta-analysis can help reduce random error. Meta-analysis is otherwise of limited value and does not take the place of a comprehensive review of the relevant literature.

Suggestions For the Best Use Of Epidemiology in the Law

Consider the use of neutral, advisory experts in epidemiology and its allied fields.

Legislators, regulatory agencies, and courts should, when practicable, consider the use of neutral, advisory experts in epidemiology and allied fields (*e.g.*, toxicology and statistics).

Public-health policy decisions that may have a major economic impact should be made by appropriately educated legislators and regulators.

Appropriately educated legislators and regulators should make final decisions on public-health policy that may have major economic impact. These decisions should be made only with explicit evaluation of the costs of such proposals measured against reduction of risk that may be achieved.

When a reliable risk assessment shows a large cost for a small reduction in risk, the decisions whether to legislate or regulate become how much, who pays, and what entities should bear the cost of regulatory compliance.

Fairness requires that agencies disclose the EPI and other evidence claimed to justify proposed regulation. The Daubert approach could be usefully applied in the context of judicial review of the science relied upon by federal agencies.

Suspect hazards should be shown to have a clear association with illness before regulation occurs. Yet agencies may sometimes judge that the protection of public health requires regulation, even when the evidence is not strong, much less conclusive.

Fairness requires that agencies disclose the EPI and other evidence claimed to justify proposed regulation, so that those who will bear the costs can understand the basis for decisions and be better prepared to specifically challenge rulemaking that they question.

Develop and apply uniform standards for the identification, characterization, and assessment of risks.

Consistent application of uniform standards for the identification, characterization and assessment of risks from suspect hazards should make regulation more efficient, encourage compliance, and facilitate changes in regulation when new scientific knowledge so requires (*e.g.*, the down-grading of saccharine from carcinogen status).

Use performance standards in preference to engineering standards.

When regulation is judged necessary, the agency should consider whether stating the public-health goal required to be achieved (a "performance" standard) is preferable to specifying the technology by which this goal must be achieved (an "engineering" or "command and control" standard).

Judges who function as "gate-keepers" of scientific evidence should make greater efforts to scrutinize the quality of research underlying an expert's opinion.

In litigation, EPI studies are not themselves admitted into evidence; they simply provide the basis for expert witness opinions. The tort law's "more likely than not" standard of proof for causation correlates with a relative risk ratio exceeding 2.0, a ratio that means that a member of the exposed population is twice as likely to get sick as someone not exposed. Statistically, a 2.0 risk ratio is rather low, and could be accounted for by many factors other than a causal connection between suspect agent and disease. Courts taking on the "gate-keeper" duty under Daubert should carefully scrutinize the quality of research underlying an expert's opinion.

Suggestions for Further Study and Action

- To raise the quality of EPI research, improve study design and execution, and help reduce misinterpretation of research results by the public and other non-specialist users, one or more professional groups of epidemiologists should develop minimum standards for the credibility of research (especially exposure assessment) and standard definitions of terms of art.

- Such a group could also fruitfully investigate, at both the theoretical and the practical level, fundamental issues common to science and the law, e.g., what constitutes "evidence," what "proof" is, the meaning of "cause," etc.

- An inter-disciplinary group, such as the one assembled for the June 1998 Annapolis workshop, could produce a non-technical set of recommendations and check-lists for judging the quality of EPI research, addressed to legislators, regulatory agencies, and courts (the main audience for this primer).

- The results of the initiatives described above could be used to help educate the public and news media.

- These standards, recommendations, and checklists could also, in a further educational effort, be tailored to the different processes of particular regulatory agencies that rely upon epidemiological research, e.g., FDA, EPA, and OSHA.

- Further consideration should be given to whether having the parties in tort litigation share the cost of securing the opinion of a neutral advisory panel of experts on the relevance and reliability of particular EPI studies, could help the disputants assess the merits of the claims at issue, and thereby foster resolution without the time and expense required for judicial decision.

Biographies of Epidemiology Workshop Participants

William Braithwaite, J.D. is a Tutor at St. John's College, in Annapolis, Maryland. At Loyola Law School, in Chicago, he taught Professional Ethics, Evidence, Remedies, Torts, and other courses from 1979-95. Prior to that he practiced law in Chicago.

Philip Cole, MD, DrPH is a professor of epidemiology at the University of Alabama at Birmingham. Dr. Cole's major interests lie in chemical and hormonal carcinogenesis and in issues of causation in epidemiology. He has published nearly 200 papers in these areas.

Alvan R. Feinstein, MD, MACP is Sterling Professor of Medicine and Epidemiology at the Yale University School of Medicine, where he is also Director of the Clinical Epidemiology Unit and the Robert Wood Johnson Clinical Scholars Program. In his research on care of patients, he has developed new clinical investigative techniques and clinical epidemiological approaches and methods that have been reported in several books.

Michael D. Green, J.D. is Professor of Law at the University of Iowa. He teaches Products Liability, Mass Torts, and Complex Litigation. He is the author and co-author of several books including the Reference Guide on Epidemiology in the Federal Judicial Center's Reference Manual on Scientific Evidence, a work prepared for the federal judiciary. In addition, he has written a number of articles in the area of Products Liability, Toxic Substances Litigation, and the use of scientific evidence as proof in legal cases.

M. Stuart Madden, J.D. is Charles A. Frueauff Research Professor and Distinguished Professor of Law at Pace University School of Law. Professor Madden is the author or co-author of several books and numerous articles on Torts, Environmental Torts and Products Liability subject matters. He is an elected member of the American Law Institute.

M. Gerald Ott, Ph.D. is Director of Epidemiology at BASF Corporation. Dr. Ott has conducted occupational health studies over a period spanning nearly 30 years. Previously, he was a commissioned officer in the U.S. Public Health Service assigned to the National Center for Health Statistics. He has published numerous studies examining the relationships between occupational exposure to a variety of substances and health outcomes ranging from cancer to targeted clinical endpoints. He has also published widely on approaches to linking industrial hygiene and health outcome data.

Gerhard K. Raabe, Dr.P.H., M.S. is Director, Medical Information and Health Risk Assessment for Mobil Business Resources Corp., Global Medical Services. Prior to joining Mobil, he was a Senior Research Scientist for New York State responsible for the Epidemiology Statistical Resources Section attached to Columbia University. He has been a consultant and author in research methods, occupational epidemiology, cancer classification, and health effects of gasoline and benzene, ethical behavior for epidemiologists and medical information systems. He is a Fellow of the American College of Epidemiology.

Alan Charles Raul, J.D., M.P.A. is a partner in the Washington, D.C. office of the international law firm Sidley & Austin. His practice involves litigation, advocacy and counseling in connection with federal government regulation, enforcement and investigations. Mr. Raul has served as General Counsel of the U.S. Department of Agriculture, and as General Counsel of the Office of Management and Budget in the Executive Office of the President. From 1986-1988, Mr. Raul served as Associate Counsel to the President.

Thomas B. Starr, Ph.D. is a principal in the Health Sciences Division of ENVIRON International Corporation. His research has focused on means for explicitly incorporating knowledge of toxic mechanisms into the quantitative risk assessment process, and improving epidemiologic methods for assessing effects of chemical exposure on worker health. He has published over 80 scientific papers and given hundreds of scientific presentations. Dr. Starr holds an adjunct faculty appointment in the Department of Environmental Sciences and Engineering in the School of Public Health at the University of North Carolina, Chapel Hill.

Annapolis Center Board Members Participating in the Workshop

Robert Hirsch, Ph.D. is a physicist and an engineer. He is a consultant with Advanced Power Technologies with considerable experience in virtually all aspects of energy in government and industry. He currently serves as Chairman of the Board on Energy and Environmental Systems at the National Academy of Sciences.

Claire Lathers, Ph.D., F.C.P. is the Chief Scientific Officer for Barr Laboratories. She teaches employees at Barr Laboratories about the clinical pharmacological aspects of drugs that the company will dose. Previously she served as President and Dean of the Albany College of Pharmacy. She has achieved international recognition for her work in the two areas of cardiovascular autonomic dysfunction associated with space flight and with sudden death in persons with epilepsy.

Ford Rowan, J.D., is an expert in crisis management. He is a lawyer with a decade of experience as a network television reporter who has successfully managed dozens of health, environmental, safety and financial issues for corporate clients. Rowan is a former NBC news correspondent and host of "International Edition," a weekly program on public TV. He is the principal author of "Crisis Prevention, Management, and Communication". He has written dozens of articles on such varied topics as news ethics and information technology.

Jack Snyder, M.D., J.D., Ph.D. is a physician-attorney with training and experience in pharmacology, toxicology, pathology, and occupational medicine. He is currently regional director for SmithKline Beecham Clinical Laboratories. Previously, Dr. Snyder taught occupational medicine, toxicology, pathology, and health law at Thomas Jefferson University. In addition, he is a frequent lecturer, advisor and consultant to corporate, academic, legal and governmental bodies in matters involving legal medicine, forensic science, laboratory medicine, toxic torts, workers' compensation, hazardous waste, occupational disease, disaster planning, and

adverse drug reactions. Dr. Snyder served as the chairperson for this Annapolis Center workshop.

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About The Annapolis Center

The Annapolis Center supports and promotes responsible environmental, health, and safety decision-making.

The Center evaluates risk and cost-benefit analysis both to assist the public in understanding hazards and the relative risks they may present and to identify areas for emphasis in research and policy. The Center's *Annapolis Accords* provide vehicles to evaluate the quality of science underlying risk analysis and the quality of the policy foundation supporting risk management, as well as cost-benefit analysis. The Annapolis Center is a non-profit, 501(c)3 educational organization.

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October 30, 2001 **(Also to be sent to: Rep. Stenholm, Combest and Boehlert)**

The Honorable Mike Pence
Chairman, Regulatory Reform and Oversight Subcommittee
United States House of Representatives
2361 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

The American Farm Bureau Federation commends the subcommittee for holding a hearing on Environmental Protection Agency (EPA) rulemaking as it impacts small business. A substantial number of farmers and ranchers across the country qualify as small businesses. Many of them are adversely impacted by burdensome regulations imposed by EPA. It has been our experience that EPA does not always adequately consider the economic impact of its rulemaking on farmers, ranchers and other small businesses, even when those costs have been submitted to the agency.

You have asked for some specific examples of how EPA rulemaking impacts small business. While there are many examples of this, we will concentrate on two current examples of EPA rulemaking that impact farmers and ranchers. We ask that this letter be made a part of the hearing record.

The first example is the rulemaking process regarding Total Maximum Daily Loads (TMDLs). We are concerned that EPA has not provided an estimate of the costs to small businesses. Congress asked for this information in the FY2001 appropriations for EPA: "EPA is directed to conduct a comprehensive assessment... In conducting this cost assessment, EPA must ... provide an estimate of ... the costs to small businesses that would result from regulatory changes to the TMDL program" (146 Cong. Rec. H10117 (October 18, 2000)).

We disagree with EPA's interpretation that Congress was asking just for the "direct" costs, but not the "indirect costs" imposed by the states in response to the TMDL rule changes.

There is no evidence that Congress wanted just the direct costs. If so, one would have expected Congress to qualify the request, but it didn't. Congress didn't direct EPA "to provide an estimate of the costs imposed by EPA" or "the direct costs of TMDL rule changes," but rather, Congress requested "the small entity impacts that would result from the TMDL rule changes."

Congress directed EPA to provide both the direct and indirect costs to small entities, because they were trying to address the same problem that H.R. 4922 was designed to address. Congress felt that it was important information to ensure that controversial TMDL rule changes would "be

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subjected to adequate public and congressional analysis and review" (see H.R. 4922). It would be difficult to draw any conclusions or make recommendations about the rule changes without some understanding of the small entity impacts and how disproportionate those impacts might be. By providing no analysis of the indirect small entity impacts, EPA might make irrational decisions.

Another example of the impact of EPA's rulemaking on small business concerns the agency's plans to impose effluent guidelines under the Clean Water Act on the aquaculture industry. As part of a consent decree to establish industry effluent guidelines under the Clean Water Act, EPA bypassed more widespread threats to further regulate the aquaculture industry, which contributes very little to the impairment of waters in the United States. In fact, in the justification for the regulation, EPA stated that "Along with concentrated animal feeding operations (CAFOs) and meat product facilities, aquatic animal production facilities have been identified as potential contributors to nutrient loadings in the Nation's surface waters." (emphasis added)

The vast majority of aquaculture producers in the United States are small businesses, with 75 percent generating annual sales of less than $100,000. With only 4,000 private facilities, aquaculture accounts for only 0.35 percent of animal production facilities, and is less than 1 percent of animal agricultural production.

Discussions with the agency indicate that development of effluent guidelines is not meant to achieve water quality goals.

EPA plans to convene a Small Business Regulatory Fairness Act (SBREFA) panel for the development of these effluent guidelines. However, it indicates that it does not intend to consider the efforts currently underway by a number of facilities to improve effluent discharges as part of the measurement of the economic costs of compliance with the guidelines, despite the fact that these facilities have incurred these costs in anticipation of this regulation. Failure to consider such costs deters individual initiative and grossly underestimates the costs of compliance to small businesses.

H.R. 4922 required EPA to estimate "the cost to small entities resulting from implementation of the regulations, as revised, by States and the [EPA]" (see proposed section (5)(b)(2)).

Thank you for your support of small business agricultural producers.

Sincerely,

Bob Stallman
President

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