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H.R. 88, REGARDING DATA AVAILABLE UNDER THE FREEDOM OF INFORMATION ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

ON

H.R. 88

TO AMEND THE TREASURY AND GENERAL GOVERNMENT APPROPRIATIONS ACT, 1999, TO REPEAL THE REQUIREMENT REGARDING DATA PRODUCED UNDER FEDERAL GRANTS AND AGREEMENTS AWARDED TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NONPROFIT ORGANIZATIONS

JULY 15, 1999

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H.R. 88, REGARDING DATA AVAILABLE UNDER THE FREEDOM OF INFORMATION ACT

THURSDAY, JULY 15, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON GOVERNMENT MANAGEMENT,
INFORMATION, AND TECHNOLOGY,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2154 Rayburn House Office Building, Hon. Stephen Horn (chairman of the subcommittee) presiding.

Present: Representatives Horn, Biggert, Ose, Ryan, and Turner.

Staff present: J. Russell George, staff director and chief counsel; Matthew Ebert, policy advisor; Bonnie Heald, director of communications; Grant Newman, clerk; Chip Ahlswede, staff assistant; Justin Schlueter, Lauren Lefton, and Christina Steiner, interns; Phil Schiliro, minority staff director; Michelle Ash, minority counsel; Trey Henderson, minority professional staff member; and Jean Gosa, minority staff assistant.

Mr. HORN. The Subcommittee on Government Management, Information, and Technology will come to order. We're here today to examine H.R. 88, a bill introduced by Representative George Brown of California, the ranking member on the House Committee on Science.

[The text of H.R. 88 follows:]

I

106TH CONGRESS
1ST SESSION

H. R. 88

To amend the Treasury and General Government Appropriations Act, 1999, to repeal the requirement regarding data produced under Federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 6, 1999

Mr. BROWN of California introduced the following bill; which was referred to the Committee on Government Reform

---

A BILL

To amend the Treasury and General Government Appropriations Act, 1999, to repeal the requirement regarding data produced under Federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

SECTION 1. REPEAL OF REQUIREMENT REGARDING DATA PRODUCED UNDER FEDERAL GRANTS AND AGREEMENTS AWARDED TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NONPROFIT ORGANIZATIONS.

Title III of the Treasury and General Government Appropriations Act, 1999 (as contained in section 101(h) of division A of Public Law 105–277) is amended by striking the fifth and sixth provisos under the heading "Office of Management and Budget—Salaries and Expenses".

○

Mr. HORN. It would repeal the provision of the Emergency Supplemental Appropriations Act for fiscal year 1999. The provision introduced as an amendment by Senator Richard C. Shelby of Alabama enhances access to federally funded research data under the Freedom of Information Act.

James Madison underscored the importance of maintaining an informed citizenry when he said, "A popular Government without popular information or the means of acquiring it is but a Prologue to a Farce or a Tragedy, or perhaps both. Knowledge will forever govern ignorance, and a people who mean to be the Governors must arm themselves with the power knowledge gives."

The Freedom of Information Act enacted in 1966 created the presumption that government records should be accessible to citizens. Before the law was approved, individuals who requested government documents were required to show a compelling reason for acquiring the information. The Freedom of Information Act shifted the burden of proof from the individual to the government, which now must justify why a citizen should not have the right to see the requested records. In its oversight capacity, this subcommittee is committed to ensuring that the intent of the Freedom of Information Act is upheld.

However, in the case of federally funded research data, the concern is that one individual's right to government information may infringe upon another's right to privacy. Up to now, Federal agencies have had the discretion to withhold raw data collected during a federally funded research project from public scrutiny. Once the Shelby amendment is implemented, this information may be released to anyone who requests it through the Freedom of Information Act.

Supporters of H.R. 88, which would repeal the Shelby amendment, are concerned that the Freedom of Information Act would not adequately protect the privacy of those who participate in federally funded research projects either as volunteers or as private researchers. They argue that this loss of privacy would be a strong disincentive to those who volunteer as subjects because their personal records might become accessible to the public. Similarly, private companies and other organizations would refrain from participating in these studies because public access to the data could result in the loss of proprietary information or trade secrets.

Today we will examine H.R. 88 and other provisions affecting public access of federally funded research data in an attempt to determine a good and lasting public policy. We will hear from a stellar group of witnesses who hold differing views on this issue. I welcome our witnesses and I look forward to their testimony.

[The prepared statement of Hon. Stephen Horn follows:]

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INDEPENDENT

Hearing on H.R. 88,
Regarding Data Available Under the Freedom of Information Act

Opening Statement
Rep. Stephen Horn, R-Calif.
Chairman, House Subcommittee on Government
Management, Information, and Technology

July 15, 1999

A quorum being present, the Subcommittee on Government Management, Information, and Technology will come to order.

We are here today to examine H.R. 88, a bill introduced by Representative George Brown of California, which would repeal a provision of the Emergency Supplemental Appropriations Act for Fiscal Year 1999. The provision, introduced as an amendment by Senator Richard C. Shelby of Alabama, enhances access to federally funded research data under the Freedom of Information Act.

James Madison underscored the importance of maintaining an informed citizenry when he said: "A popular Government without popular information or the means of acquiring it is but a Prologue to a Farce or a Tragedy, or perhaps both. Knowledge will forever govern ignorance, and a people who mean to be the Governors, must arm themselves with the power knowledge gives."

The Freedom of Information Act, enacted in 1966, created the presumption that Government records should be accessible to citizens. Before the law was approved, individuals who requested Government documents were required to show a compelling reason for acquiring the information. The Freedom of Information Act shifted the burden of proof from the individual to the Government, which now must justify why a citizen should not have the right to see the requested records. In its oversight capacity, this subcommittee is committed to ensuring that the intent of the Freedom of Information Act is upheld.

However, in the case of federally funded research data, the concern is that one individual's right to Government information may infringe upon another's right to privacy. Up to now, Federal agencies have had the discretion to withhold raw data collected during a federally funded research project from public scrutiny. Once the Shelby Amendment is implemented, this information may be released to anyone who requests it through the Freedom of Information Act.

Supporters of H.R. 88, which would repeal the Shelby Amendment, are concerned that the Freedom of Information Act would not adequately protect the privacy of those who participate in federally funded research projects, either as volunteers or as private researchers.

They argue that this loss of privacy would be a strong disincentive to those who volunteer as subjects because their personal records might become accessible to the public. Similarly, private companies and other organizations would refrain from participating in these studies because public access to the data could result in the loss of proprietary information or trade secrets.

Today, we will examine H.R. 88 and other provisions affecting public access of federally funded research data in an attempt to determine a good and lasting public policy. We will hear from a stellar group of witnesses who hold differing views on this issue. I welcome our witnesses and look forward to their testimony.

Mr. Horn. I now yield time to the gentleman from Texas, the ranking member on the subcommittee, Mr. Turner, and he will be followed by the ranking member on the full committee Mr. Waxman.

Mr. TURNER. Thank you, Mr. Chairman. I would like to yield first to the ranking member of the Government Reform Committee, Mr. Waxman.

Mr. WAXMAN. Thank you very much for yielding to me and giving me this opportunity to make a statement before the hearing begins.

Mr. Chairman, I want to thank you for holding this hearing on H.R. 88, which repeals the public access requirement regarding data produced under Federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations. I'm a strong supporter of H.R. 88 and am hopeful that this hearing will highlight the bill's numerous benefits.

H.R. 88 is quite simple. It repeals Senator Shelby's amendment to the fiscal year 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act requiring public access to federally funded research data collected by nonprofit institutions. The Shelby amendment was added as a rider, so there was no opportunity for the appropriate authorizing committees to review whether or not there was a problem with regard to data availability. Senator Shelby's amendment is not good government legislation, as some will suggest. The amendment was simply an expression of opposition to the Environmental Protection Agency creating tighter restrictions under the Clean Air Act. In fact, one Internet website espousing support for the Shelby amendment explains that the amendment will ensure that agencies have a more difficult time imposing regulations on the business community.

There are a number of technical defects with the Shelby amendment, including the fact that it was written with vague terms that are not defined, leaving open the definitions of data published and in developing policy and rules. However, I want to emphasize one particular defect: its unfairness. The Shelby amendment only applies to nonprofit grantees and not to contractors. Consequently, data collected by a private corporation under contract to the Federal Government would not be subjected to the FOIA, but data collected by a nonprofit under a grant from the Federal Government would be subject to the FOIA.

And at a minimum I would hope that this committee considers having the Shelby language applied to both Federal contractors and nonprofit grantees.

Mr. Chairman, there are also numerous substantive defects in the Shelby amendment. The amendment will hurt valuable research by placing patient confidentiality at risk, threatening intellectual property, increasing nonprofits' administrative burdens and costs, and increasing harassment of researchers. This only will lead to a reduction in the number of human subject volunteers, a reduction in the number of private public partnerships, and research no longer being conducted in certain research areas.

I want to thank the Science Committee's distinguished ranking member, Representative George Brown, who cannot be with us today, for introducing H.R. 88. Repeal of the Shelby amendment is

necessary to assure that scientific research continues to develop and grow.

Thank you, Mr. Chairman. I yield my time to Mr. Turner, and want to explain to the witnesses that a conflict in my schedule prevents me from being here to hear all the testimony but I certainly will have a chance to review it. Thank you.

[The prepared statement of Hon. Henry A. Waxman follows:]

THE HONORABLE HENRY WAXMAN
OPENING STATEMENT BEFORE THE SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY
JULY 15, 1999

Mr. Chairman, I want to thank you for holding this hearing on H.R. 88, which repeals the public access requirement regarding data produced under federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations. I am a strong supporter of H.R. 88 and I am hopeful that this hearing will highlight the bill's numerous benefits.

H.R. 88 is quite simple. It repeals Senator Shelby's Amendment to the FY 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act, requiring public access to federally-funded research data collected by nonprofit institutions. The Shelby Amendment was added as a rider, preventing the appropriate authorizing committees from reviewing whether or not there was a problem with regard to data availability.

Senator Shelby's Amendment is NOT "good government" legislation as some will suggest. The Amendment was simply an expression of Senator Shelby's opposition to the Environmental Protection Agency (EPA) creating tighter restrictions under the Clean Air Act. In fact, one Internet web site, espousing support for the Shelby Amendment, explains that the Amendment will ensure that agencies have a harder time imposing regulations on the business community.

There are a number of technical defects with the Shelby Amendment including the fact that it was written with vague terms that are not defined, leaving

open the definitions of "data," "published," and "in developing policy and rules." However, I want to emphasize one particular defect, its unfairness. The Shelby Amendment only applies to nonprofit grantees and not to contractors. Consequently, data collected by a private corporation under contract to the federal government would not be subject to the FOIA, but data collected by a nonprofit under a grant from the federal government would be subject to the FOIA. At a minimum, I would hope that this committee consider having Shelby apply to both federal contractors and nonprofit grantees.

Mr. Chairman, the number of substantive defects with the Shelby Amendment is also voluminous. The Shelby Amendment will hurt valuable research by placing patient confidentiality at risk, threatening intellectual property, increasing nonprofits administrative burdens and costs, and increasing harassment of researchers. This only will lead to a reduction in the number of human subject volunteers, a reduction in the number of private-public partnerships, and research no longer being conducted in certain research areas.

I want to thank the Science Committee's distinguished Ranking Member, Representative George Brown, who cannot be with us today, for introducing H.R. 88. Repeal of the Shelby Amendment is necessary to ensure that scientific research continues to develop and grow. Thank you.

Mr. HORN. The gentleman from Texas, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. Appreciate you holding this hearing on H.R. 88 regarding the data available under the Freedom of Information Act. Included in the fiscal year Omnibus Consolidated and Emergency Supplemental Appropriations Act was the amendment introduced by Senator Shelby which requires public access to data produced under Federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations.

This legislation before us, H.R. 88 introduced by Representative George Brown, would repeal the Shelby amendment. I am a strong supporter of ensuring openness and accountability in government. Government transparency helps enhance the public's trust and we all understand that. In addition, I support the sharing of scientific data. Free and open exchange of information helps us to understand science and such exchanges can promote scientific advancement and progress.

However, it is imperative that we create data sharing. When we create these data sharing opportunities, we do not compromise the privacy of research participants or increase the potential for theft of intellectual property. We do not want human subject volunteers, who before gave information on the condition that their information would remain strictly confidential, to no longer be willing to release such information.

Similarly, we should adhere to the principle that those who gather the data should have the opportunity to interpret it first. If data is available before the grant recipient has completed his research, there may be an opportunity for others to profit from that research. In addition I'm concerned that this amendment raises fairness issues. Shelby does not apply to Federal awards, to businesses or contractors, only to awards to nonprofits. Therefore, a small community nonprofit which receives a community development block grant from its State would be subject to the new Freedom of Information Act requirements, but a large defense contractor would not have to comply.

The Shelby amendment has generated considerable interest. In fact, the Office the Management and Budget's recently published proposed regulation to comply with the Shelby amendment generated 40 times the average number of comments OBM usually—or OMB usually receives from a proposed regulation.

A second comment period will commence at the end of this month with final rule due at the end of September. OMB, I understand, expects a similar response during the second comment period.

One criticism with which I agree is the lack of a legislative record on this issue. The Shelby amendment was a rider to an appropriations bill and therefore the appropriate authorizing committees did not have the opportunity to thoroughly review the amendments's affects.

In closing, I want to comment that I'm sorry that Ranking Member Brown, who has been most active on the issue, cannot be with us today because of health reasons. And I look forward to hearing from all of our witnesses on their thoughts as to whether there's

a need for public access to data produced under Federal grants and agreements awarded to nonprofits.

Thank you, Mr. Chairman. I look forward to hearing from all of our witnesses.

[The prepared statement of Hon. Jim Turner follows:]

OPENING STATEMENT OF THE HONORABLE JIM TURNER
GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY
HEARING ON H.R. 88, REGARDING DATA AVAILABLE UNDER
THE FREEDOM OF INFORMATION ACT
July 15, 1999

Mr. Chairman, thank you for holding this hearing on H.R. 88, regarding data available under the Freedom of Information Act. Included in the FY 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act was an amendment introduced by Senator Richard Shelby which requires public access to data produced under Federal grants and agreements awarded to institutions of higher education, hospitals, and other nonprofit organizations. H.R. 88, introduced by Representative George Brown, would repeal that Shelby Amendment.

I am a strong supporter of ensuring openness and accountability in government. Government transparency helps enhance the public's trust. In addition, I support the sharing of scientific data. Free and open exchanges of information can help us understand science and such exchanges can promote scientific advancement and progress.

However, it is imperative that when we create data sharing opportunities, we do not compromise the privacy of research participants or increase the potential for theft of intellectual property. We do not want human subject volunteers, who before gave personal information on the condition that their information would remain strictly confidential, to no longer be willing to release such information. Similarly, we should adhere to the principal that who gathers the data should have the opportunity interpret it first. If data is available before the grant recipient has

completed his research, there may be an opportunity for others to profit from that research.

In addition, I am concerned that this Amendment raises fairness issues. Shelby does not apply to federal awards to businesses and contractors, only awards to nonprofits. Therefore, a small community nonprofit which receives CDBG monies from its state would be subject to new FOIA requirements but a large defense contractor would not have to comply.

The Shelby Amendment has generated much interest. In fact, the Office of Management and Budget's recently-published proposed regulation to comply with the Shelby Amendment generated forty times the average number of comments OMB usually receives on a proposed regulation. A second comment period will commence at the end of this month, with a final rule due at the end of September. OMB expects a similar response during the second comment period.

One criticism, with which I agree, is the lack of a legislative record on this issue. The Shelby Amendment was a rider to an appropriations bill and therefore, the appropriate authorizing committees did not have the opportunity to thoroughly review the Amendment's effects.

In closing, I want to comment that I am sorry that Ranking Member Brown, who has been most active on this issue, cannot be here today because of health reasons. I look forward to hearing from our witnesses to hear their thoughts on whether there is a need for public access to data produced under Federal grants and agreements awarded to nonprofit organizations. Thank you.

Mr. HORN. Thank the gentleman. And we'll now proceed with the first panel. Let me describe our process here in terms of how it works. Some of you have been prior witnesses, some of you haven't. The fine statements you have presented to us have been read by staff and members prior to the hearing, and they will automatically go in the record when we call on you. We'll still use the agenda you have before you. It's carefully put together of pros and cons, everyone. So, there won't be a bunch of pros and there won't be a bunch of cons, but you'll hear combating arguments as you would in a court.

Here we do swear in all witnesses, and this is an investigating subcommittee of the full Committee on Government Reform. We would like you not to read your testimony to us—we can read—but what we would like you to do is summarize it. We allow about 5 minutes. And we, you know, loosen that up a few minutes if we can. But, if we're to get through this panel—there are three panels, I believe this morning—or two major panels. We need to get out of here before noon or we'll be swallowed up by another subcommittee holding a hearing. So if you can summarize it in 5 minutes, that will leave more chance for dialog between the members and the panels and within the panel. We believe in dialog. So it's been very helpful so far.

So, if you would stand and raise your right hands and take the oath we can proceed. Is there anybody behind you that might be giving you advice, I might add? If so get them up. I only like the baptism once.

[Witnesses sworn.]

Mr. HORN. The clerk will note that six witnesses did that.

Now, we will start with our colleague, Mr. Rush Holt, Member of Congress from New Jersey. And we're delighted to have you here. You have taken a lead in this area. And we look forward to hearing from you.

STATEMENTS OF HON. RUSH D. HOLT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY; JAMES C. MILLER III, COUNSEL, CITIZENS FOR A SOUND ECONOMY AND FORMER DIRECTOR OF OMB; HAROLD E. VARMUS, DIRECTOR, NATIONAL INSTITUTES OF HEALTH; JAMES T. O'REILLY, VISITING PROFESSOR, COLLEGE OF LAW, UNIVERSITY OF CINCINNATI; AND BRUCE ALBERTS, PRESIDENT, NATIONAL ACADEMY OF SCIENCES

Mr. HOLT. Thank you Chairman Horn. And I'm pleased to be here with these distinguished panelists and to address my colleagues, Mr. Ose, Mrs. Biggert, and Mr. Turner. As a cosponsor of H.R. 88, I'm sorry that our colleague George Brown can't be here today to speak on behalf of his bill. There is no one in Congress who has a better appreciation of the role of science and the process of science than George Brown. I think his bill is important, is very important. And that's why I've taken time to join you today.

The provision was added in haste to last year's Omnibus appropriations bill to change Circular A–110. It has four major problems. I think it can force researchers to breach the confidentiality of their subjects, especially in medical studies; it's an infringement of intellectual property which could force release of data before research-

ers gain the benefits of the work; it creates an opportunity for harassment of science, of scientists and politicization of science; and it would impose a significant administrative burden on institutions and on scientists.

As a representative of the district which is home to world class research, I strongly support H.R. 88. The 12th District of New Jersey is home to many researchers, particularly in the biotechnology and pharmaceutical fields, as well as in telecommunications, as well as at Princeton University, Monmouth University, Rider University, the College of New Jersey and neighboring Rutgers University. Federal research support and partnerships between public and private research are vital to the present and future economic success of my constituents as well as yours as those of the Nation.

I support H.R. 88, because as a scientist I know that without the open exchange of information and ideas we could not have achieved the state of knowledge and the standard of living that we enjoy today. Without an open exchange of information and science, we will not maintain the progress of research, which is the source of new ideas to propel our economy.

Contrary to the rhetoric that's been put forward by the proponents to change Circular A–110, this change in law will not make the scientific process more open and accessible either within the scientific community or to society as a whole. In fact, it will make certain lines of inquiry more difficult, if not impossible.

The openness of scientific exchange which is so vital to the maintenance of scientific progress is not primarily a function of data access. It is dependent upon providing scientists with the opportunity to pursue all lines of inquiry and to freely and openly exchange their findings without fear of harassment or theft of their intellectual property by vested interests. Scientists have established means of sharing research through collaborations, conferences, publications, and peer review, all of which are essential to the process.

As a representative of central New Jersey I'm greatly concerned about the possibility of harassment of scientists by groups with ulterior motives. They can seriously disrupt research. If research data are released prior to the completion of the academic review process, the public could come to rely on distorted interpretations and unfairly discredit the particular study and ultimately scientific inquiry in general.

Also, ambiguity in determining which data might be subject to disclosure will make industries reluctant to continue or enter partnerships with federally funded researchers. Once data are commingled in a partnership it may be difficult to distinguish the data produced with Federal funds from those produced with other funds. The resulting reluctance of industry to participate in partnerships will significantly hurt the fast-paced pharmaceutical and biotech industries, I'm sure.

As a scientist, I receive support for my work from the National Science Foundation, the Department of Energy, and indirectly from other Federal agencies. I never believed these Federal awards to be entitlements. As a grant recipient I knew that I had many responsibilities tied to the receipt of my award: a responsibility to manage the funds and conduct the research in accordance with my proposal

and the terms of the general agreement, a responsibility to conduct my work in a thorough and careful manner and to communicate—to communicate my results to my colleagues and the public through presentations and publication in peer-reviewed publications that are publicly available in a manner inviting examination and replication, key to the scientific process. Scientists who do not make their findings public can have no expectation of further support.

As a Member of Congress, I am concerned that Congress has hastily enacted legislation which is in direct contradiction to a Supreme Court decision which determined that data generated under Federal grants is not the property of the agency and not subject to the Freedom of Information Act. Any change to this decision deserves discussion with the parties affected.

Finally, I support H.R. 88 because as a scientist and as a Member of Congress, I believe it was unfair, undemocratic, and unwise of Congress and the administration to enact a significant change in law without ever providing members of the academic scientific community and their private sector partners, representatives of research hospitals and other nonprofit organizations, an opportunity to participate in the process that directly impacted them.

This is a sunshine provision enacted in the dark. The process now underway at the Office of Management and Budget—a mandatory rulemaking with predetermined outcome—is unwise, dangerous, and an inadequate substitute for an open, democratic legislative process such as we are engaged in this morning. The enactment of H.R. 88 would allow Congress to do what the public expects scientists to do: consider the views of all interested parties as we examine the nature and the scope of problems and to debate the merits of proposed solutions.

As a society, we've enjoyed many benefits as a result of our decision to foster an open exploration of ideas. The public contract with science is critical to our society. Through Federal support of scientific research, we have created a powerful engine of social progress and economic growth. Let's not jeopardize this enterprise by hastily implementing a law that was crafted without the participation of all interested and affected parties.

I thank you, Mr. Chairman, for the opportunity to speak with you this morning.

[The prepared statement of Hon. Rush D. Holt follows:]

STATEMENT OF REP. RUSH HOLT (NJ)

BEFORE THE SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION AND TECHNOLOGY

COMMITTEE ON GOVERNMENT REFORM

HEARING ON H. R. 88

JULY 15, 1999

Thank you Chairman Horn and Ranking Member Turner for holding this hearing on H.R. 88 and for giving me the opportunity to speak to you about this legislation. I am a co-sponsor of H.R. 88 and I hope the Committee will move this legislation forward. I wish our colleague George Brown were able to be here today to speak on behalf of his bill. I believe no one in Congress has a better appreciation of the role of science and the process of science than George Brown.

The provision added in haste to last year's Omnibus Appropriations Bill to change Circular A110 has four major problems. It can force researchers to breech the confidentiality of their subjects, especially in medical studies. It is an infringement of intellectual property, which could force release of data before the researchers gain the benefits of their work. It creates an opportunity for harassment of scientists and politicization of science. And it would impose a significant administrative burden on institutions.

As the Representative of a district which is home to world-class academic research, I strongly support H.R. 88. The 12th District of New Jersey is home to many researchers, particularly in the biotechnology and pharmaceutical industries, as well as at Princeton University, Monmouth University, Rider University, the College of New Jersey, and neighboring Rutgers University. Federal research support and partnerships between public and private research are vital to the present and future economic success of my constituents as well as our nation.

I support H.R. 88 because, as a scientist, I know that without the open exchange of information and ideas, we could not have achieved the state of knowledge and standard of living that we enjoy today. Without the open exchange of information in science, we cannot maintain the progress of research – the source of new ideas necessary to propel our economy. Contrary to the rhetoric that has been put forward by the proponents of the provision to change Circular A110, this change in law will not make the scientific process more open and accessible either within the scientific community or to society as a whole. In fact, it will make certain lines of inquiry more difficult, if not impossible to pursue. The openness of scientific exchange, which is so vital to the maintenance of scientific progress, is not primarily a function of data access. It is dependent upon providing scientists with the opportunity to pursue all lines of inquiry and to freely and openly exchange their findings without fear of harassment or theft of their intellectual property by vested interests. Scientists have established means of sharing research through collaborations, conferences, publications, and peer review.

As a Representative of central New Jersey, I am greatly concerned about the possibility of harassment of scientists by groups with ulterior motives. This can seriously disrupt research. If research data are released prior to the completion of the academic review process, the public could come to rely on distorted interpretations, unfairly discrediting the particular study and, ultimately, scientific inquiry in general. Also, ambiguity in determining which data might be subject to disclosure will make industries reluctant to continue or enter partnerships with federally-funded researchers. Once data are commingled in a partnership, it may be difficult to distinguish data produced with federal funds from those produced with other funds. The resulting reluctance of industry to enter partnerships will significantly hurt the fast-paced pharmaceutical and biotech industries.

As a scientist, I received support for my work from the National Science Foundation, the Department of Energy, and indirectly from other federal agencies. I never believed these federal awards to be entitlements. As a grant recipient, I knew that I had many responsibilities tied to receipt of my award: a responsibility to manage the funds and conduct the research in accordance with my proposal and the terms of the grant agreement; a responsibility to conduct my work in a thorough and careful manner and to communicate my results to my colleagues and the public through presentations and publication in a peer-reviewed, publicly available journal in a manner inviting examination and replication. A scientist who does not make their findings public can have no expectation of receiving further government support.

As a Congressman, I am concerned that Congress has hastily enacted legislation which is in direct contradiction to a Supreme Court decision which determined that data generated under federal grants is not the property of the agency and not subject to FOIA. Any change to this decision deserves discussion with the parties affected.

Finally, I support H. R. 88 because, as both a scientist and a Congressman, I believe it was unfair, undemocratic, and unwise of Congress and the Administration to enact a significant change in law without ever providing members of the academic scientific community and their private sector partners, representatives of research hospitals, and other non-profit organizations an opportunity to participate in a legislative process that directly impacted them. This is a "sunshine" provision enacted in the dark. The process now underway at the Office of Management and Budget – a mandatory rule-making with a pre-determined outcome is a pathetic and inadequate substitute for an open, democratic legislative process such as we are engaged in this morning. The enactment of H.R. 88 would allow Congress to do what the public expects scientists to do – consider the views of all interested parties as we examine the nature and scope of problems and debate the merits of proposed solutions.

As a society we have enjoyed many benefits as a result of our decision to foster the open exploration of ideas. Through federal support of scientific research we have created a powerful engine of social progress and economic growth. Let's not jeopardize this enterprise by hastily implementing a law that was crafted without the participation of all interested and affected parties.

Thank you for the opportunity to speak with you this morning.

Mr. HORN. Thank you very much.

And we now move to the next witness, the Honorable James C. Miller III, former Director of the Budget, now the council for the Citizens for a Sound Economy. Welcome to this subcommittee.

Mr. MILLER. Thank you, Mr. Chairman. In addition to those qualifications and more pertinent to the hearing this morning, I was the first Administrator of the Office of Information and Regulatory Affairs at OMB. I have prepared a statement that I hope you will include in the record. Attached to that statement is a letter signed by all of my successors in the Reagan and Bush administrations, except for two who are now Federal judges and could not participate, though I suspect their private views are in accord.

So all of the Reagan-Bush heads of that agency support the open language of the Shelby amendment and oppose H.R. 88.

Now, why? Well, I think, No. 1, the taxpayer has paid for this information and it's theirs. They have a right of access to it.

No. 2, I think that the notion of H.R. 88, or going against the Shelby-Aderholt language, places the notion of open accountable government on its head.

What do I mean by that? Well, if agencies do not have to make available data on which they base reports that they cite as justification for rulemaking, for policymaking, then at best the public won't be informed about, or adequately informed about, the reasons for their decisions; and, at worst, you give the agencies an enormous license to play "hide the ball" and make decisions according to their own political preferences. Bear in mind that the language addressed here only covers reports that are published and are relied upon by agencies where the data collected was at public expense.

Now, we hear criticisms of this language and support for H.R. 88. First, they say privacy would be invaded. I don't know of any reputable physical or social scientist that would maintain that you have to reveal the individual records of Aunt Jane's personal behavior in any report or web providing data.

As we all know, when you do hypotheses testing, the specific records and details are masked; in fact, it is the aggregate data, the summary data, that is relevant. There is no need to find out whether Aunt Jane calls her nephew three times a week or not.

More importantly, the Aderholt-Shelby language requires that the dissemination of such information go through Freedom of Information Act procedures. And FOIA procedures explicitly deny the release of data where it is on an individual record basis. So the revealing of personal data simply is not an issue.

Second, you've heard criticism that Aderholt-Shelby will raise the cost of research. The answer is, yes, it will raise Federal costs a little bit. Why? Because under today's circumstances, researchers, not all, universities, not all, but some buy into research because they get the data base and can monopolize to some extent its use. But that's simply revealing that the real costs are higher than they should be. So, even if you had a little bit of an increase in the cost to the taxpayer of such research, it would represent a reduction in the total cost of research.

Third, you hear the argument that there would be confiscation of property, of intellectual property or whatever. But FOIA proce-

dures deny the release of data where it would compromise a proprietary interest.

There's been a lot of research on how well FOIA has worked. There are glitches from time to time. But for the most part they are perceived to be working very, very well.

Finally, I would raise the following. We have a larger issue here, and that is scientific method. And you don't progress unless you rely on scientific method. And scientific method doesn't work unless you have an opportunity for replication. What happens is that scientists or others will advance the ball by presenting new ideas, new perceptions, new hypotheses, and you advance the ball only by being able to replicate and check the validity of these allegations or these arguments. And if researchers hide the ball, if they don't release the data, you can't replicate.

And so with respect to my colleagues here on this panel, I would probably venture to say they would agree that science is very important. I'm suggesting, recommending, that you not adopt H.R. 88 because, contrary to the view just expressed by the Congressman, I believe scientific method is enhanced by Aderholt-Shelby, and is not enhanced and in fact is compromised by H.R. 88.

Thank you, Mr. Chairman.

Mr. HORN. We thank you.

[The prepared statement of Mr. Miller follows:]

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James C. Miller III
Counselor
Citizens for a
Sound Economy

PREPARED STATEMENT
of
JAMES C. MILLER III[1]
before the
SUBCOMMITTEE ON GOVERNMENT MANAGEMENT,
INFORMATION, AND TECHNOLOGY
of the
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
JULY 15, 1999

During the late 1970s, public outcry over excessive government regulation and red tape led to the creation by Congress of the paperwork commission. Based on that commission's work, in 1980 Congress passed the Paperwork Reduction Act, the last bill signed into law by President Carter. That act established an Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). I was the first Administrator of that office, which was given by Congress a responsibility to guide information collection *and dissemination* policies of the federal government. Thus, I have a keen interest in the topic of today's hearing: whether to overturn the so-called Aderholt-Shelby language regarding the dissemination of data collected by the federal government, undergirding some published work, and relied upon by a federal agency for rulemaking or policymaking purposes.

Not only do I have such an interest, but so do those who followed me in this post during the Reagan and Bush administrations. In fact, all of us, save for the two who are now serving as federal judges and for that reason cannot participate, have signed a letter to Members of the Appropriations Committee, urging them not to adopt a rider that would accomplish the same result as H.R. 88. (A copy of that letter is attached.)

The reasoning behind my opposition to H.R. 88 is straightforward. First, the data at issue is information that has been bought and paid for by the taxpayers, and they deserve to have it. (The cost of making available information already collected is

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[1]Citizens for a Sound Economy accepts no money from the federal government and, to the best of my recollection, neither have I during the relevant period.

negligible.) Thus, one must make a compelling case why the taxpayer should *not* have access to such data.

Second, making policy or issuing rules based on information known to the policymaker/regulator but not known to the general public turns the goal of open, accountable government on its head. At best, the public will not be adequately informed about the basis of public decisions. At worst, the agencies will play "hide the ball" and be afforded a degree of freedom from accountability that is altogether contrary to accepted norms. There is only a small step from "trust me, I know what's in your interest," to "don't bother me, I don't have to answer."

No doubt you have heard it said that dire consequences would ensue if the OIRA/OMB guidance requiring public dissemination of the relevant information were to go forward. Let me deal with the three major criticisms.

First, it is said that people's privacy would be invaded. But the data that is relevant for policymaking or rulemaking purposes is not the individual records, but aggregations of such data. For example, a study of the effects of smoking on heart disease doesn't require information on whether Aunt June smoked two or three packs per day, much less whether she telephones her nephews regularly. What's relevant is the characterization (aggregation) of many, many (anonymous) Aunt Junes. No one needs to know about Aunt June.

Moreover, the language of Aderholt-Shelby and the draft OIRA/OMB guidance explicitly require agencies to release requested data *only through Freedom of Information Act (FOIA) procedures*. These procedures prevent the release of personal data. Research into the application of FOIA procedures indicates that they work very well.

Second, it is said that the OIRA/OMB language would increase the cost of research. There would be a slight increase in cost to the federal government, but the total cost of research would go down. When researchers (at universities and elsewhere) see an opportunity to become part of a research project financed by the federal government, they often "buy in" because they know they can monopolize the data and reap the rewards, whether pecuniary or non-pecuniary, direct or indirect. Just as one expects lower costs in a competitive market than in a monopolistic one, one may expect lower research costs overall when data is made freely available rather than being monopolized by a few researchers.

Third, it is said by some that the OIRA/OMB language would lead to confiscation of property. Yet, the FOIA procedures mentioned above explicitly bar the release of data when the result would compromise proprietary interests. Here again, the research on this issue suggests that FOIA procedures, while not perfect in some metaphysical sense, work well.

The bottom line is that the major criticisms of the Aderholt-Shelby language do not hold up under close scrutiny.

There is another issue here, and that relates to scientific method. We owe progress to pushing back the frontiers of knowledge. How do we do this? In major part it involves painstaking research, where often scientists (social as well as physical) make breakthroughs and tell us the world is different than previously thought. Science proceeds by a two-step process: first the new discovery, view, or whatever. And second, the *verification* of such findings. How is one to verify claims made if an opportunity to replicate doesn't exist? In my own field of economics, for example, the flagship publication, the *American Economic Review* (in which I have published twice in my career), states in its directions to authors:

> It is the policy of the *American Economic Review* to publish papers only if the data used in the analysis are clearly and precisely documented and are readily available to any researcher for purposes of replication.

Aderholt-Shelby is consistent with this language and is supportive of scientific method and progress. H.R. 88 is not.

FORMER ADMINISTRATORS
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
OFFICE OF MANAGEMENT AND BUDGET

c/o Suite 700 1250 H Street, N.W. Washington, D.C. 20005 202-942-7617 (V) 202-942-7668 (F)

June 7, 1999

Dear Appropriations Member:

Except for two who are now federal judges and are thus precluded from joining us, we the undersigned constitute all of the Administrators of OMB's Office of Information and Regulatory Affairs (OIRA) who served during the Reagan and Bush presidencies. We urge you to oppose the Price-Walsh amendment to rescind the Aderholt-Shelby provision in last year's omnibus appropriations bill directing OMB to issue rules requiring agencies to make public, at reasonable cost and through Freedom of Information Act procedures, data which results from publicly-funded research and which is used to develop policies and rules.

We realize, of course, that researchers have a proprietary interest in their work and are reluctant sometimes to share data with others. And we realize that if the mandate of the Aderholt-Shelby provision is carried out researchers may be less anxious to do work for the federal government and thus the contractual costs of such work may rise. But this would simply reveal the length to which such researchers will go to deny the public's right to know and would not represent an increase in the real costs of such research.

Moreover, we realize that certain objections have been raised concerning potential loss of privacy and (legitimate) intellectual property. In our opinion such objections are altogether groundless, as the Freedom of Information Act, through which the OMB requirements would have to operate, provides specific protections against the release of data in such instances.

The simple truth is that the data at issue have been bought and paid for by the American people, and they deserve to have access to it. Moreover, the essence of the scientific method is replication, wherein others may analyze, evaluate, and duplicate the results of the research to establish its true credibility. We are aware that in the past certain agencies have relied on the results of studies where the analysis and underlying data have not been subject to public scrutiny. We believe such situations to be wholly contrary to the principles of good government and destructive of the public's trust in government.

Carrying out the Aderholt-Shelby provision will greatly improve the transparency of government and result in public policies that are more targeted and more supportable. We respectfully urge you to support the Aderholt-Shelby language and to vote against the Price-Walsh amendment.

Sincerely,

James C. Miller III
(OIRA Administrator, 1981)

Christopher DeMuth
(OIRA Administrator, 1981-1983)

Wendy Lee Gramm
(OIRA Administrator, 1985-1987)

James B. MacRae, Jr.
(Acting OIRA Administrator, 1989-1992)

Mr. HORN. We now go to the distinguished Director of the Nation's National Institute of Health and a shared Nobel Prize with a colleague at the University of California, San Francisco—a very distinguished institution in our State—Dr. Varmus.

Mr. VARMUS. Thank you. Chairman Horn, Mr. Turner, other members, thank you for having this hearing and bringing this issue into the light. I am Harold Varmus, Director of the NIH, and I'm very happy to be here to support H.R. 88, a bill authored by your distinguished colleague, George Brown, ranking member of the Science Committee and a longtime advocate of openness in scientific research. I, too, am an advocate for openness in research. Exchanging ideas and sharing data are vital to the success of all research, including the research sponsored by the NIH.

A true understanding of the breakthroughs we're making in genetics and clinical research and other realms of investigation could not be accomplished without the open sharing of methods and data. Openness has many virtues. It allows us to achieve trust in scientific outcomes and trust in the use of Federal dollars in biomedical research. It engenders faith that human subjects and animals are adequately protected in the research we do. And it sparks technical innovation.

But a word of caution. I think it maybe a mistake to argue for opening all underlying scientific data to public scrutiny, simply because of the concept that openness is good. There are pitfalls in unrestrained openness, including unwarranted violations of privacy, potential harassment of scientific investigators, and a chilling effect on the free exchange of ideas and the entry of scientists into research.

The widespread access to data envisioned by the A–110 amendment that H.R. 88 seeks to repeal could result in unforeseen abuses. In particular, patient privacy rights could be violated, and the willingness of scientists to speak openly about new ideas and take risks experimentally could be fettered by unrestricted data access. In addition, new requirements could undercut the ability of researchers to build private sector partnerships that now lead to the marketing of products.

It's because of these concerns that we at the NIH have taken the position that while expanded access to scientific data should be encouraged, the A–110 amendment is a poor vehicle to achieve this. We are particularly concerned about the requirement that the Freedom of Information Act be the tool of regulatory implementation.

FOIA is not designed to accommodate the confidentiality requirements of the most sensitive scientific data. Under FOIA, Federal agencies cannot place restrictions upon who obtains Federal records or on their intended use. Consequently, it might be possible for the privacy of patients to be compromised or for individual scientists to be harassed by selected interests opposed to their work for moral or for financial reasons. These intrusions could stop promising research in its tracks. Indeed, and perhaps even more importantly, the mere threat of such intrusions could impede the Nation's effort to recruit the best, most talented students into publicly supported research.

As one example of the potential misfirings of the amendment to A–110, consider what would happen if HIV-infected patients thought that their condition might be revealed by someone using the new requirements to examine raw experimental data. Patients might not participate in clinical trials if they believed there was a chance that their infected status would be revealed. Progress toward treatment of the disease might thereby be curtailed.

There are many aspects of the amendment to A–110 that trouble us, and many have already been mentioned. But I want to bring to your attention a particular provision that presents a new challenge to those who would want to make data accessible through this mechanism. I am thinking about the multiplicity of partnerships between public sector researchers, private companies, nonprofit organizations, even foreign governments that allow research to be conducted in many of our nonprofit organizations. Some of these partnerships make strict requirements on the researcher not to share data further. Without such agreements, investigators from private firms might not participate in these partnerships. Industry scientists are likely to avoid collaborations with publicly funded institutions, including universities, if they believe they can no longer protect their data from exposure. The A–110 amendment threatens those protections.

I am aware that the administration is working to implement the A–110 amendment in the least intrusive manner possible, and I congratulate my colleagues at OMB for their efforts. However, it is my view that, on balance, you should support H.R. 88 and repeal the A–110 amendment. Taking such action will not, however, mean the end of data access. Instead, it will signal the beginning of efforts to establish a more responsible approach to data sharing, one that will protect the rights of individuals, recognize the proprietary interest of commercial enterprises, and consider the needs of our flourishing scientific community that has been built over a long period of time, with a great deal of thought and communal effort.

I pledge to work with you and your colleagues in the efforts to expand data sharing and I would be happy to answer any questions you might have.

Mr. HORN. Thank you very much for that presentation.

[The prepared statement of Mr. Varmus follows:]

FOR RELEASE UPON DELIVERY

STATEMENT OF

HAROLD VARMUS, M. D.

DIRECTOR

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON

GOVERNMENT MANAGEMENT, INFORMATION AND TECHNOLOGY

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

JULY 15, 1999

Chairman Horn, Mr. Turner and other members of the Subcommittee on Government Management, Information and Technology. I am Harold Varmus, the Director of the National Institutes of Health. I am pleased to be here today to testify about H.R. 88, a bill authored by your colleague George Brown, the Ranking Member of the Science Committee, and a long-time advocate of openness in scientific research.

I too am an advocate for openness in scientific research. Exchanging ideas and sharing data are absolutely vital to the success of biomedical research. They are the hallmarks of the success of the NIH research programs. The true understanding of the breakthroughs we are making in genetics research, medical imaging, clinical research, and all other scientific investigation funded by NIH could not be accomplished without public access to methods and data.

Openness has many virtues. It fosters trust in scientific outcomes as well as trust in the use of federal dollars to conduct biomedical research. It engenders faith that human subjects and animals participating in research trials are adequately protected. And it sparks technological innovations that help us find the answers to public health problems. However, we know that the requirements in different scientific fields vary and that great care must be taken in crafting such strategies. There are many examples of responsible data-sharing at NIH. The remarkable strides we are making in our understanding of the genetic components of various diseases would not be possible without the sharing of data. Also, NIH's firm stance regarding the patenting of early DNA sequencing data has ensured that such data are easily available to the scientific community.

And we require that coordinate data developed by x-ray crystallographers be made available at the time of publication in a peer reviewed journal. In these cases, and many others, we promote openness.

But a word of caution. I think it would be a mistake to open all underlying scientific data to public scrutiny simply because of the concept that all openness is good. There are pitfalls in unrestrained openness, including unwarranted violations of privacy, the potential harassment of scientific investigators and the chilling effect that inappropriate public scrutiny could have on the free exchange of ideas and the willingness to take risks to find answers.

The amendment to OMB circular A-110 contained in Public Law 105-277 could have unintended, but nonetheless grave consequences. The regulatory requirements embodied in the law are far more complex than the apparently simple mandate to share data. The kind of widespread access to data envisioned by the Act could result in unforeseen abuses. Unless otherwise protected, patient privacy rights could be violated. The willingness of scientists to speak openly about new ideas and take experimental risks could be fettered by unrestricted data access. Further, I am concerned that inappropriate sharing of preliminary data could lead to misinterpretation of results. Finally, the new requirements could undercut the ability of researchers to build private sector partnerships that now lead to the eventual marketing of products.

It is because of these concerns that we at NIH have taken the position that, while expanded access to scientific data should be encouraged, the A-110 amendment may be a poor vehicle to achieve this goal. I am particularly concerned about the legislation's requirement that the Freedom of Information Act (FOIA) be the tool of regulatory implementation. FOIA was not designed to accommodate the confidentiality requirements of the most sensitive scientific data. Consequently, without additional protections, it would be possible for the privacy of patients to be compromised or individual scientists to be harassed by selected interests opposed to their work due to moral or financial concerns. Such intrusions could stop promising scientific research in its tracks, and the mere threat of such intrusions could impede the Nation's efforts to recruit its most talented students into publicly-supported research.

For example, imagine what would happen if HIV-infected patients thought their condition might be revealed by someone using the new requirements to examine raw experimental data. Patients would not participate in clinical trials if they believed there was an opportunity for their infected status to be revealed. Progress toward treatment of the disease would be stymied.

Under this new application of FOIA embodied in the A-110 amendment, a request for research data would be directed to federal agencies, such as NIH. We would be required to forward the request to grantee institutions and to the scientists with direct responsibility for the data. Their data often contains information about individuals who entered into the research project under a promise of confidentiality. This information would be forwarded from grantee institutions to federal agencies, who would be responsible for determining what to release and what to exempt.

It may sound simple to make that determination, but it is not. FOIA would allow the government agency to remove obvious identifiers such as name, Social Security number, telephone number, but in a given data set it is quite feasible to identify subjects using other information. If the requestor knew a few items about an individual's history, such as place of birth, education, occupation, marital history, or other general information, an individual could be identified. Such identification would then open up the whole research record, including personal medical information to the requestor.

While there are many aspects of the A-110 amendment that trouble us, there is a particular provision that presents a new challenge to those who would make their data accessible. I am thinking about the multiplicity of partnerships between public sector researchers and private companies, non-profit organizations, and even foreign governments. Some of these partnerships make strict requirements on the researcher not to share data further. Without such agreements, private researchers would not participate in these partnerships.

In regard to proprietary data, the Bayh-Dole Act specifically provides protections for the intellectual property of individual researchers. But the A-110 amendment threatens these protections for our partners. Industry scientists may avoid collaborations with publicly-funded institutions, including universities, if they believe they can no longer protect their data from exposure.

The A-110 amendment will lead to increases in administrative burdens and cost for granting agencies, such as NIH, but also for grantees. Universities and other institutions that receive Federal grants will need to create formalized procedures to respond to FOIA requests. Increased administrative costs are not in themselves a reason not to move forward with policies in the public interest, but we would like to ensure that the benefits are commensurate with the costs. Increased administrative costs will come at the expense of research, in both dollars and in investigator time. The paperwork that requests will generate is enormous and counter to the reduction in paperwork efforts. Entire staffs will have to be recruited to make the decisions that will have to be made, with consequent increases in costs of conducting research.

In addition to the administrative burdens, the A-110 amendment is likely to lead to the filing of lawsuits by individuals or organizations whose requests for data are rejected, which would be costly to the government and private institutions that perform publicly-funded research.

I am aware that the Administration is working to implement the A110 amendment in the least intrusive manner possible. However, it is my view that on balance, you should support H.R. 88 and repeal the A-110 amendment. Taking such action will not mean the end of data access. It will signal the beginning of efforts to establish a more responsible approach to data sharing, one that will protect the rights of individuals, recognize the proprietary interests of commercial enterprises, and consider the needs of the scientific community. I pledge to work with you and your colleagues toward those efforts. I would be pleased to answer any questions you may have.

Mr. HORN. Now we have a longtime expert on the FOIA Act, and that's Mr. James T. O'Reilly, visiting professor, College of Law, University of Cincinnati. I think you have been with us since the beginning.

Mr. O'REILLY. It just feels that way.

Thank you, Mr. Chairman, distinguished members and friends, thank you. I'm honored to be back in Congress talking about the Freedom of Information Act, as I have done numerous times before.

For background, I have authored the national standard reference text that's going into its third edition next year, written dozens of articles and 25 books on related subjects. I have advised the Japanese, the English, the Canadians, on freedom of information. The message that you get from other countries is your infrastructure of dealing with information is remarkable and we wish in our country we had a similar infrastructure.

From my studies for the Congressional Office of Compliance and my work for the Federal Administrative Conference, I have done a lot of background reading and thinking and writing on this subject. So I am here as a technical resource rather than advocate specific to H.R. 88.

I want to offer four very specific facts: First, there is a viable infrastructure in the Freedom of Information Act. It's world recognized. The effect of the Shelby amendment was not to change that infrastructure and not to change the set of exemptions, but rather to expand the set or pool of information that's subject to that infrastructure. I also want to emphasize that the costs adopted as a result of the Shelby amendment will be transferred to requesters through the vehicles already present in the Freedom of Information Act of charging requesters for the costs of searching and processing data.

Second, the Freedom of Information Act's exemptions for personal medical data, which I can say as a former participant in a Federal medical research project, are very sensitive. Those private information documents and data are protected under the (b)(6) amendment to the Freedom of Information Act. That exemption is not changed by Shelby.

The third fact, the Freedom of Information Act exemption protecting persons who have interest in actual competition against the damage to their profit or proprietary interest is a very serious issue which agencies take very seriously in their protection of information—of that private commercially valuable, competitively valuable information. Executive Order 12600, the Supreme Court, and the most recent D.C. Circuit decision on June 25th, for example, have adequately safeguarded the profit and the proprietary desires of those persons subject to government grants and contracts. Shelby does not alter that protection. The experienced infrastructure is in place to manage that profit and competitive interest.

The fourth fact is that Congress has been so protective of the public's accountability and sunshine interest that the Congress has declined to carve further exemptions into the Freedom of Information Act and none have been added to the act since 1976. If the Congress wished, it could take 1 of the 100 or more specific exempting statutes, as was done in the medical device research field, for example, and address that concern in a specific substantive

statute for that type of information. If there is a specific articulated problem, then carve out that niche by an exemption for a specific program while leaving the Freedom of Information Act and indeed the Shelby amendment untouched. Historically, niche exemptions are the way to go, rather than trying to reconstruct or deconstruct the coverage of FOIA.

To briefly explain, the Shelby amendment expands who the FOIA covers. It doesn't change what it exempts or how it operates. But the Forsham case in 1980 was poorly reasoned. I support the position of the dissent in that case. The Justices made a very good point in saying secret government would flourish if contract and grantee research, in that particular case for a diabetes drug, was not accessible.

The Shelby action does not change the concept that the public has a right to know. It, rather, expands the pool of documents to which the Freedom of Information Act infrastructure and exemptions apply.

I also want to point out as to costs the standard form Federal contracts and grants do provide that there be access by the agency to the specific records prepared under the grant or contract, and FOIA does pass the cost of the research, review and copying onto the requester. So recoupment of access costs will make this largely a user—funded process, though I recognize that will take time within the existing agency budgets and resources.

Second, medical and mental health privacy is a very important topic, that I can say as a test subject in Federal research, I understand the sensitivity of this issue. The courts and the case law have very adequately protected this. I have had the misfortune of having to read every published freedom of information case from 1967 on to today—and that could have a mental effect on a person—but those protections are in place, and individual records are protected.

Third, the patent and confidential information provisions are adequately protected. The infrastructure of Executive Order 12600 is in place.

And, fourth, the advocates for change have a specific opportunity to pass specific laws that will cover their specific items.

I want to compliment the American Society of Access Professionals, and those who are the front line people in government agencies handling FOIA requests. They do a great job of screening and protecting personal privacy and commercial privacy. I believe the track record is factually clear that the Freedom of Information Act infrastructure has worked, that the exemptions have worked, and that while there's misunderstanding about being put into the pool, the Freedom of Information Act is a viable accountability mechanism, and adding more documents to the pool is not going to change either the quality of the work done in screening those documents, or the access and privacy protection issues under FOIA.

Thank you for the opportunity to participate and I look forward to your questions.

Mr. HORN. Thank you very much. We appreciate your testimony.

[The prepared statement of Mr. O'Reilly follows:]

TESTIMONY OF
JAMES T. O'REILLY
Visiting Professor of Law
University of Cincinnati College of Law[1]

I am honored to be back again to share views on FOIA. I have testified several times in past FOIA hearings, and as the author of the standard reference treatise *Federal Information Disclosure* and dozens of articles, I've had to read every reported FOIA court decision back to the 1960s and up to today. I learned a great deal from my work with the federal Administrative Conference on FOIA's exemption 4, and from my study of Congress and the FOIA that resulted in my consultancy for the Congressional Office of Compliance on effects of the Congressional Accountability Act. I try to impart to my students the versatility of the Act and lessons I have learned as an active FOIA requester and critic of agencies.

I'm here today to offer a technical resource about FOIA, since there seem to be such misunderstandings of the Act and of what the Shelby Amendment does. I will briefly offer 4 facts, explain them, and remain available for your questions about FOIA and how it relates to the Shelby Amendment.

FACT 1. THE FREEDOM OF INFORMATION ACT OF 1966, AS AMENDED, CREATED A VIABLE INFRASTRUCTURE FOR THE PUBLIC RIGHT TO KNOW, THAT HAS BEEN WORLD-RECOGNIZED AS A MODEL OF GOVERNMENT SERVICE TO THE PUBLIC. THAT INFRASTRUCTURE IS IN PLACE AT THE AGENCIES AND SHELBY DOES NOT ALTER IT. SHELBY'S EFFECT IS TO WIDEN THE POOL OF PUBLIC ACCOUNTABILITY, NOT TO CHANGE THE RULES OR PROCESSES OF DISCLOSURE. AS TO COSTS, THE CURRENT PRACTICE OF CHARGING REQUESTERS FOR THE COST OF GATHERING, REVIEWING AND COPYING DOCUMENTS WILL MAKE THE FISCAL IMPACT OF SHELBY MODEST AT BEST.

FACT 2. THE FOIA EXEMPTION FOR PERSONAL MEDICAL DATA COLLECTED BY OR FOR THE GOVERNMENT HAS, FOR MORE THAN A QUARTER CENTURY, PROTECTED THE INTERESTS OF

[1] Views expressed are those of the witness and not necessarily those of the University.

MEDICAL AND MENTAL HEALTH PATIENTS AND THE AGENCY INFRASTRUCTURE FOR THAT PROTECTION IS VERY VIABLE TODAY. THAT EXEMPTION IS UNCHANGED BY SHELBY.

FACT 3. THE FOIA EXEMPTION PROTECTING PERSONS WITH INTERESTS IN ACTUAL COMPETITION, AGAINST THE CONCERNS THAT FOIA WOULD DAMAGE THEIR PROFIT OR PROPRIETARY INTERESTS BY PREMATURE DISCLOSURE, IS A VERY VIABLE PROTECTION TODAY. THE SUPREME COURT, THE D.C. CIRCUIT EN BANC, AND EXECUTIVE ORDER 12,600 HAVE ADEQUATELY SAFEGUARDED PROFIT AND PROPRIETARY DESIRES OF RESEARCHERS. SHELBY DOES NOT ALTER THAT PROTECTION AND THE EXPERIENCED INFRASTRUCTURE IS IN PLACE TO MANAGE THOSE PROFIT AND COMPETITIVE INTERESTS.

FACT 4. THE CONGRESS HAS BEEN SO PROTECTIVE OF PUBLIC ACCOUNTABILITY AND SUNSHINE THAT IT HAS DECLINED TO CARVE FURTHER EXEMPTIONS TO FOIA, RELYING INSTEAD ON THE 100 OR SO SPECIAL EXEMPTING STATUTES. THE CONFLICTS OVER SPECIFIC RESEARCH INTERESTS IN MEDICAL DEVICE TESTING DATA, FOR EXAMPLE, HAVE ALREADY BEEN ADDRESSED IN SPECIFIC SUBSTANTIVE LAWS. YOUR COMMITTEE IS FREE, SHOULD YOU FIND A SPECIFIC ARTICULATED PROBLEM, TO CARVE OUT A NICHE OF EXEMPTION FOR A SPECIFIC PROGRAM WHILE LEAVING BOTH FOIA AND SHELBY UNAFFECTED. HISTORICALLY, THE BURDEN OF JUSTIFYING SUCH NARROW "NICHE" EXEMPTIONS HAS BEEN ON THE PROPONENTS OF SECRECY IN PARTICULAR FIELDS.

Now I'll briefly explain these points. The Shelby Amendment expands <u>who</u> the FOIA covers; it does not change <u>what</u> FOIA exempts or <u>how</u> FOIA operates. It reverses a poorly reasoned Supreme Court majority decision, the <u>Forsham</u> case, for reasons predicted by the Supreme Court's dissenting justices. Administrative law scholars have noted that agencies are relying more on outside contract or grant-generated data than ever before; the "government by contractor" and "government rules by contractor-supplied reasons" are not prudent concepts; but that topic is larger than today's hearing allows. Shelby expanded accountability of agencies by closing the loophole for such agency use of hidden data. Shelby did not change FOIA's exemptions or procedures. The topic of rulemaking that was based upon a

secret or hidden body of data, a theme addressed 20 years ago in federal agency studies, needs to be addressed in the present context with more accountability, as the phenomenon of "outsourcing" of data by agencies reaches a dramatic proportion. Let's see what the Shelby "sunshine" approach can do in actual operation.

Regarding cost, as you may know, standard form federal contracts already provide for federal agency access to the data generated under the contract or grant and those contracts already are priced to include the costs of records handling in the pricing of the contract or grant. Since FOIA passes the costs of records search, review and copying documents back to the requester, the long term fiscal cost of Shelby will be modest, since recoupment of access costs will make this a user-funded process under appropriate agency rules.

Secondly, FOIA has protected medical and mental health privacy, and the agency infrastructure is in place to use both FOIA exemption 6 and the federal Privacy Act, as well as specific laws where applicable, to shield patient identifying details. Years ago, I was a test subject in federal government experiments with medical products, so I understand the sensitivity of the topic. The courts and case law, together with agency rules and policies, do very adequately protect these important interests. These protections apply to shield one individual's file and to shield sensitive data about groups of persons that could be broken apart or dis-aggregated. The fact of FOIA coverage under Shelby does not mean an end to privacy rights, and FOIA has worked effectively to protect such rights.

Third, some researchers are concerned that they will lose financial opportunities and patent potential under FOIA. This aspect of the law has become settled and the infrastructure is in place. If the researcher has a legitimate competitive situation and the research data gives him or her a competitive advantage, then the FOIA exemption 4 claim will readily succeed. Executive Order 12600 gives rights of advance notice before the agency discloses that special set of valuable information. If you have a form of patentable discovery, you will be able to make a sound case for exempt status, and the sophisticated FOIA staffs within agencies are experienced in handling these claims. Shelby does not reduce the amount or process of protection for valuable proprietary technology.

Fourth, your committee and others already know how to pass specific laws to protect specific types of research data. The FOIA's exemption 4 for

competitively sensitive data has been augmented by specific laws for FDA medical device research data, for example, and for EPA chemical formulation data. If the advocates for change to Shelby have a valid concern and can articulate the scope of protection they will need, then it is simple to add a statutory protection in NIH legislation or EPA statutes, without need to revisit FOIA itself. But the burden is on those who want secrecy to justify it, against FOIA's long standing principle of public accountability.

Finally a word about how FOIA operates in day to day practice. Agencies funnel the incoming FOIA requests to skilled specialists who screen the documents and excise or cut out exempt portions. The specialists use the agency guidelines and regulations very effectively. The awareness of the exemptions, especially of medical privacy, is reinforced by training sessions inside the agency and through the FOIA leadership group, the American Society of Access Professionals. Education makes the difference; education will need to accompany the rollout of the amended OMB Circular. So the track record since 1966 is clear; the FOIA infrastructure works, the exemptions are in place, and the FOIA works as an accountability mechanism. Shelby adds more documents to the pool; it does not change the rules and exemptions.

Thank you for the opportunity to participate and I look forward to your questions later.

Mr. HORN. Dr. Bruce Alberts, very distinguished scholar and biology, an expert on the cell, and president of the National Academy of Sciences. We're glad to see you here again.

Mr. ALBERTS. Mr. Chairman, thank you. It's a pleasure to be here, and I thank you for holding these important hearings. I want to start by saying the Academy and the scientists do not disagree with the basic objective of the Shelby amendment to the extent that it would make scientific data publicly available for reevaluation by other scientists. This is a very important aspect of science. The Academy has issued many reports stressing the importance of data sharing and openness for both science and Federal decision-making. I have quoted from one of them in my written testimony.

I personally chaired a committee in 1987 for the Academy to ask whether there should be a project to map in sequence the human genome. That report published in 1988 set the stage for the very successful human genome project. And the central element of that project has been based on our recommendations to free access to all data that's been obtained. As you probably know, all sequence data is immediately put into the public data bases from that project and the Academy and scientists are very much interested in this kind of data sharing which is vital to the advance of science.

However, there are numerous problems with the Shelby amendment that arise from three of its fundamental aspects. First, it relies solely on the Freedom of Information Act as a mechanism for disclosure, and we do not believe that this is the appropriate mechanism.

Second, the Shelby amendment does not define the key phrase in the amendment, "all data produced under award."

And, third, the public data availability specified would not necessarily follow the completion of the researcher's scientific work as signaled by its publication in the scientific journal. I will deal briefly with each of these issues in turn.

First, application of Freedom of Information Act to federally funded research grantees will be extremely burdensome and costly to researchers and research institutions. And we have not seen any evidence that the application of this new concept and its impact have been thoroughly thought through by Congress. In fact, as you know, this is the first hearing on the subject. We had legislation before any informing of Congress of the issues. A very unusual situation.

We predict that the amendment will have a chilling effect on joint university industry research collaborations, something that—a very vital part of our economy and expanding part of our economy—and that it will be used by various special interest groups, of which there are many, to harass researchers doing research that these particular interest groups would like to stop.

New, legislation will also be exploited by both foreign and domestic concerns as well as foreign military interests as a new tool for scientific espionage. As you know we're the clear leader in world science and technology. Many countries are already trying to do espionage; and what we're doing, this would give them a new avenue, a powerful new avenue that we don't reciprocally enjoy for their science.

Well, the second fundamental problem with the Shelby amendment is understanding what the term "data" means in this legislation. We have suggested to OMB that it should mean research data as witnessed by the conversations on the Senate floor. On the other hand, OMB Circular A–110 does not define the term, "research data."

We have suggested that the research data contemplated by the Shelby amendment are the broad data that result from research observations and experiments under Federal grant awards. We also point out that the U.S. Supreme Court's decision, *Feist Publications* v. *Rural Telephone Service Company*, provides the legal definition of, "raw data" as uncopyrightable facts.

We have thus suggested to OMB that research data should be defined to mean, "facts, which are in the public domain and may not be copyrighted that result from scientific observation, experiment, or similar methods of research."

We have also suggested to OMB that the definition of research data should contain a provision that, for research involving human subjects, would define research data in a way that would require that any information that would identify any specific individual be aggregated or redacted before this data is being sent to a government agency. This is not the case with FOIA. It's all sent to the government agency and thereafter the government agency decides what to do with it.

The third fundamental problem with the Shelby amendment is that the Freedom of Information Act clearly does not protect the scientist's right to publish the result of the scientist's own research. Thus, federally funded research grantees now face a threat under the Shelby amendment of having their research data made public before the Freedom of Information Act—under the Freedom of Information Act, before they have had the opportunity to publish the results of their research. Publication of research results in peer-reviewed scientific journals is one of the most critical elements of the entire research process. It's what makes science so successful. It's the means by which new discoveries are communicated to others in the scientific community and to the public at large.

Permitting the researcher who actually collected the data, worked for years to collect the data and to be the first to analyze and publish the conclusions concerning that data is an absolutely essential motivational aspect of all research. If you require public release of this data before publication, it would seriously short-circuit the entire scientific research progress that has been so effective in making the United States the world leader in science and technology. It would severely disadvantage federally funded research scientists while providing unreasonable advantages to all their competitors, both their competitors inside the United States and their international competitors.

A premature release of research data before careful analysis of results, of course, would increase the risk of misleading conclusions being drawn from that data, no peer review would have been applied, and might create a loss of confidence in science on the part of the public because of the great unnecessary confusion that would arise. Any reasonable approach, in short, must make publication

the triggering of that for application of legislation such as this Shelby amendment.

I want to close by emphasizing that in my opinion FOIA is really fundamentally flawed as the mechanism here because it fails to require any evidence from the data requester that the disclose of the data in question is in the public interest. In other words, no prescreening of requests is involved. This actually invites harassment of scientists by those who don't like what particular scientists are doing. It will make the life of a scientist difficult. It will prevent us from attracting the very best people into scientific enterprise, a vital part of the success of our enterprise.

In short, the Shelby amendment is throwing out the baby with the bath water. If I was one of our competitors looking with envy at the United States scientific enterprise and its driving of our economy, say I was from France, for example, I would say, Boy, this is a great thing for us; the United States is trying to stab themselves in the foot with this legislation.

For this reason, I believe that Congress should hold additional hearings to gain a better understanding of the problems that would be created by the application of the Freedom of Information Act to the Federal grantee research data. Then Congress could craft specific legislation to provide for public access to federally funded research data, using a mechanism that balances the interest of the public in access to data with other important public interests.

Of course, the National Academy of Sciences would be pleased to help in any way we can with that effort by Congress.

I also offer for the record copies of two letters that I have sent to OMB concerning the Shelby amendment.

Mr. HORN. Without objection. It will be in the record at this point, those letters.

[The information referred to follows:]

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April 5, 1999

F. James Charney
Policy Analyst
Office of Management and Budget
Room 6025
New Executive Office building
Washington, D.C. 20503

Dear Mr. Charney:

These comments are being submitted on behalf of the National Academy of Sciences in response to the notice which appeared in the Federal Register for Thursday, February 4, 1999 at pages 5684-85.

As explained in the Federal Register notice, Public Law 105-277 enacted by Congress last year includes a provision (hereinafter sometimes referred to as "the Shelby amendment") that directs the Office of Management and Budget to amend Section ___.36 of OMB Circular A-110 "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Public Law 105-277 further provides that "if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data."

As also explained in the Federal Register notice, OMB proposes to satisfy this requirement of Public Law 105-277 by amending Section ___.36(c) of OMB Circular A-110 in two ways. First, the introductory phrase "Unless waived by the Federal awarding agency" would be deleted from existing Section ___.36(c) so that the first sentence of Section ___.36(c) would be revised to read as follows: "The Federal Government has the right to (1) obtain, reproduce, publish or otherwise use the data first produced under an award, and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes."

Second, the following four additional sentences would be added to Section ___.36(c): "In addition, in response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were use by the Federal Government in developing policy or rules, the Federal awarding agency shall, within a reasonable time, obtain the requested data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A))."

As I stated in my previous letter to the Director of OMB on this subject dated January 26, 1999, the Academy has issued a number of reports through the National Research Council supporting the concept of data sharing, but FOIA is not a reasonable mechanism for achieving that goal. We believe that the Shelby amendment and OMB's well-intentioned efforts to limit its scope are fatally flawed. Our view is that new legislation will be needed, either to repeal the Shelby amendment or to provide a more reasonable approach for making selected data collected under particular research grants available to the public. In the latter case, Congress should hold hearings and commission objective studies to determine how to write comprehensive legislation without doing damage to the federally funded research enterprise.

Regarding OMB's proposal, the Academy offers the following comments.

A. OMB's proposal to limit the scope of the Shelby amendment is fundamentally flawed because the phrase "all data" in the Shelby amendment will likely be interpreted by the courts to mean ALL DATA.

1. Legislative Intent

The wording of the Shelby amendment is remarkably clear. OMB has been directed to amend Section ___.36 of OMB Circular A-110 "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Yet the OMB proposed revision in the Federal Register notice would transform this requirement into a requirement that applies only to "data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules." That seems to be clearly inconsistent with the legislative intent embodied in the Shelby amendment.

In commenting on the conference report for the Treasury and General Government Appropriations Act for fiscal year 1999, Senate Majority Leader Lott stated on the Senate floor that the Shelby amendment "requires the Director of OMB to amend OMB Circular A-110 to require Federal awarding agencies to ensure that all research results, including underlying research data, funded by the Federal government are made available to the public through the procedures established under the Freedom of Information Act." 144 Cong. Rec. S12134

(October 9, 1998). Senator Lott also stated that "[t]his provision represents a critical step forward in assuring that the public has access to the research and underlying data used by the Federal government in developing policy and rules." *Id.* At no point did Senator Lott state that the scope of the Shelby amendment was *limited* to this purpose or that the scope was any less than what he had already stated it to be--namely "all research results, including underlying research data, funded by the Federal government...."

Senator Campbell, the chairman of the Treasury and General Government Appropriations Subcommittee which reported out the appropriations bill, stated on the Senate floor that "[t]he language included in the Conference Report [i.e., the Shelby amendment] will require Federal agencies to make all Federally funded research data available to the public through procedures established by the Freedom of Information Act....The provision applies to all Federally funded research data...the amended Circular shall apply to all Federally funded research...." *Id.* He said nothing to suggest that the scope of the Shelby amendment was limited to data used in developing Government policy or rules although, if such a limitation had been intended, it surely would have been an important point for comment on the Senate floor since the actual wording of the appropriations bill contained no such limitation.

It is true that Senator Shelby stated on the Senate floor that his amendment "represents a first step in ensuring that the public has access to all studies used by the Federal government to develop Federal policy." *Id.* But even Senator Shelby did not state that the scope of the amendment was limited to data used in developing Government policy or rules.

2. Impact on the Application of FOIA

Until the Shelby amendment, it had been clear as a result of the U.S. Supreme Court's decision in *Forsham* v. *Harris,* 445 U.S. 169 (1980), that data generated by a privately controlled organization that had received grants from a federal agency are not "agency records" subject to public disclosure under FOIA if the data had not at any time been "obtained" by the agency. 445 U.S. at 178. This was true even if the agency had the unexercised right to obtain such data. 445 U.S. at 185-86.

In reaching this conclusion the Supreme Court was clearly influenced by its perception of congressional intent. Thus, the Court noted in *Forsham* v. *Harris* that "Congress could have provided that the records generated by a federally funded grantee were federal property even though the grantee has not been adopted as a federal entity. But Congress has not done so, reflecting the same regard for the autonomy of the grantee's records as for the grantee itself." 445 U.S. at 180. The Court also noted that "Congress excluded private grantees from FOIA disclosure obligations by excluding them from the definition of 'agency,' an action consistent with its prevalent practice of preserving grantee autonomy." 445 U.S. at 445 U.S. at 179. To the Court these two factors indicated "that Congress did not intend that grant supervision short of Government control serve as a sufficient basis to make the private records 'agency records' under [FOIA], and reveal[ed] a congressional determination to keep federal grantees free from the direct obligations imposed by the FOIA." 445 U.S. at 182.

In assessing congressional intent, the Court was also influenced by its perception of the practical realities of making federal grantee records subject to FOIA. Thus the Court said: "We need not categorize what agency conduct is necessary to support a finding that it has 'obtained' documents, since an unexercised right of access clearly does not satisfy this requirement. Government access to documents clearly could not be the central component of the definition of agency records contemplated by Congress since the Federal Government has access to near astronomical numbers of private documents....Even if the Court were to accept petitioners' argument that only contractual access should give rise to 'agency record' status, a limitation which does not appear readily supportable, the class of documents subject to FOIA disclosure would still be staggering. The record in this case indicates that [the National Institute of Arthritis, Metabolism, and Digestive Diseases, at the time one of the Institutes of the National Institutes of Health] alone has some 18,000 research grants outstanding." 445 U.S. at 186, n. 17.

The Shelby amendment represents a drastic change in congressional intent. The amendment directs OMB to amend Section ___.36 of OMB Circular A-110 to require Federal awarding agencies "to ensure that all data produced under an award will be made available to the public through the procedures established under [FOIA]." In explaining this provision on the Senate floor Senator Campbell, the chairman of the Treasury and General Government Appropriations Subcommittee which reported out the appropriations bill, stated that "[t]he language included in the Conference Report [i.e., the Shelby amendment] will require Federal agencies to make all Federally funded research data available to the public through procedures established by the Freedom of Information Act. *The Conferees recognize that this language covers research data not currently covered by the Freedom of Information Act. The provision applies to all Federally funded research data regardless of whether the awarding agency has the data at the time that the request is made. If the awarding agency must obtain the data from the recipient of the award, the provision specifically states that the awarding agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data."* 144 Cong. Rec. S12134 (October 9, 1998) (emphasis added). The clear implication is that Congress intended that federal awarding agencies now have a *duty* to "ensure that all data produced under an award will be made available to the public" under FOIA, even if the awarding agency has to "obtain" the data from the grantee.

The question of whether or not federal grantee records are "agency records" subject to public disclosure under FOIA where a federal agency has a *duty* to obtain the records was *not* addressed in *Forsham* v. *Harris.* 445 U.S. at 176-77, n. 6. But the Court did make it clear in *Forsham* v. *Harris* that FOIA "empowers federal courts to order an 'agency' to produce 'agency records improperly withheld' from an individual requesting access." 445 U.S. at 171. Plaintiffs in FOIA lawsuits may now argue that the Supreme Court's decision in *Forsham* v. *Harris* does not prevent the federal courts from ordering federal agencies to obtain and disclose federal grantee records where the agency is improperly withholding them, because federal agencies now have a *duty* to obtain and disclose such records as a result of the Shelby amendment.

FOIA has been an enormous source of litigation. There have been more than 4000 reported court decisions interpreting and applying FOIA. If OMB directs federal agencies to do anything less in response to the Shelby amendment than make "all data produced under an

award" available to the public under FOIA, that directive when converted into agency regulations and applied to specific FOIA requests will surely be challenged in the courts on the ground that "agency records" are being "improperly withheld" in any case where less than "all data" are made available.

Even if OMB's view of the Shelby amendment ultimately prevails, there could be years of litigation before the matter is resolved if Congress fails to intervene. Federal circuit courts of appeal in various regions of the country could arrive at different and even conflicting interpretations of the application of FOIA to federal grantee research data. Different rules might apply to the same kinds of research sponsored by the same agencies depending upon the geographic location of the grantee. In other parts of the country, the validity of agency regulations might be unclear. For federal research grantees, the result would be confusion and chaos.

B. In addition, OMB's attempt to limit the scope of the Shelby amendment to data "used by the Federal Government in developing policy or rules" is not sufficiently defined or developed to be workable.

1. Applicable Only to True Research Grantees

If the scope of the Shelby amendment were limited to grantee data "used by the Federal Government in developing policy or rules" as OMB suggests, the amendment would generally *not* apply to data that were produced for the principal purpose of being used by a federal agency to develop policy or rules. Under Section 4 of the Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6303 (formerly 41 U.S.C. 503), *procurement contracts* must be used when the principal purpose of the funding instrument is the acquisition of property or services for the direct benefit or use of the federal government. See *Forsham* v. *Harris,* 445 U.S. at 180. OMB Circular A-110 does not apply to procurement contracts because Subpart A ___.2(e) excludes "contracts which are required to be entered into and administered under procurement laws and regulations" from the definition of "award" under Circular A-110.

So if a federal agency wants to use a funding instrument for the principal purpose of acquiring data to be used by the agency to develop policy or rules, the agency must use a procurement contract. For example, the Comptroller General ruled in *In Re Council on Environmental Quality and Office of Environmental Quality --Cooperative Agreement with National Academy of Sciences,* 65 Comp. Gen. 605 (1986), that the proper funding instrument for a proposed study developed and submitted by the National Academy of Sciences (the institution submitting these comments) to the Council on Environmental Quality for funding at the request of the Environmental Protection Agency was a procurement contract rather than a cooperative agreement, citing the Federal Grant and Cooperative Agreement Act. The purpose of the proposed study was to provide information on risks and benefits of certain pesticides to help federal regulatory agencies such as EPA in analyzing prospective regulations. Since the

primary purpose of the study was to acquire information for the direct benefit or use of the federal government, a procurement contract was required. 65 Comp. Gen. at 606-07.

If the Shelby amendment as interpreted by OMB generally would *not* apply to data that were produced for the principal purpose of being used by a federal agency to develop policy or rules because such data must be developed under a procurement contract, what would the Shelby amendment apply to? The Shelby amendment as interpreted by OMB would apply to data generated by a federal grantee if "published research findings [of the grantee]...were used by the Federal Government in developing policy or rules." Thus, the Shelby amendment as interpreted by OMB would apparently apply only to true research grantees doing basic and applied research if any published research findings of the grantee were subsequently used by the federal government in developing federal policy or rules.

2. What is "Use" in Government Policy Making and Rule Making?

The implications of applying the Shelby amendment as interpreted by OMB to research grantees doing basic and applied research only when published research findings of the grantee were subsequently used in federal government policy making or rule making would be far-reaching and complex. The factual situation addressed by the Supreme Court in *Forsham* v. *Harris*, as described in the Court's opinion, provides an interesting real-life model for illustrating the kinds of issues and problems that might arise.

The *Forsham* v. *Harris* case involved the University Group Diabetes Program (UGDP). In 1959 a group of private physicians and scientists specializing in the treatment of diabetes formed UGDP to conduct a long-term study of the effectiveness of five diabetes treatment regimens. Two of these treatment regimens involved diet control in combination with the administration of either tolbutamide or phenformin hydrochloride which were both oral hypoglycemic drugs. UGDP's participating physicians were located at 12 clinics nationwide and the UGDP study was coordinated at the University of Maryland. The UGDP study was funded solely by federal grants from the National Institutes of Health (NIH).

The UGDP study generated more than *55 million records.* In 1970, UGDP presented the initial results of the UGDP study indicating that the treatment of adult-onset diabetes with tolbutamide increased the risk of death from cardiovascular disease over that present when diabetes was treated by the other methods studied by UGDP. UGDP subsequently reported a similar increased incidence of heart disease when patients were treated with phenformin hydrochloride.

The Committee on the Care of the Diabetic (CCD), a national association of physicians involved in the treatment of diabetics, and others were critical of the UGDP study. CCD requested access to the UGDP raw data in order to facilitate CCD review of the UGDP findings but UGDP declined. Arrangements were subsequently made for a separate assessment of the UGDP study by the Biometric Society under a contract with NIH.

After the Food and Drug Administration (FDA) became aware of the UGDP results, the FDA issued a statement recommending that physicians use tolbutamide in the treatment of diabetes only in limited circumstances. In 1971, after UGDP had also reported its findings with respect to phenformin, the FDA proposed changes in the labeling of both oral hypoglycemic drugs but delayed action pending completion of the Biometric Society study. In 1975 after the Biometric study had been issued, FDA renewed its proposed change in labeling, clearly relying on the UGDP study.

In 1977 the New Drug Application for phenformin was suspended, premised in part on the findings of the UGDP study. The suspension decision was subsequently upheld in administrative proceedings that were not based substantially on the UGDP study. *Nearly 400 published articles* were included in the record of the phenformin proceedings.

Under the Shelby amendment as interpreted by OMB, when would FOIA have applied? Presumably not for the period from 1959 to 1970 until the initial results were presented. In 1970 FOIA would not have applied simply because the initial results were important and controversial. Would the statement issued by the FDA have triggered the application of FOIA? Was that rule making or policy making? What about the FDA's 1971 labeling proposal? Or would FOIA have applied only in 1975 when the FDA, in the words of the Supreme Court, "clearly relied on the UGDP study" to support the labeling proposal? 445 U.S. at 174.

Perhaps any federal government "use" of the UGDP study results would have triggered the application of FOIA. But what about the phenformin proceeding in which *nearly 400 published articles* were included in the record. How many of those articles were the result of federally funded grantee research? Would all of the data relating to such articles have become subject to FOIA? Were the research findings in those articles "used" by the Government for rule making or policy making?

It is also interesting to note that OMB is not proposing that FOIA would apply to research grantees doing basic and applied research when published research findings of the grantee "are being used" in federal government policy making or rule making. Under the OMB proposal, FOIA would apply to research grantees doing basic and applied research when published research findings of the grantee "were used" in federal government policy making or rule making. Is the use of the past tense intentional? Would FOIA apply to the grantee's research data only *after* the federal government rule or policy had been developed? Given the secrecy that often surrounds the deliberation and development of federal government policy, that interpretation seems plausible.

For roughly the first 10 years of the UGDP study, FOIA apparently would not have been applicable under OMB's proposal since apparently (based upon the Supreme Court's recitation of the facts) no research findings were announced until 1970. And during that time it might have been very reasonable to expect that FOIA might *never* apply because FOIA would apply only if the research findings were used to develop Government policy or rules. Probably no one could predict whether that would happen or not. For one thing, no one knew in advance what the results of the study would be. Perhaps the results would not reveal any significant problems.

But when the FDA--an agency separate from NIH, the granting agency--did "use" the results of the UGDP study (whenever that was exactly), perhaps without any notice to or consultation with UGDP, FOIA would have suddenly become retroactively applicable to the *55 million records* of the UGDP study. That is apparently the regime that OMB is proposing.

3. What is "Policy"?

One of the confounding aspects of the OMB proposal is that the application of FOIA to research grantees doing basic and applied research would be triggered when published research findings of the grantee were subsequently used in making federal government rules or "policy." But the federal government has many kinds of "policies"--national security policy, economic policy, foreign policy, public health policy, environmental policy, budgetary policy, social welfare policy, energy policy, science policy, etc., etc. The word "policy" in the federal government is amorphous and omnipresent. It would not provide a clear and reliable standard for determining the application of FOIA to grantee research records.

4. No Definition of "Data"

The basic underlying concept of the Shelby amendment seems to be that the public should have access not only to the results of federally funded grantee research (which is already true for the vast majority of federal research grants) but also to the underlying raw data. However, the OMB proposal contains no definition of "data," and under current agency regulations the term "data" may not be limited to information resulting from original observations and measurements, or to similar kinds of raw data. The definition of "data" under some agency regulations is very broad, encompassing not only data in the conventional sense but all recorded information in all media including such items as computer programs, copyrightable works, and procedural manuals. Under an expansive definition of "data," drafts of research papers, for example, might be available to the public under FOIA even before the drafts are peer-reviewed, finalized and published, potentially confusing the public and unfairly penalizing the researcher. Important legal rights in certain kinds of "data" might be altered or impaired.

If the term "data" is not properly defined by OMB, there will surely be those who will argue that FOIA now applies not simply to underlying federal grantee raw data but rather, like civil discovery, to all recorded information which is relevant. And since "relevance" is not a very meaningful concept within the context of FOIA, this could easily be expanded into an argument that FOIA now applies to virtually all federal grantee information recorded under a grant, including computer programs, email, copyrightable works, drafts of research papers and proposals, etc. Burdensome disputes due to uncertainties over the scope of the term "data" and its application would be inevitable.

5. No Definition of "Published Research Findings"

Under the OMB proposal, the application of FOIA to a federal research grantee's data would be triggered by federal government use of "published research findings" produced under

the grant that were used in the development of federal government policy or rules. But what are "published" research findings? Does that mean published in a peer reviewed scientific journal? Could it mean published in the newspapers? Could it mean published on the internet? Would it have to be a written "publication"? Could research findings be "published" orally, for example at a public symposium or in a conversation with a federal government official who then "uses" the information in developing federal government policy or rules?

6. Data "Relating to" Published Research Findings

The OMB proposal would not simply make FOIA applicable to data that are cited in or relied upon in published research findings that are used by the federal government for developing federal government policies and rules. Instead, the OMB proposal would make FOIA applicable to data "relating to" published research findings. The vagueness and potential expansiveness of the phrase "relating to," particularly within the context of a failure to define the term "data," would be especially troubling.

The phrase "relating to" will be used as the basis for arguing for a very expansive interpretation of the application of FOIA to federal grantee research data. For example, assume that the first published research paper under a multi-year grant is immediately used by the federal government to develop policies or rules. All new data developed during the remaining years of the grant would in some sense probably "relate to" that first paper. Would that mean that all such new data would be immediately and continuously subject to FOIA because the data "relate to" published research findings--i.e., the first paper--that were used by the federal government to develop policies or rules?

C. OMB's proposed amendment of Circular A-110 would have serious adverse effects on federally funded grantee research.

1. Impact on Scientific Publication and Peer Review

One of the most troublesome aspects of OMB's proposed application of FOIA to federal grantee research data is the possibility that FOIA may not allow a federal research grantee to publish the results of his or her research in scientific journals before the underlying research data must be made available to the public (including competitors and foreign countries) under FOIA. This problem results directly from the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Burka* v. *U.S. Department of Health and Human Services,* 87 F.3d 508 (D.C. Cir. 1996).

The *Burka* case involved a FOIA request for computer tapes recording survey responses about smoking habits and attitudes and whether or not such information could be withheld from public disclosure under Exemption 5 of FOIA. Exemption 5 protects inter-agency and intra-agency memorandums or letters which would not be available by law to a party in litigation with the agency from public disclosure under FOIA. In other words, the parameters of Exemption 5

are determined by reference to the protections that are available to litigants with respect to document and information discovery in civil lawsuits. If material would not be available in civil discovery, it may be withheld under Exemption 5 of FOIA. 87 F.3d at 515-16.

The lower court had ruled that even though some scientific articles had already been published based upon the data, a number of other scientific articles remained to be published based upon those data, and therefore Exemption 5 protected the data from disclosure under FOIA until those remaining articles had been published. The court of appeals reversed, holding that the research data could not be withheld under Exemption 5 of FOIA for the purpose of allowing the researchers to publish the remaining scientific articles because there is no "established or well-settled practice of protecting research data in the realm of civil discovery on the grounds that disclosure would harm a researcher's publication prospects." 87 F.3d at 521.

Under the OMB proposal, data "relating to published research findings" of a federal grantee--where the research findings were used by the federal government in developing federal policies or rules--would be subject to FOIA. And under the *Burka* decision, such data could not be protected from public disclosure under Exemption 5 of FOIA, even though additional scientific articles remained to be published describing the results of the research, based upon the data.

Publication of research results in peer-reviewed scientific journals is one of the most critical elements of the research process. It is the means by which new discoveries are communicated to others in the scientific community and to the public at large. Permitting the researcher who actually collected the data to be the first to analyze and publish conclusions concerning the data is an essential motivational aspect of research. Requiring public release of data prior to publication in scientific journals would seriously short-circuit the scientific research process that has been so effective in the United States. Moreover, it would severely disadvantage federally funded scientists while providing unreasonable advantages to their competitors, both in the United States and internationally.

Premature release of research data before careful analysis of results, and without the independent scientific peer review that is part of the normal process of publication of scientific research, would also increase the risk of public disclosure of erroneous or misleading conclusions. It would thereby confuse the public, which is against the public interest.

2. Implications for the Performance of Scientific Research

Under the OMB proposal a federal awarding agency, in response to a FOIA request for the data of a particular federal research grantee, would be required to obtain the requested data from the federal grantee and would then process the FOIA request in accordance with standard substantive and procedural FOIA rules, including what constitutes an "agency record" and the statutory FOIA exemptions. Thus, the OMB proposal is premised on the assumptions (1) that when the agency goes to the grantee to obtain the "data," the "data" will be there, and (2) that the important federal function of identifying and maintaining the "data" will be performed by federal

grantees and not federal officials. And while the incremental costs of *obtaining* "data" in response to a FOIA request are addressed, there is no indication of how the costs would be covered that are incurred by federal grantees in *identifying* and *maintaining* "data," possibly for years, in anticipation of a possible FOIA request.

But federal research grantees are generally not well-equipped by inclination, training or experience to deal with the legal and definitional subtleties of "data" and the bureaucratic responsibilities that go with being custodians of "agency records" nor with the very substantial financial and administrative burdens of doing so. The net result would be a major shift of valuable intellectual and financial resources away from scientific research and into disruptive paperwork production. Frequent FOIA requests for data by particular interest groups and individuals might even be used as an effective means to discourage certain research, attack ongoing research, or delay the publication of research results.

FOIA contains a number of exemptions from its public disclosure requirements which are designed to balance various legitimate interests in confidentiality of information with the public's right to know, and which are very important to making the statute work effectively. But these exemptions are seriously inadequate for protecting the legitimate interests of federal research grantees.

For example, as noted above, FOIA may not allow a federal research grantee to publish the results of his or her research in scientific journals before the underlying research data must be made available to the public under FOIA. In addition, although FOIA protects certain trade secrets and commercial or financial information from public disclosure, this provision may have only limited application in the case of federally funded grantee research. See *Washington Research Project* v. *Department of Health, Education and Welfare,* 504 F.2d 238, 244 (D.C. Cir. 1974), *cert. denied,* 421 U.S. 963 (1975) ("a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce"). Thus, legitimate interests of federal research grantees regarding the confidentiality of certain kinds of information may not be respected because these issues simply are not addressed by FOIA as presently written.

Another major concern would be the impact of the OMB proposal on the privacy and use of individually identifiable grantee data records--e.g., personal medical records. OMB's Federal Register notice specifically refers to the fact that FOIA Exemption 6 exempts "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." But even if Exemption 6 would fully protect such personal information from public disclosure, *such information would still be fully accessible to the federal government.* Under OMB's proposal, federal agencies would have the right (which apparently could no longer be waived by the agency) to "obtain, reproduce, publish or otherwise use the data first produced under an award," apparently at any time. That right would, of course, be subject to applicable statutory restrictions, but those restrictions could change over time. The simple fact is that individuals who might otherwise be inclined to participate in important federally funded research studies might decline to do so if their medical or other personal records created during the study *would be accessible to and available for use by the federal government*

at any time. Reasonable people who would willingly cooperate with their local university or hospital or their own physician in a research study might not have the same degree of confidence in the federal government.

D. Instead of a one-sentence policy statement, OMB should develop comprehensive guidance for federal agencies on public access to federal grantee research data in a manner that fully provides for public access but does not damage or infringe upon equally important aspects of performing, and publishing the results of, federal grant-funded research.

1. Federal Agencies Need Real Guidance

The OMB proposal would add only *four* sentences to OMB Circular A-110, *three* of which would deal with fees. That is simply not a sufficient response for an issue of this magnitude.

The OMB proposal would make FOIA potentially applicable to a pool of tens of thousands of federal research grants. The National Institutes of Health and the National Science Foundation, for example, have a combined total of about *70,000* research grants outstanding.

Federal research grantees probably possess hundreds of millions of "data" records. And *every* federal grant would be affected by the OMB proposal to the extent that the grantee must be prepared at any time in the future to respond to a federal agency request for "data" to satisfy a FOIA request.

The OMB proposal reflects no appreciation of the volume, complexity, and variety of federal grantee research data being generated by astronomers, molecular biologists, atmospheric chemists, high energy physicists, geoscientists, clinical investigators, plant biologists, materials scientists and engineers, epidemiologists, etc. The complexities of individual scientific fields are often so great that only scientists working in those fields will really understand the details of their particular field of research and the data being generated. The effective application of FOIA to data of such diversity and complexity will be very difficult. The functions of identifying and maintaining such data, possibly for years, are certain to be very costly to both research institutions and the federal government.

OMB cannot simply respond to a one-sentence directive from Congress with a one-sentence policy statement to federal agencies. OMB needs to do what Congress did *not* do. OMB needs to fully analyze and understand the implications and impact of the Shelby amendment on federal grantee research, report back to Congress, and work with Congress in developing comprehensive guidance for federal agencies on public access to federal grantee research data in a manner that fully provides for appropriate public access but does not damage or infringe upon equally important aspects of performing, and publishing the results of, federal grant-funded research.

2. Some Suggestions

As I stated in my letter to the OMB Director dated January 26, the federal support of scientific research is one of the nation's most important and enduring public policies. As we stand on the threshold of the 21st century, a moment of reflection on the past one hundred years will call to mind the tremendous impact of science and technology on the 20th century here in the United States and around the world. The continuing importance to this country of federally funded research in developing new knowledge that can lead to new products and services, new industries, new treatments for disease, new weapons for national defense, new means of communication, and so on, is widely accepted.

There is *nothing* in the Shelby amendment which suggests in any way that the amendment was intended to damage or diminish the productivity of this research enterprise. The challenge now is to achieve the public access objectives of the Shelby amendment without damaging or diminishing the productivity of federal grantee research. In carrying out this responsibility, OMB and Congress should be guided by at least the following principles:

(1) create a narrow definition of federal grantee research data which makes it clear that the term "data" applies only to underlying raw data and not to preliminary data analyses, drafts of scientific papers, plans for future research, peer reviews, personal communications with colleagues, emails, etc.;

(2) provide that federal grantee research data involving human subjects shall never be made available to the federal government in individually identifiable form;

(3) require that each grant agreement specify at the outset what types of research data are proposed to be collected under the grant and potentially subject to public disclosure so that the grantee will have specific guidance from the outset as to exactly what "data" must be identified and retained under that grant;

(4) except in unique and unusual situations, provide that the grantee be required to send the relevant research data produced under the grant (and specified under (3) above) to the sponsoring federal agency no earlier than when the grant has been completed, so that the grantee will have the uninterrupted period of the grant to complete the research and publish the results;

(5) provide additional safeguards to protect the publication rights, patent rights, rights of industry co-sponsors, and other legitimate interests of federal research grantees while providing for timely public access to appropriate federal grantee research data;

(6) provide guidance on the requirements for, and the reimbursement of costs associated with, identifying and maintaining any federal grantee research data that must be kept by grantees in order to be able to respond to possible requests for public disclosure.

Sincerely,

Bruce Alberts
President

Mr. ALBERTS. Thank you.
Mr. HORN. All right. If you would like, complete your statement.
Mr. ALBERTS. Yes.
Mr. HORN. That was the completion of it?
Mr. ALBERTS. Yes.
[The prepared statement of Mr. Alberts follows:]

Statement of

DR. BRUCE ALBERTS
President, National Academy of Sciences

before the

Subcommittee on Government Management, Information,
And Technology
Committee on Government Reform

U.S. House of Representatives

on

July 15, 1999

Mr. Chairman,

Thank you for holding these hearings and for providing this opportunity to present testimony concerning the provision of Public Law 105-277 commonly referred to as "the Shelby amendment." As you know the Shelby amendment requires the Office of Management and Budget to amend OMB Circular A-110, which applies to Federal grant awards, "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act."

I do not disagree with the basic objective of the Shelby amendment to the extent that it would result in making scientific data publicly available for reevaluation by other scientists. We have issued a number of reports through the National Research Council (NRC) stressing the importance of data sharing and openness for both science and federal decisionmaking. Such sharing is an important tradition in science. As emphasized in our 1995 booklet for students, ON BEING A SCIENTIST: RESPONSIBLE CONDUCT IN RESEARCH, "After publication, scientists expect that data and other research materials will be shared with qualified colleagues upon

request. Indeed, a number of federal agencies, journal and professional societies have established policies requiring the sharing of research materials. Sometimes the materials are too voluminous, unwieldy, or costly to share freely and quickly. But in those fields in which sharing is possible, a scientist who is unwilling to share research materials with qualified colleagues runs the risk of not being trusted or respected. In a profession where so much depends on interpersonal interactions, the professional isolation that can follow a loss of trust can damage a scientist's work."

However, there are numerous problems with the Shelby amendment that arise from three of its fundamental aspects. First, the Shelby amendment relies solely on the Freedom of Information Act (FOIA) as the mechanism for disclosure. Valuable resources will be deflected from science into FOIA related administration, bookkeeping and legal battles. Second, the Shelby amendment does not define the key phrase "all data produced under an award". And third, the public data availability specified would not necessarily follow the completion of the researcher's scientific work, as signaled by its publication in a scientific journal.

Application of the Freedom of Information Act to Federally funded research grantees through the Shelby amendment will be extremely burdensome and costly to researchers and research institutions , and we see little evidence that the application of this new concept and its impact have been thought through. For example, researchers could be forced to make certain information publicly available, including their lab notebooks, draft manuscripts, electronic mail, and raw research data, even before its publication and analysis. We can predict that it will have a chilling effect on joint university-industry research collaborations, and that it will be used by various special interest groups to harass researchers doing research that these interests groups would like to stop. It will be exploited by both foreign and domestic concerns, as well as foreign military interests, as a new tool for scientific espionage.

For example, commercial interests that have a strong competitive interest in particular areas of research will now be able to use FOIA requests to obtain university-based research data for their own use and competitive

advantage in an effort to dominate or control that area of research, ultimately discouraging independent university research in these areas. Where universities have industry partners for jointly sponsored research projects, commercial concerns can use FOIA requests to obtain research data from these projects to the detriment of the actual project sponsors, who are their competitors. Existing legal precedent is unclear on what protection, if any, would be available under FOIA to such industry sponsors, and as a result they are likely to be much less inclined to participate in research with universities. And foreign military interests acting through intermediaries will surely use FOIA requests to obtain Government-funded basic research data for use in their own research and development programs.

Another fundamental problem with the Shelby amendment is understanding exactly what the word "data" means in this legislation. Some of the definitions of the term "data" within the Federal government are extremely broad. However, we have suggested to OMB that statements by Senators Lott, Campbell, and Shelby on the Senate floor concerning the

scope and purpose of the Shelby amendment make it clear that the "data" to which the Shelby amendment applies is "research data."

OMB Circular A-110 does not define the term "research data." We have suggested to OMB that the "research data" contemplated by the Shelby amendment are the raw data that result from research observations and experiments under Federal grant awards and that the U.S. Supreme Court's decision in *Feist Publications, Inc.* v. *Rural Telephone Service Co., Inc.*, 499 U.S. 340 (1991), provides the legal definition of "raw data."

The *Feist Publications* case is a copyright case in which the Supreme Court explained the distinction between "facts" that cannot be copyrighted and "compilations of facts" in which there can be a copyright under appropriate circumstances. The decision equates the concept of "raw data" with "uncopyrightable facts." (499 U.S. at 361).

As the Supreme Court explained in *Feist Publications*, all facts -- scientific, historical, biographical, etc. -- are inherently part of the public domain and may not be copyrighted. They are available to everyone and

merely await discovery. In scientific research, these "uncopyrightable facts" are the "raw data" which it is the purpose of scientific research to discover as part of the process of increasing our scientific understanding of natural processes and phenomena.

Relying upon this concept, we have suggested to OMB that "research data" should be defined to mean "facts, which are in the public domain and may not be copyrighted that result from scientific observation, experiment, or similar methods of research." These facts in the public domain are the raw data of scientific research.

We have also suggested to OMB that the definition of "research data" should contain a provision that would, for research involving human subjects, define "research data" in a way that would require that any information that would identify any specific individual be aggregated or redacted. Research data on human subjects are currently routinely shared, transferred and used by researchers in aggregated or redacted formats that reasonably prevent the identification of specific individuals.

The third fundamental problem with the Shelby amendment is that the Freedom of Information Act clearly does not protect a scientist's right to publish the results of the scientist's own research. In *Burka* v. *U.S. Dep't. of Health and Human Services*, 87 F.3d 508 (D.C. Cir. 1996), the U.S. Court of Appeals for the District of Columbia squarely held that research data could not be withheld under Exemption 5 of FOIA (which applies to certain inter-agency and intra-agency materials) to allow researchers to publish scientific articles because there is no "established or well-settled practice of protecting research data in the realm of civil discovery on the grounds that disclosure would harm a researcher's publication prospects." 87 F.3d at 521. And we know of no other generally applicable basis under FOIA for protecting a researcher's publication rights.

Thus, Federally funded research grantees now face the threat under the Shelby amendment of having their research data made public under the Freedom of Information Act before they have had the opportunity to publish the results of their research. But publication of research results in peer-reviewed scientific journals is one of the most critical elements of the entire research process. It is the means by which new discoveries are

communicated to others in the scientific community and to the public at large. Permitting the researcher who actually collected the data to be the first to analyze and publish conclusions concerning the data is an essential motivational aspect of research.

Requiring public release of research data prior to publication in scientific journals would seriously short-circuit the scientific research process that has been so effective in the United States. It would severely disadvantage Federally funded scientists while providing unreasonable advantages to their competitors, both in the United States and internationally. And premature release of research data before careful analysis of results, and without the independent scientific peer review that is part of the normal process of publication of scientific research, would also increase the risk of public disclosure of erroneous or misleading conclusions, thereby creating unnecessary confusion and loss of confidence in science on the part of the public.

To address this problem, we have suggested to OMB that Circular A-110 might be amended, for example, to provide that when research findings

produced under an award are published, the principal investigator would promptly send a copy of (or citation to) the publication to the Federal awarding agency. *Thereafter (assuming the Shelby amendment remains in place)* in response to a Freedom of Information Act request directed to the Federal awarding agency for the publication and the underlying research data, the Federal awarding agency would (1) send a copy of the publication to the requester and (2) obtain from the principal investigator the underlying research data identified by the principal investigator as the basis for the research findings in the publication so that these research data can be made available to the requester and the public under FOIA.

This approach would make "publication" the triggering event for application of the Shelby amendment -- although this may be controversial because there is no explicit reference to "publication" in the Shelby amendment. It would also introduce the problem of defining what it means to "publish" the results of scientific research.

We have pointed out to OMB that the scientific community would generally regard publication in the peer reviewed scientific literature to

constitute "publication" and not press reports, seminars or talks at scientific meetings. However, the world of scientific publishing is changing as it becomes increasingly electronic, and any precise definition of "publication" of research may need to be modified in the future. While we recognize that a dispute over the definition of "publication" could easily lead to litigation in the future, this seems to be the only available method of protecting the essential publication rights of researchers under the Shelby amendment.

Finally, in my opinion, FOIA is fundamentally flawed as the mechanism here, because it fails to require evidence from the data requestor that the disclosure of the data in question is in the public interest. Congress needs to do more investigation of this concern.

The Freedom of Information Act was designed to provide public access to Government records, not to all of the research data of Federal research grantees. I welcome this hearing today and believe that Congress should hold additional hearings to gain a better understanding of the problems that would be created by the application of the Freedom of Information Act to Federal grantee research data. Then Congress can craft

specific legislation to provide for public access to Federally funded research data that balances the interests of the public in access to data with other important public interests.

Such legislation should, at a minimum, provide specific statutory language for the protection of the publication rights of researchers and the proprietary interests of participants in joint university-industry collaborative research projects. In the meantime, the Shelby amendment should either be set aside or at least temporarily suspended to permit a congressional study of these issues and the enactment of specific legislation.

The National Academy of Sciences would be pleased to work with the committee and the Congress to help develop a workable system –one that would properly balance the interests of the public in having research data made public with the interests of the scientific community, so that our scientists and engineers can continue to contribute to the improvement of our living conditions and our economy.

I offer for the record copies of two letters that I have sent to OMB concerning the Shelby amendment. I would also be pleased to answer any questions that you may have.

Mr. HORN. OK. Mr. Hahn, we haven't sworn you in yet so if you will stand and raise your right hand.

[Witness sworn.]

Mr. HORN. Mr. Hahn has been in a number of key institutions this year. You're in my path. We have followed each other over time. You were at Brookings and also involved with the American Enterprise Institute and also at the John F. Kennedy School. So we're delighted to have you here. And please proceed. You didn't hear—as we said earlier, we don't want the statements read, we want them summarized eyeball to eyeball, and that gives us more chance for dialog from here to there and among your colleagues.

STATEMENT OF ROBERT W. HAHN, DIRECTOR, JOINT CENTER FOR REGULATORY STUDIES, AEI-BROOKINGS

Mr. HAHN. Thank you, Mr. Chairman. Let me start out by saying that some of the concerns I've heard from the scientists here are a little overblown with respect to FOIA. I have had one experience with FOIA in my life where I couldn't get information out of a bureaucracy. It took about a year to get requests through all of their legal counsel, and I finally got a technical letter explaining why they couldn't give me some data. So I don't think the flood banks are going to open right away, but I'll defer to Mr. O'Reilly and others as to the legal complexities of that.

I want to offer to you today a slightly different perspective than you've heard from some of the panel members, and one which may allow some room for compromise. It's based on some research I've done with Professor Linda Cohen at U.C. Irvine, and a short version of that research will be published in Science, hopefully in the next couple of weeks, and I'll look forward to the responses of my distinguished colleagues to my right here.

You've asked me to offer views on H.R. 88, which would repeal the requirement to make data publicly available under Federal grants and agreements awarded to universities, the so-called Shelby or Aderholt-Shelby provision. To cut to the chase, my feeling is that the Shelby provision is not perfect, but it's something that we should work with and we should certainly try to build on its strengths. Thus, I don't support H.R. 88 or the Walsh-Price amendment, and I think Congress should work with the Executive to craft a regulation that builds on the strengths of the Shelby provisions.

I want to discuss where we are now and make a couple of recommendations for your consideration. As you heard today, the scientific establishment, which we also have to view as an interest group—and I like to think of myself as a member of that establishment but we definitely are an interest group—is deeply——

Mr. HORN. Would you put that microphone a little closer to you?

Mr. HAHN. Sure. The scientific establishment is deeply concerned over a proposed OMB regulation and the underlying law that would require data to be publicly available under FOIA or the Freedom of Information Act. Opponents of the regulation, and there are many, correctly point out that it is ambiguous in important respects and could be costly to scientists. I believe that's true.

At the same time, I believe that the status quo fails to address a larger, more important problem, and we need to balance these competing costs and benefits. At present, as you are well aware,

analyses used in policymaking are rarely checked carefully before big regulations are put into place. That was the whole genesis of the discussion of whether we should provide greater public access to data, which I'll talk about in a minute.

So what I recommend is essentially allowing greater access to information that pertains to the formulation of big regulations. And I also propose, unrelated to this law but related to some other matters before Congress, that an agency be created to replicate key findings that are used to support regulations before they are finalized. I think that just conforms with common sense.

As you know, one of the motivations for this law and the OMB regulation was the EPA regulation on ozone and particulate matter and, in particular, a Harvard study that suggested that reducing emissions of fine particles could lead to substantial reductions in premature mortality.

I don't want to get into the merits of who should have given what to whom, but I want to introduce one point the Administrator of EPA, Carol Browner, suggested that this study was fine to use because it had been peer reviewed. And you have also heard two of the leading scientists on this panel suggest that peer review is a wonderful process.

As one who participates in the peer review process, I think it is wonderful, but I don't think it's necessarily adequate when we're developing big regulations.

I want to offer one example for you suggesting that the peer review process has serious flaws. There was a study, now famous, in the early 1980's that requested the data used in papers with statistical analyses published in a leading economics journal. And they sent the paper out and tried to get reviewers to replicate the results. The study authors found errors in nearly every paper that were sufficiently serious that the results could not be replicated. I repeat: could not be replicated.

Well, that gives one pause for thinking about using such studies cavalierly in the development of huge regulations, when tens of billions, hundreds of billions of dollars are at stake in some of the regulations like particulate matter or, if we move toward regulating greenhouse gases or whatever. Those findings, in my view, cast serious doubt on the peer review process even for academic processes.

I think it's noteworthy in this regard that some of the leading journals, such as Nature, Science, the American Economic Review, and others are now requiring data availability to editors and members of the scientific community. And I think the Aderholt-Shelby provision would take it further and I think that that provision is well advised, at least in the area of regulations.

Now, why do I say that? Well, if all regulations that the Federal Government passed were great for society, no problem, right? But when you actually look at those regulations and apply rigorous—well, from an economist point of view, benefit-cost tests, I find in my research, based on the government's own analyses, that somewhere on the order of half of the government regulations would fail benefit-cost tests. That doesn't mean we shouldn't necessarily have these regulations but it gives one pause for reflection.

To help weed out such bad regulations, it's important to have key data available in a timely manner so that policies can be analyzed

before they are put in place. Because you and I know, once a regulation is put in place, it often takes on a life of its own.

Let me move on to my recommendations briefly because I see that I am out of time. The first and most important one I have touched on is that the data access requirements should be restricted to economically significant regulations developed by all regulatory agencies. I think targeting such regulations meets some—in some ways meets some of the scientific concerns halfway—certainly not all of them, but I think it is a useful compromise. I would also urge Congress to consider creating an agency to replicate findings for economically significant regulations so that the public has some idea of what it's getting for the expenditures associated with these regulations.

To conclude, Congress and the Executive are in a position to develop a sensible rule for promoting public access to data that is based on the strengths of the Aderholt-Shelby provision. The basic approach that I advocate is to proceed incrementally. Because I believe the biggest potential gains for society lie in providing greater access to major regulatory decisions, I have suggested that the OMB rule target proposed regulations that could have substantial economic impacts.

Thank you very much.

Mr. HORN. Well, we thank you. You and your colleagues' statements have been very helpful to us, a clash of ideas always does work.

[The prepared statement of Mr. Hahn follows:]

J O I N T C E N T E R

AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

A Proposed Solution to Concerns Over Public Access to Scientific Data

Testimony before the Subcommittee on Government Management, Information and Technology Committee on Government Reform U.S. House of Representatives

Robert W. Hahn

Testimony 99-4

July 1999

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Robert W. Hahn is director of the AEI-Brookings Joint Center for Regulatory Studies, a resident scholar at AEI, and a research associate at Harvard University. A copy of this testimony can be obtained from the Joint Center's web site: www.aei.brookings.org. The author has benefited from the research assistance of Irene Chan and Amy Wendholt. This testimony relies on research done jointly with Professor Linda Cohen. The views expressed here represent those of the author and do not necessarily reflect those of the institutions with which he is affiliated.

Executive Summary

The scientific establishment is deeply concerned over a proposed regulation that would require data to be shared on projects that are federally funded. The proposed rule responds to a provision by Senator Richard Shelby in the 1999 Omnibus Appropriations Bill that requires data generated under federal awards at universities and non-profit institutions to be available to the public.

This testimony develops an economic framework for evaluating proposals to provide greater access to research data. It also offers specific recommendations for improving OMB's proposed regulation as well as the broader regulatory process. The economic analysis suggests that there could be substantial gains from allowing greater public access to data in certain circumstances. A second conclusion is that traditional peer review done by scientific journals is not adequate for purposes of relying on research for major public policy decisions.

On the basis of economic analysis, I argue that the Shelby provision, which is now law, is too broad but is workable. Thus, I do not support H.R. 88, which would repeal the Shelby provision, nor do I support the Walsh-Price amendment, which would delay implementation of the Shelby provision for at least one year. Instead, I urge Congress to work with the executive branch to craft a regulation that builds on the strengths of the Shelby provision.

A Proposed Solution to Concerns Over Public Access to Scientific Data

Robert W. Hahn

1. Introduction

I have studied and written about regulatory issues for over two decades. Recently, my colleague, Robert Litan, and I helped the two institutions with which we are affiliated—the American Enterprise Institute and the Brookings Institution—form a new Joint Center for Regulatory Studies. The Joint Center addresses several issues related to improving the regulatory process, including reviewing federal regulatory and legislative proposals. The Joint Center just released an economic analysis of the issue of providing greater public access to scientific data.

Your committee has asked me to provide my views on H.R. 88, which would repeal the requirement to make data publicly available under federal grants and agreements awarded to universities. I will refer to that requirement as the Shelby provision, named after the senator who introduced it. I will also discuss an amendment by Congressmen Walsh and Price, referred to as the Walsh-Price amendment, which would essentially delay the introduction of a regulation based on the Shelby provision for twelve months to allow an independent group to examine the unintended negative consequences of the Shelby provision.

My basic conclusion is that the provision advanced by Senator Shelby, which is now law, is too broad but serves as a useful starting point. Thus, I do not support H.R. 88 or the Walsh-Price amendment. I would urge the Congress to work with OMB and the executive branch to craft a regulation that builds on the strengths of the Shelby provision.

My testimony proceeds in three parts: first, I provide an analysis of the proposed OMB regulation. Second, I offer some recommendations for improving that regulation. Third, I briefly address the different legislative proposals and suggest an appropriate direction for policy.

2. The General Issue of Providing Greater Public Access to Data

The scientific establishment is deeply concerned over a proposed regulation that would require data to be publicly available under the Freedom of Information Act. The change was proposed by the Office of Management and Budget as a consequence of an amendment added by Senator Richard

Shelby to the 1999 Omnibus Appropriations. The regulation would apply to any federally funded data sets that have been reported in a publication and are being used in forming policy. Opponents of the regulation correctly point out that it is ambiguous in important respects and could be costly to scientists. I believe that the status quo, however, fails to address a larger, more important problem. At present, analyses used in policy making are rarely checked carefully before big regulations are put in place. I recommend allowing greater access to information that pertains to the formulation of such regulations and propose that an agency be created to replicate key findings used to support regulations before they are finalized.

Scientists are justifiably concerned that the proposed regulation before Congress could reduce the productivity of scientists, expose them to unfair attacks by special interest groups, and place unnecessary burdens on researchers. They also argue that the rule could place severe restrictions on researchers who obtain data only by guaranteeing anonymity to subjects. Further, researchers and institutions with ties to industry fear that forced disclosure of proprietary information could jeopardize university-industry partnerships, which frequently help spur innovation. To address those concerns, my proposal recommends narrowing the focus of the regulation to those areas where public access to data is likely to have the greatest social value.

The controversy over public access to data arose when the Environmental Protection Agency (EPA) finalized a regulation on particulate matter in July 1997 that gives the agency vast new powers to regulate a variety of emission sources ranging from power plants to lawn mowers and barbecue grills. The regulation, estimated to cost between $9 billion and $37 billion annually in 1990 dollars, was based partly on a Harvard study that suggested that reducing emissions of fine particles could lead to substantial reductions in premature mortality.

Several members of Congress and a number of industry organizations requested that the EPA obtain the data and then release it. The EPA requested the data, but the researchers refused to turn them over. They subsequently agreed to an alternate plan, whereby the Health Effects Institute, an independent research institute funded by industry and the EPA, would convene an expert panel to reanalyze the data. The results of that study are not expected to be available until later this year—two years after the regulation was made final. In this case, the EPA administrator argued that the Harvard study had been peer-reviewed, and that this was sufficient for using the findings in a public policy setting.

A closer look at the peer-review process reveals serious flaws. In fact, studies have been published that demonstrate how easily errors slip through the system. In the early 1980s, a now-famous study requested the data used in papers with statistical analyses published in the *Journal of Money, Credit and Banking*, a leading economics journal. The study authors found errors in nearly every paper that were sufficiently serious that the results could not easily be replicated. The authors also found that, notwithstanding both the general norm that data be available and the requirement of the National Science Foundation (NSF) that data be produced on NSF-funded projects, their requests for data were ignored, denied, or otherwise frustrated in a substantial number of cases.

Another study, published in the *Journal of the American Medical Association*, gave a paper with eight deliberate errors to 420 people to review. For the 221 reviewers that responded, the maximum number of errors detected was five, the median was two, and 16 percent of the respondents did not find any.

Those findings cast doubt on the peer-review process, even for academic purposes. It is noteworthy that an increasing number of the most prestigious journals, such as *Nature,* the *American Economic Review*, and *Science,* now require data availability to editors and members of the scientific community as a condition for publication. Other journals, such as *Cell*, require that data be made available for scientific scrutiny when there are disputes.

Even if the peer-review process were adequate for academic purposes, however, it is frequently not adequate for major public policy decisions, such as those involved in regulation. Requiring that data be made available before passage of a regulation offers important benefits for regulatory decision making. First, such a requirement could improve the quality of information by exposing it to widespread comment, thus leading to better decisions. If the findings of researchers were shown to be false or misleading before the development of a costly environmental regulation, such as one addressing particulate matter or toxic substances in the air, then that regulation could be withdrawn or revised. Second, public access to data ensures greater transparency, which lends legitimacy to the regulatory process. Transparency is a valuable aspect of public decision making in a democracy.

If all regulations were good for society at large, there would be little need for concern. Research suggests, however, that more than half of the federal government's regulations would fail a strict benefit-cost test based on the government's own numbers, even though total benefits are positive. Reanalysis of government regulations, programs, and supporting data frequently reveals

that the initial analysis contains major problems that correcting those deficiencies yields substantially different policy conclusions. For example, a researcher argued that modifying some standards for lead that the EPA recently proposed could increase net benefits by more than $20 billion. Ample research shows that regulation could be significantly improved, so that more lives could be saved with fewer resources. One study found that a reallocation of mandated expenditures toward those regulations with the highest payoff to society could save as many as 60,000 more lives a year at no additional cost.

To help weed out potentially bad regulations, it is important to have key data available in a timely manner, so that policies can be analyzed carefully before they are put in place. Once a regulation is passed, it becomes more difficult to modify because constituencies grow in support of the regulation, both inside and outside government. That is true for bad regulations as well as good ones, because some constituency invariably benefits from a regulation and thus will defend it.

3. Policy Recommendations

Because of the potential for improving public policy decisions by allowing public access to data, the government needs to develop a policy that carefully weighs the costs and benefits of the proposed rule. The costs include potentially adverse impacts on research, data development, and industry-university-researcher partnerships that help commercialize technology. Although those costs are important, the social benefits of increased public access to data under specified conditions could also be substantial. They include better public policies and increased transparency and accountability.

I believe that the Shelby provision, which would have allowed access to any publicly supported data subject only to the restrictions of the Freedom of Information Act, is too broad. My analysis suggests, however, that academic norms alone provide very limited access to scientific data. The bottom line is that greater access to data is needed to enhance accountability and to improve the decision making process. Here are five recommendations that I think would improve the process.

Recommendation 1: The data-access requirements should be restricted to economically significant regulations developed by all regulatory agencies.

Targeting economically significant regulations is likely to yield the greatest economic gains for society. A reasonable cutoff point, currently used by federal regulatory agencies, is to allow

access to data that affect regulations with an annual economic impact of at least $100 million.

Recommendation 2: The data-access requirements should be limited to new federally funded grants and agreements.

The government should abide by the terms of existing grants and agreements with researchers or at least should not impose major additional costs on researchers without compensation. The terms of new federally funded grants and agreements that fall under the new regulation should be restricted to data used in published research in refereed journals that are directly related to the grant.

Recommendation 3: The researcher should be required to provide as full a rendering of the data set as possible.

A natural tendency in some research fields is to report the results that are statistically significant or that will increase the chances for publication, even if they tell only part of the story.

Recommendation 4: The new rule about data access, if implemented, should be evaluated after five years by an expert panel selected by the National Academy of Sciences.

The panel should include individuals who can evaluate the economic, social, and scientific impacts of the regulation. The panel should offer recommendations for improving the regulation, if needed.

Recommendation 5: Congress should create an agency to replicate findings for economically significant regulations that have an annual economic impact of at least $100 million. Government should be allowed to use those research findings in developing regulations only after the agency has certified that the results have been independently replicated.

Replication is a key to ensuring the quality of results. Replication should require a finding by the newly created agency that the data support the basic conclusions drawn from the data. The replication exercise could be defined narrowly in terms of reproducing the results of the initial research or policy analysis. I would prefer to define the replication exercise a little more broadly, although that could make it harder to define the conditions under which the data actually support the

results.

The requirement for replication before promulgation of the regulation is critical. Because of the difficulty attached to changing a poor regulation once it is already in place, the benefits of such replication for improving regulation are likely to be large.

4. Should We Provide Greater Public Access to Data?

The concerns about greater public access to data raised by Congress deserve a serious response. We now have the opportunity to lay the foundation for a regulatory system that is more accountable and has more scientific integrity.

H.R. 88 supports the old status quo, which provides very limited public access to data from federally funded research. The Walsh-Price amendment recognizes a need for improving public access to data but would result in unnecessary delay. I believe that some of the concerns raised by the amendment are legitimate, but I also believe that they can be effectively addressed now.

The OMB and Congress are in a position to develop a sensible rule for promoting public access that is based on the strengths of the Shelby provision. The basic approach that I have advocated is to proceed *incrementally*. Because I believe that the biggest potential gains to society lie in providing the public with greater access to major regulatory decisions, I have suggested that the OMB rule target proposed regulations that could have substantial economic impacts. As scholars develop a better understanding of the effects of providing greater openness to selected data, policymakers will be in a better position to determine whether and how to extend the scope of public access.

Related Readings

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Mr. HORN. I now yield 5 minutes to the gentleman from Mr. California, Mr. Ose, to begin the questioning.

Mr. OSE. Thank you, Mr. Chairman. I have but a few questions. I want to make sure I understand, Congressman Holt, you support H.R. 88?

Mr. HOLT. Yes. I'm a cosponsor.

Mr. OSE. Mr. Miller, you oppose it.

Mr. MILLER. I oppose it.

Mr. HORN. I might tell the gentleman that the way we have set up the panels is it goes supportive, oppose.

Mr. OSE. Well, I got Dr. Varmus; I understand he supported. I'm sorry, but with Mr. O'Reilly and Mr. Alberts, I didn't quite understand.

Mr. ALBERTS. Speaking for myself, Alberts, we support H.R. 88, with the idea that Congressmen do something in a more thorough fashion to meet what I see is a problem. But we have the wrong solution.

Mr. O'REILLY. Individually, as a scholar I oppose it, not for any institution but for myself.

Mr. OSE. That was the substance of my questioning. Thank you, Mr. Chairman.

Mr. HORN. OK. We have one question on this side? OK. The vice chairwoman of the committee, Mrs. Biggert of Illinois.

Mrs. BIGGERT. Thank you, Mr. Chairman. Not having been through this and having been here for very long, I hope that I understand what's going on. But some of the things that I've heard—let's take for an example a study or research project on a health issue, and a study is being conducted and it has to be—the data has to be given out. And let's say we have a study where there are two groups of individuals, one is the placebo, and then the other group that's receiving the medicine.

Now, could the individual go by the Freedom of Information Act and receive a list of those that are participating in the study and whether they are receiving the placebo and whether they are receiving the proposed medicine?

Mr. O'Reilly.

Mr. O'REILLY. The answer is no. The citation is in the Food and Drug Administration's regulations at 21 CFR 20.63 and 20.—I think it's 113. They specifically cover that and say that the individual names, identifications and the like, in clinical studies subject to the Food and Drug Administration's powers for drugs, vaccines, and medical devices are not disclosable.

Mr. VARMUS. Could I comment on that? Mr. O'Reilly is much more familiar with the details of FOIA than I am; however, there are some important things that I think were not included in his answer. First of all, our complaint is not that there shouldn't be access to data. Our concern is the use of FOIA in obtaining that data. We have other ways to ensure that a study of the kind you described is exposed so everyone can see what the grounds are for recommending that a drug should or should not be used.

We're concerned that in a request for data of that kind through FOIA, the university scientists, for example, who did the study under an NIH grant, would have to supply unredacted information to the agency, where the redaction would occur.

That by itself does a couple of things. First of all, it changes the delicate balance between nonprofit investigators in the academic sector and the government agency. In a sense, it turns the whole enterprise into a government agency. It means that the information comes to the NIH, where we have to count on accurate redaction, which may or may not occur, because information in a computer age may not be so easily manipulated to remove all personal indicators. The very fact that the information comes centrally, in my view, will cast a pall on the public's attitude toward participation in clinical trials, because that information is going to be traveling centrally. The possible reduction in our ability to attract people into those studies and to attract investigators to work on studies supported in that way might actually have the effect of driving more and more such research into the private sector where FOIA wouldn't apply.

Thank you.

Mrs. BIGGERT. Well, I know that the Freedom of Information Act is always thought of as sacrosanct. And even in school boards or public bodies, we're always, you know, very concerned. That is a good reason. But why—what is the compelling reason, then, that this information and the data should be given before it's published by the researchers?

Mr. MILLER. It's not.

Mr. O'REILLY. Referring to the OMB proposal, it was published research, ma'am.

Mrs. BIGGERT. But published means after—I think that Mr. Hahn said something about that they had taken the studies then and tried to do that, and there was something about peer pressure or peer review hadn't been done yet before this data was published.

Mr. ALBERTS. That was me.

Mr. HAHN. Well, two points. One is, as Mr. Miller said, the OMB regulation applies after a publication so you would only have to share it after your first publication. The point I was making about peer review was that while it's a useful process for helping to ensure quality, it has some serious defects. And when we're spending—or we're asking companies and individuals to spend billions of dollars on regulation, we may want to apply a higher quality standard than is typically applied in the peer review process.

Mr. HORN. Dr. Alberts.

Mr. ALBERTS. Let me just be clear, the Shelby amendment says nothing about publication. The OMB draft regulations bring in publication as a contributing element. My legal counsel sitting behind me, who would be happy to talk about this, does not think that the OMB regulations will stand up in court. It will certainly be challenged. So I think it's unwise of Congress to rely on the OMB interpretation of a law that says something different than what OMB in trying to improve the law has put in their regulations.

Mr. HORN. Mr. Miller.

Mr. MILLER. Mr. Chairman and Congresswoman, let me followup on what Dr. Hahn was saying. The flagship journal of economics, a profession we both share—is the American Economic Review. And it contains a policy admonition to its authors that says, it's in my testimony, "It is the policy of the American Economic Review

to publish papers only if the data used and the analyses are clearly and precisely documented and are readily available to any researcher for purposes of replication.''

I know from personal experience, the American Economic Review is peer reviewed. I have published twice in that journal in my career, and I can tell you my pieces were peer reviewed. But the journal, in addition to having peer review, requires that the data be made available.

Let me just suggest if there is a question, Mr. Chairman, members, of whether it's published data, then maybe you can clarify that. But I would not repeal the Shelby language. Modify it, perhaps.

Mr. Hahn has some suggestions that personally I could live, though they would not necessarily be my choices, but if there are problems of that sort, it would seem to me appropriate to identify those problems and direct legislation to those, rather than repealing language when requiring published data, when data is—when reports are published and agencies act on those reports for policymaking or rulemaking purposes, the underlying data be made available.

Mr. HORN. Dr. Varmus.

Mr. VARMUS. I'm concerned that we're pursuing a red herring here with respect to peer review. We all know that peer review is important. But also clearly fallible. The scientific community feels very strongly about replication in research. It is one of the credos of the way in which we operate. We all subscribe to that. The issue here is not whether peer review is a good thing; the issue is the proper way to gain access to data and to facilitate replication of studies to establish the truth. Our concern is that the scientific enterprise in this country, an incredibly productive, flourishing pillar of our society, is not served well by the Shelby amendment.

Mrs. BIGGERT. Thank you, Mr. Chairman.

Mr. HORN. The gentleman from Wisconsin, Mr. Ryan, 5 minutes for questioning.

Mr. RYAN. Thank you, Mr. Chairman.

Dr. Alberts, I would like to just start with a couple questions for you. My staff has showed me one or more of your later reports from the National Research Council, which is an arm of the National Academy of Sciences. It's a report of 1985, entitled, ''Sharing Research Data.'' and that included the following recommendation from this report: that data relevant to public policy should be shared as quickly and as widely as possible.

I notice that a later 1997 National Research Council report, entitled, ''Bits of Power Issues in Global Access to Scientific Data,'' recommended that, ''data derived from publicly funded research are made available with as few restrictions as possible on a non-discriminatory basis for no more than the cost of reproduction and distribution.''

All right. Given this track record and given this clear position of the NAS on this issue, what steps has the NAS taken since 1985 to seek implementation of this type of policy? For instance, during this period has the NAS submitted principles to Congress, a plan for revealing this type of data on a timely basis, as was recommended in these reports? And up until the passage of this law,

I'm concerned that we haven't seen much follow-through on this policy.

Mr. ALBERTS. I will provide to you a letter that I wrote with the other two presidents of our organization, the president of the Institute of Medicine and the president of the National Academy of Engineering, I believe was 8 months ago, was sent to all scientific societies, widely distributed, expressing our worry that the openness that we all want is not adequately being provided for now and encouraging the scientific societies to take this very seriously.

So, you know, we can't—through legislation we can only argue morally. My testimony also includes a quote from a major booklet we produce, called "On Being a Scientist." It's being distributed in all graduate schools. It's used as a basis of teaching the practice of science, the ethics of science to young scientists, and it explicitly talks about the obligation and importance of scientists sharing data. So we don't make legislation. We try to get our colleagues to behave in the ways that we think is best for science. And I will be happy to provide you after this session with some of these letters and publications.

Mr. RYAN. Dr. Hahn, I notice that comment got a little bit of a rise out of you. Would you care to comment?

Mr. HAHN. It's great to ask scientists to do things, but when it's not in their immediate self-interest to do them, you're not going to get a lot of them to change their behavior. I think it is a fundamental problem in science. In spite of the fact that we have this norm or ethic of data sharing, there is not enough of it. What I have argued is that when we're developing public policies where billions of dollars are at stake, you deserve access to data that's been validated.

Mr. ALBERTS. Let me say I do not disagree with Mr. Hahn's testimony. I think that in these cases we have an obligation to do more. And I think Congress has a role to play here. I just think Congress needs to think carefully about how to do it so it keeps the best aspects of the scientific enterprise, along with what you're trying to accomplish, which is making sure that you have access to the data you need.

Mr. RYAN. Let me ask you this, Dr. Alberts. Given that FOIA currently applies to all research conducted by the Federal Government and other sensitive personal information is already protected under FOIA, we got 30 years of case law supporting privacy of rights and those type of concerns, do you believe that, you know, given the NAS publicly declared policy dating back to 1995, do you believe that the research community needs separate and distinctly different protections, such—different from those that the Federal Government currently has—or do you think that this is sort of a double standard opposing data access when the Federal Government direct research is already subject to these types of scrutinies and given the fact that the NAS since 1985 has, you know, quote, endorsed the fact that data relevant to public policy should be shared as quickly and as widely as possible?

Mr. ALBERTS. Of course we're talking about data that is in the public domain because things have been published. The Shelby amendment does not talk about published or unpublished informa-

tion, so by implication it covers all data, whether or not you have had a chance to publish it.

As I said, the OMB draft regulations tried to fix that. But I don't think that's going to stand up in court. It will certainly be challenged. So we were not talking—and anything the Academy has put out about making data available to the public before you've had a chance to analyze it, we all know—we all grew up with this little thing about the little red hen who was growing the wheat, making the flour and then making the bread and, you know, we all believe that people should profit from their very hard efforts and have a chance to use their own ingenuity to interpret their own data without having the obligation of making that public before they've had a chance to do so.

And so I want to be very clear about the fact that we would support journal policies like that. We've heard, we all want journals to require of their people who publish in their journals, access to data as the Economics Journal does, as Nature and Science does, it's the kind of things we like. It's quite different than saying your data should be available at any time, even when you haven't had a chance to publish your results.

Mr. RYAN. Rush, I notice you had your hand up there.

Mr. HOLT. Yes. As someone who is developing an expertise in the difference between science and politics, I would like to point out that the Freedom of Information Act is intended to ensure political openness. It is a very different tool. You ask, Do we need different procedures? And I would say, indeed, yes. And I see here a real assault on the scientific progress. You know, if Dr. Alberts hadn't mentioned it, I would have mentioned the National Academy's publication which was distributed to all societies, all universities, to get to all graduate students. It actually has been quite an effective piece.

Indeed, young scientists and all practicing scientists do have a real motivation toward openness. They must abide by the general rules of publication and subjecting themselves to criticism, or their work to criticism, and to replication in order to continue. So there is a very strong motivation there. The problem is we end up—well, we're going off perhaps in a red herring in publish, because the Shelby amendment that we're talking about here doesn't talk about that. But even as implemented, we end up with real questions about at what stage is it published, what are the data, when are the data preliminary? Which parts of the data, of commingled data, are preliminary? Which parts of the data are publicly funded?

So I think—and furthermore the FOIA exemption to protect—going back to what Mrs. Biggert was talking about, she was concerned about protection of privacy and protection of individual information.

Mr. RYAN. Let me——

Mr. HOLT. FOIA's exemption is limited, but it does not protect communities and institutions. It would allow some, let's call it reverse engineering, that really could compromise personal privacy.

Mr. RYAN. Let's put this in a little bit broader perspective. Let me ask you this question. Does it bother you—now, I understand your background, but now that we are here as public stewards and that we have in essence about $700 billion a year through regula-

tions that are imposed on our citizens, our constituents, does it bother you that at any level of government, often issues based on scientific data have not been reviewed by the government even before they're implemented, let alone by public and other scientists?

For instance—and I have to just go back to one of the cases we've been talking about quite a bit, the ozone 2.5 the PM, particulate matter standard. It's my understanding is that the EPA could not even obtain the data for review. Does this make sense? If no one else can see the data, what kind of checks and balances exists if there is a mistake in the date and the data collection?

And going back to the peer review point, isn't it true that most peer reviewers do not actually review the raw data and that they don't replicate the study?

Mr. HOLT. Well I don't know about the ozone data you're talking about. I'm not sure how it was published. Certainly in making public policy, we should rely on tested, accepted, scientific evidence, you know. But the emphasis has to be on data available for replication of the experiment, not data available for exposure of the people involved for exposure, including the scientists involved. It's—the whole point is to maintain the scientific process here. And that's what I think is threatened.

Mr. RYAN. If I could, just 1 second, Mr. Miller. I noticed that that caused a rise out of you as well. But I guess what it really comes down to are we going to seek the truth in formulating laws and public policy that affect the very lives of everyone we represent? And that's really what it's coming down to. These are valid concerns, but sometimes these concerns seems like they're going overboard and they're actually contradictory with what the scientific community really seeks to achieve. But I notice, you know, Mr. Miller you had something you wanted to say.

Mr. MILLER. Mr. Ryan, I want to make two points. First, in response to your comment on regulation, I have experienced both on the regulatory budget side and on the fiscal side. We really have two kinds of budgets here, two kinds of Federal expenditures: those that are accommodated through direct outlays, and those that are accommodated through impressing people in the private sector to do things differently than they would have done otherwise. And the second is the regulatory budget side.

In my judgment there is far more accountability and evidence on the fiscal side than there is on the regulatory side. If anything, you want to increase the accountability on the regulatory side. H.R. 88 would reduce accountability on the regulatory side.

Then, second, an anecdote. One of the articles I published in the American Economic Review was coauthored with George Douglas. It was based on a book published by the venerable Brookings Institution. At both the AER and at Brookings, we went through extensive review, peer review. Yet, when the Civil Aeronautics Board in its assessment of the effects of airline regulation replicated our study, they found some mistakes. Nothing critical, but they found some mistakes.

Mr. HORN. I will have to intervene at this point because we have a vote on the floor. We'll take a 20-minute recess now and get back to the questioning, because I haven't spoken yet and Mr. Turner, the ranking member has not been here yet. So please come back.

[Recess.]

Mr. HORN. The subcommittee will come to order. We were in the middle of questioning the various members, and we now have the ranking member returning from the Committee on Agriculture. Did you win that battle or didn't you——

Mr. TURNER. We made progress.

Mr. HORN. OK. Mr. Turner from Texas will question the witnesses; 5 minutes.

Mr. TURNER. Thank you, Mr. Chairman. One concern that I have about the Shelby amendment is the fact that it only applies to nonprofits, hospitals, et cetera.

I might ask you, Mr. O'Reilly, what do you think about the wisdom of that narrow application of the amendment?

Mr. O'REILLY. It is quite appropriate since Federal contractors have already been subject to a number of FOIA lawsuits and case decisions. Grantees have been protected since Forsham in 1980, but contractor data is extensively requested and extensively disclosed in current FOIA procedure, the most recent case being June 25 in the D.C. Circuit. McDonnell Douglas was the contractor, NASA was the agency, and NASA made a decision to disclose the contractor's data regarding a space or missile project. There the commercial confidentiality interests of McDonnell were not adequately considered by NASA, and Judge Silverman for the panel held strictly to the protection of that data of the contractor, and NASA was ordered to rethink its disclosure. The contractors have for years been involved in disputes, particularly about pricing and unit pricing. It is a very arcane area called "Reverse Freedom of Information Act" cases.

The short answer to your question is, yes, grantees have not been covered until Shelby, so Shelby fits a narrow niche which previously had been exempt from the definition of an agency record that now will be covered.

Mr. TURNER. What about State and local government research that would be federally funded? They would not be subject to the same disclosure requirements, would it?

Mr. O'REILLY. I'm sorry. What would you think of the State——

Mr. TURNER. A grant from the Federal Government to a State government would not be subject to the same disclosure as required by Shelby for nonprofit groups.

Mr. O'REILLY. That is really an area—the reason that I am hesitant is there are 50 different State laws. I believe six of the States specifically talk about this in their State laws. Some of the States are well ahead of the Federal Government requiring government-funded research to be disclosed. If I were to generalize, I would say in most States because the State is not subject to the definitions in Shelby, as I understand them, the State doing the research would not be covered unless it was covered by a State law.

Mr. HORN. Excuse me, if I might.

Suppose there was Federal money involved with the State? In 1954, I did a study for the National Science Foundation with several colleagues on State-conducted research. It was amazing what California had in the department of health. Les Breslow—a lot of you will remember him—one of the great public health officials, and Earl Warren would simply buy people off from the Federal

Government, pay them a better salary and bring them to the sunshine. So there was a lot of research going on.

Wouldn't that really follow then that the FOIA would go on if there was a Federal grant, or would it?

Mr. O'REILLY. I would have to do a more specific analysis. This is one of those aspects of Shelby that, as you see, the OMB is struggling with at the moment. The short answer is, I don't know, but the California Open Records Act would probably not reach it, so Shelby might.

Dr. VARMUS. I am concerned about one comment that Mr. O'Reilly made that would suggest that we are making a narrow cut—addressing a very narrow issue. It would seem to me the opposite is true.

On the one hand, we all agree that the government should have—and the Congress should have—its best shot at evaluating the scientific data on which it is going to base regulatory changes that have major economic impact. But, in fact, the NIH alone has 30,000 grants. NIH-supported investigators are doing a variety of things with additional support from the States, support from industry, support from other governments, support from private philanthropies. All of that comes under the risk of possibly threatening, possibly irrelevant FOIA requests that are not addressed to the core issue. That is why we feel strongly that we should go back to ground zero.

We should start to address the problem in a more rational way and ask what it is we are trying to solve rather than use the very broad powers that we see embedded in A–110. We recognize that OMB is attempting to narrow those powers. We also recognize there is a very strong likelihood that that restriction is going to be subject to court challenge.

Mr. O'REILLY. I would like to subsequently write to the subcommittee giving a more detailed response to your question. It is a good question.

[The information referred to follows:]

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July 17, 1999

Hon. Stephen Horn
Chair, Subcomm. On Govt. Management
House Comm. On Govt. Reform
2157 Rayburn House Office Building
Washington DC 20515-6143

Re: H.R. 88 Hearings, July 15

Dear Mr. Chairman:

Thank you for the opportunity to testify Thursday at your hearing on Data Available Under the Freedom of Information Act (H.R. 88).

I enclose a supplemental statement of questions asked by the members, and of some from other panelists' testimony, and I request that these be included in the record.

My compliments to your staff, particularly Matthew Ebert, for such a substantive and well-balanced dialogue on this important topic. As stated at the hearing the views are my own and not necessarily those of any institution.

Cordially,

James T. O'Reilly
Visiting Professor of Law

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An affirmative action/equal opportunity institution

RESPONSES TO MEMBERS' QUESTIONS IN THE JULY 15 HEARINGS RE H.R. 88 AND SHELBY AMENDMENT

PROF. JAMES O'REILLY[1]

Does the Shelby Amendment impose on nonprofits any different federal agency access requirements than they now face?
No. Standard administrative conditions in grants include rights of agency access to the data generated by the grantee. Congress' use of A-110 which has long set the norms for such grants ties in to that existing right of agency access. What is different is that most of the time agencies have not invoked these rights. Now, a FOIA requester can ask the agency to access and process that data and the agency FOIA staff will respond with review of the data and will withhold the portions that are exempt under FOIA, while disclosing the remainder.

Could Congress do this by specific statutory language?
Yes, the 1998-enacted delegation to OMB, an existing expert agency, to make rules by modifying coverage of its existing vehicle (Circular A-110), could be replaced by a specific statutory system that supersedes A-110 and replaces the OMB rulemaking process with defined statutory terms. Under the Presentment Clause of the Constitution, both Houses would have to adopt their bills and the President would have to sign them. The last time Congress added a substantive exemption to FOIA was 1976 with the expansion of exemption (3)(B).

Does Shelby Amendment coverage apply to States as grantees?
It *could* if OMB so decides, because the term "award" is open-ended. However, the format of the amendment is not self-executing, but delegates authority to OMB in its authority to revise Circular A-110, so OMB could take into account the legislative history which was directed to nonprofit grantee institutions. OMB's construction of the legislative meaning to exclude a state grant from the term "award" would be likely to be upheld under the Chevron deference doctrine as well as the longstanding deference of courts to federal contracting rules of OMB, GAO, etc.

Are records generated by federal contractors subject to FOIA?
Yes, about a dozen court cases have involved the contractor's claim of confidentiality for details of its performance and pricing when these have been requested from agencies. A

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[1] Views expressed are personal and not necessarily those of the University of Cincinnati or other institutions.

distinction is that contractors are far more likely to be asked for their "data produced under an award" than grantees have been asked, prior to the Shelby Amendment.

Is the Shelby Amendment "poorly drafted and vague"?
Perhaps, but it is no more so than many other delegations with weightier consequences. The fact is that Congress often delegates its power by directives to expert agencies. The 1974 Privacy Act is an example of an equally obscure set of definitions that caused courts to wrestle with interpretations for years, in some cases overruling the delegated agency (OMB) in interpreting that legislative language. By the process of delegating vague terms, with a very specific vehicle (A-110), the onus falls on the expert agency to follow the intent of Congress.

Will it cost agencies more?
With reimbursement of costs by the requester mandated in clause 2 of Shelby, and with reimbursement systems already provided in FOIA, 5 U.S.C. 552(a)(4)(A)(i), this should not be a significant additional cost in the long term; in the near term, grant-issuing agencies will need additional temporary processing staff. As to costs at nonprofits, Dr. Shelton testified that institutions collect as much as 26% of the value of the grant for their administrative "overhead". Clause 2 of the Shelby Amendment says that the agency "may authorize a reasonable user fee" which presumably will be paid to cover the institution's costs that are "incremental" to its existing contract obligation to deliver the data as agreed at the time it signed the grant documents.

Will community development block grants be affected?
In my experience working with federal funding issues for our city infrastructure commission, the CDBGs were typically used for a physical object such as a building or tangible improvement. The CDBG did not generate research data or documents about science or technology. The new OMB rules amending A-110 will define what is "data produced under an award" and this might be discussed there.

What will happen with drug testing privacy for patients?
No change occurs. Nothing is different than now happens with testing data submitted by drug developers under new drug applications or federal contracts. Identities and identifying details ("reverse-engineering") are withheld under 21 C.F.R. 20.63 and 21.71(c) at FDA and corresponding rules of other agencies.

Further responses to questions raised by the panel discussion:

Why has the Shelby Amendment drawn such criticism?
It's "fear of the unknown" by a spectrum of grantees who never before have been subjected to full public scrutiny of the publicly funded work they do. This fear can be overcome by understanding the FOIA process that any requests for the contract

researchers' records will follow, as well as by viewing the work agencies already do in screening out medical and other privacy records, and shielding proprietary documents. The system works; and the Shelby Amendment actually enhances public accountability of the processes that spend federal funds on research.

What harm did the Shelby Amendment address?
"Secret" government - including secrecy among the data that government pays to have generated - diminishes the openness, legitimacy and accountability of agency decisions. In practice, agencies have long had the power to call for this set of data but they did not do so, and the prior law did not require them to make this data part of an agency file

Is disclosure of valuable intellectual property likely?
Not if the existing structure of data protection works as it has in the past. Adding a record to the existing availability of millions of records under the FOIA process does not mean the record is going to be automatically disclosed. The existing structure for processing requests for disclosure has worked fairly well. Agency FOIA officers have shown their sensitivity to medical and personal privacy issues that has made FOIA access, in recent years, remarkably free of errors that would jeopardize private medical data.

Is Shelby a revolutionary change to data ownership?
No. It ties in existing A-110, existing exemptions, and existing cost reimbursement provisions. Evolutionary changes have been made by the Amendment. Adding to the existing FOIA processing system, the data that was paid for by federal dollars and prepared by nonprofit institutions, is not revolutionary, but evolutionary. Grantees already sign contracts providing for federal agency access to the work product paid for by the government. This means the agencies will exercise access rights more often, will bring in the data, and will screen it carefully.

What of nonprofit grantees' for-profit research efforts?
A nonprofit group that generates data can also ask that agency FOIA officers protect their ability to gain future private commercial advantages, to the extent that these persons are allowed to use federal funds to develop knowledge which they then sell to future customers.

What about threatened loss of licensing income to universities?
No change occurs. If the university hopes to license a product it developed with federal funds, its claim to justify withholding by the agency FOIA staff will be just as well received as claims by the regulated companies for commercial confidentiality protections.

Is this too burdensome?
No. Justifying the secrecy of a commercially valuable technology is not difficult in the FOIA process. Technology developers' voluntary submissions are exempt and will not be disclosed if the institution "customarily" does not disclose them. For those required to be submitted, the researcher will tell the agency FOIA staff what part of the documents is either commercially valued data or personal/medical privacy data.

Just what research will remain confidential?
A grantee's submission of research data that is requested will remain undisclosed if the grantee shows the agency that its data affects some actual competition, such as to develop a new vaccine; and that substantial (not theoretical or trivial) harm would result from this premature disclosure. This is not an excessive barrier - especially since commercial firms and all federal commercial contractors already have the same set of burdens and responsibilities. The June 25, 1999 D.C. Circuit decision in McDonnell-Douglas Corp. v NASA, 1999 Westlaw 420463 (D.C. Cir., June 25, 1999), again shows that courts will protect intellectual property rights of the recipients of federal funds, where an appropriate competitive interest exists.

Can agencies handle this data?
Yes, the Department of Health & Human Services, the FDA, FBI, CIA, EPA and other agencies all have well developed FOIA criteria and trained staffs. The federal agencies have not been derelict in protecting medical and other highly personal data about individuals. In the time period between enactment and full implementation of the reimbursement of costs provision in the Amendment, some temporary funding for FOIA staffs may be needed at a few federal agencies.

What if the grantee and the agency disagree?
On June 25, the federal appeals court in Washington confirmed rights of submitters to be protected from arbitrary agency denials of confidential commercial status [McDonnell Douglas Corp. v NASA, 1999 Westlaw 420463 (D.C. Cir., June 25, 1999)]. If it would be to the advantage of a commercial firm to get the grantee's research data, the grantee's licensing interests would be harmed and exempt status can be claimed. Though that case involved prices of federal contractors' components, courts here and in prior decisions like the Supreme Court Chrysler v Brown case in 1979 have told agencies to be careful in handling valuable submissions.

What about patent rights?
These are unaffected because the research data can be claimed confidential and withheld under FOIA before the patent is issued. Some nonprofits aspire to use federal money for the equivalent of a private product development effort. It is quite predictable that a federal agency's grantee will ask the agency not to

a request for access to the device's test results is received. Under Shelby as with all other FOIA contexts, the agency FOIA office will routinely withhold the portions of the report that are marked as proprietary commercial data for which the researcher claims (prior to patent issuance) a need for treatment as confidential data, to avoid competing device firms' preempting the patent status of that device. Shelby makes no net difference, so long as there's a confidential commercial situation in which the product or design is "competing" for competitive advantage.

Do FOIA exemptions hurt proprietary rights?
No, agency FOIA officers have closely followed Exec. Order 12,600 which establishes the process for marking and notification prior to any disclosure of commercially sensitive records. Voluntary submissions of valuable data that are "customarily" withheld from the public remain confidential and mandatory submissions can be protected if there is a showing of actual competition, and the potential exists for substantial harm, e.g. by premature dissemination while a patent is pending. These situations vary greatly, but it's useful to note that agency FOIA officers handle commercial confidential data daily under adequate procedures, and that none of the academic witnesses called FOIA protection for commercial data inadequate when extensive testimony was heard on FOIA revisions in 1996 [Pub.L. 104-231].

Does the Shelby Amendment add costs on to researchers?
No, when FOIA requests are received, their processing costs are borne by the agency and then costs of search and screening are charged to the requester. The second clause of the Shelby Amendment will have agencies passing their costs along to the requester, and possibly the costs of the nonprofit as well. Delivery of data under contract is already a "cost" of being a government contractor. The same researchers who do work for industry, e.g. drug developers, already expect agency FOIA staffs to properly process FOIA requests for access. Marking "proprietary" portions of records for which patents will be filed is simple and routinely done.

Does FOIA damage public/private research partnerships?
No, identical FOIA exemptions apply just as if the privately paid research were being examined by FDA, EPA, or other regulators who see reams of industry research submissions daily. The identical process is followed whether the request was made pre- or post-Shelby Amendment.

Does FOIA protect research done by entities that are nonprofit?
Yes, FOIA's exemption for commercial data is available where the nonprofit has an actual competitive position with an invention that could be licensed, a patent pending, etc., so long as there's some proprietary advantage to be protected. The same FOIA officers at agencies who handle commercial submissions will apply the same criteria for preserving confidential status.

Will researchers be harassed in their ongoing work?
It's unlikely that Shelby will change current methods of scientific accountability. OMB has proposed to limit access to published work; publication presumably carries both peer review critiques and responsive letters critical of the author's research. The scientific research review process in published literature and in the federal courts since the Daubert evidence-screening decision are not likely to be affected by FOIA applicability. Publication may draw criticism but the marginal additional scope of external access to data (comparing current system with peer reviewers' access to data versus post-Shelby access to data) is not a basis for undue concern. Note, of course, that the same data generated inside an agency or bought by the agency from its contractor is subject to being disclosed today under FOIA if it is not exempt from disclosure.

Mr. O'REILLY. I also want to point out that in Texas the governmental body owns the information or has a right of access to it. It becomes a public record under 552–002, Texas statute. So Texas is even broader than California's Open Records Act.

Mr. HORN. I just thought that I would round it out, 5 minutes to Mr. Turner so that he can complete the questioning.

Mr. TURNER. So, Mr. O'Reilly, I take it that you are saying that you don't see any problems whatsoever with the Shelby language, that is even to the extent of the vagueness of the use of the words "all data" and "work produced" and those kinds of things that some have expressed concern about?

Mr. O'REILLY. I would not grade this well if this were a law school exam paper. The wording has to be sharper, and ideally one would have had much longer statutory language and a much more detailed statutory exercise.

Mr. TURNER. You expressed the opinion earlier that any legitimate concern from the research community could be addressed by specific exemption. I guess—first of all, do you think there is a legitimate concern being expressed here from the research community, and if so, how do you think that could be addressed by a specific exemption?

Mr. O'REILLY. Yes, it is legitimate for those who have never been familiar with or affected by the Freedom of Information Act to be concerned about it. I would respond to them, with education, to say that the infrastructure is in place, the exemptions are there and the system works and it is a model around the world. So it is OK to feel worried about it; but in fact, the more you look at it, the system will work.

If there is a specific research problem, perhaps something involving the joint—we heard this morning about public-private partnerships. If there is something in that area, then I certainly support what is called a B3 exemption statute, a statute specific to these joint university and private research projects. That kind of a narrow statute would be quite adequate in dealing with this problem.

Mr. TURNER. Do you think there is any legitimacy to the complaints that some have levied against the use of the Freedom of Information Act just as a means of discovery in lieu of a lawsuit and the discovery procedures there, but using that act for those purposes?

Mr. O'REILLY. I have got about 40 pages in the book on that topic so I will spare you that detail. Yes, discovery can be augmented by the Freedom of Information Act. No, the exemptions are a better protection for the public than are discovery exceptions. Rule 26 and the other exceptions from discovery in the Federal Rules of Civil Procedure give more access to data for specific litigants under protective orders than they would get from the Freedom of Information request.

Mr. TURNER. I have been told that there was a situation in Georgia where a cigarette manufacturer used the State Freedom of Information Act to get the names of children involved in a research study which looked at whether Joe Camel cigarette advertisements were directed to children.

Is that a legitimate use of the Freedom of Information Act or is that a misuse of it?

Mr. O'REILLY. If it were, in fact, disclosed, it would be a misuse.

Mr. MILLER. A violation.

Mr. O'REILLY. It would probably go beyond the terms of Georgia Open Records Act. I would point out that Georgia is in the 11th Circuit and that is where the Farnsworth decision that held that the names of individual women in a medical research study done by the Centers for Disease Control had to be protected so they could not be disaggregated. At least in the Federal Freedom of Information Act and the Federal discovery rules, there is adequate protection.

Mr. TURNER. Mr. Holt suggested, I understand while I was gone, and made the comment that seemed to me to suggest that the Freedom of Information Act originally started out trying to be sure that those of us in public office and those of us who hold administrative positions did not withhold information that rightfully belonged to the public, but that when we look at independent scientific research, there are some other interests that should be protected.

Do you agree with that?

Mr. O'REILLY. There are adequate protections for those interests. I would point out that the Congress, in 1996, amended the purpose of the Freedom of Information Act so that the purpose language is now allowing any private reason for access. It amended the section of the act which said that the purpose of the Freedom of Information Act is to allow public access for the public review of what government was doing and now it is, "for any purpose." So the Congress has amended the act's purposes.

Specific to your question, it is very, very concerning to any medical research patient that your information, your specific information might be released. I, as a person subject to government, I would be concerned about it. But the answer is (b)(6), the Freedom of Information Act exemption, has worked very well in agencies around the government and is an adequate protection.

Mr. TURNER. Correct me if I am wrong, but I understand that the exemption with regard to disclosure of medical files, which says that disclosure is not required if the disclosure would clearly constitute unwarranted invasion of personal privacy, that that exemption is merely permissive with the agency rather than a required exemption.

Am I correct on that?

Mr. O'REILLY. On its face, you are correct. But it is tied in and has been tied in by the courts to 552a, the Privacy Act. The Privacy Act protects those documents and systems of records withheld by the agency. The agency loses its discretion about those personal and medical records that are kept in what is called a "system of records" under the Privacy Act.

Mr. TURNER. You mentioned that you thought there were other requirements of disclosure that applied to private contractors as opposed to nonprofit groups and hospitals. Give me the specifics on what exemptions exist or what requirements of disclosure exist that would, in effect, as you are suggesting, sort of equalize the requirements that the law places on nonprofits and on for-profit organizations. I am not sure that I understood that the parallel had actually been reached.

Mr. O'REILLY. A government contractor who is providing the agency something under a specific contract is subject to Freedom of Information requests directed at the agency, typically by competitors. And those disclosure issues have been litigated in about seven appellate cases, I believe most of them in the D.C. Circuit. Grantees, the recipients of grants, have been exempted as a result of the majority opinion in the 1980 Supreme Court case *Forsham* v. *Califano*. The Shelby amendment reverses that 1980 decision and takes the position that the dissenters held in that case.

Mr. TURNER. It seems to me from your comments today that, as you say, you would not grade the Shelby amendment very highly if it were a law school exam, that this committee perhaps has the obligation to address the issue and try to resolve some of the uncertainties that OMB is struggling with in order to avoid a large volume of litigation that would appear to likely flow from the confusion that now exists.

Mr. O'REILLY. The new statute I was speaking of, the specific statute, would have to be framed by the committee as you observed the working of Shelby—how does Shelby work in real practice after OMB is done with it, and then what needs to be protected.

Mr. HOLT. Mr. Turner, if I may, Mr. O'Reilly commented about the need for perhaps additional language to clear up the problems that might be caused with a private-public mix. In fact, this gets to the heart of it. What about the private-private mix? What about the mix of data that are part of the published paper, maybe mixed with data that were not part of that publication, data that are not ready for release? We really do the public a disservice if we allow the forced release of data that are in process, a real disservice.

One of the things that scares me about how this will, I expect, be implemented, it provides an opportunity for back-door regulatory reform. And we should not underestimate the intensity and tactics that will be used by interest groups, political groups, companies who might be critical of results that would run counter to their perceived political or financial interests.

Mr. HORN. I am going to have to shut off this question right now so that other members can question, if I might.

Five minutes to Mr. Ose of California.

Mr. OSE. Thank you, Mr. Chairman. Are we on the first round or second round? Am I reclaiming my time? Thank you, Mr. Chairman.

I want to go back to a comment. I don't recall who said it. Something to the effect that regulatory reform—excuse me, there might be a back door to regulatory reform by opposing H.R. 88. I am not quite sure I got that right. But my primary concern here is that I want to make sure that the provisions of this bill only apply to government agencies. Am I correct on that? It does not apply to a private-private transaction?

Mr. O'REILLY. Research paid for with Federal funds in whole or in part.

Mr. OSE. The concern that I have—and I think it was Congressman Holt. The concern that I have is that the research, at least in California, where we tend to lead the States in regulatory rulings, oftentimes the research that is partially done leads to regulatory rulings that are based—in other words, the research isn't

done, complete, I should say. But the edict comes out and all of a sudden farmers and small business people and home gardeners are impacted.

What I am trying to get to is—I am looking for some guidance here. I have no doubt that you are smarter than I am, Congressman Holt, but given the difficulty that business faces if these regulatory edicts that are based in part or in whole on uncompleted data, how do small business owners, for instance, confront that dilemma where they didn't get to the underlying data? You come to me in my business and say that you have to do *X*, *Y*, and *Z* because we think this is an impact. I say to you, show me your data. All of a sudden, you say, I can't.

Tell me how to get out of that dilemma.

Mr. HOLT. Mr. Ose, yes, I did use that phrase, back-door regulatory reform. First of all, I don't pretend to be smarter than any of you up there on the panel.

Mr. OSE. I know you. You are smarter than I am.

Mr. HOLT. I have a somewhat of a different background. I do think that the disclosure of undigested partial data can create real problems and a real opportunity for disruption of the process, and as I mentioned earlier, harassment.

You pointed out, as Mr. Ryan pointed out, a real problem of public policy if regulations are based on inappropriate or undigested or wrong scientific information or preliminary scientific information. But this should not be a fix for that. Certainly we want regulations promulgated following laws that we enact to be based on the best accepted understanding of relevant science.

But this is something else. This is not a fix for that. And I will repeat what I said earlier, the Freedom of Information Act, even as amended, is intended for political openness. That is the intention of the bill. That is why—of that law. That is why it exists. We are talking about something else here. We are talking about scientific process.

Mr. OSE. I appreciate your humility, but I know that you are smarter than me, first of all.

Mr. HORN. Would the gentleman yield to me while you are figuring out who is smarter? I am just a country boy and I have to listen to all of this. I want to ask one question.

How many of you were here in 1993 and 1994 in this town? You might remember this. In this room we, on a bipartisan basis, voted to elevate the Environmental Protection Agency to Cabinet status and the so-called Thurman—Democrat from Florida—Mica—Republican from Florida—addition was made to that. We had a majority. The majority in brief on this bipartisan Thurman-Mica, Mica-Thurman—two common-sense people, I might add, that are in my class, very fine legislators—they put in language that we would have to have unbiased science. The then-Democratic leader refused to bring the matter to the floor. He is still now the Democratic leader.

But the fact is, what we are getting down to is the values that go behind social science research and policy research. This is not necessarily what you find in the chemical-biological-engineering areas, although we have had fraud at the highest levels, and a few handfuls of people that are just with the greed that comes with try-

ing to get the Nobel Prize and all of the rest of it. Their colleagues caught them at that. That is what the whole replication process is in science. Now, when you get down to social science, and I am a political scientist; although my daughter, when asked at age 2 what her daddy did, she put her hands on her hips and said, he is a pitiful scientist.

I come to you as a pitiful scientist, but I started my life in education for 30 years as a dean of research. So I have an interest in this. But when you get to social science matters, be it the Democrats sitting here or the Republicans sitting here, they can say, hey, was there some bias in this? They have already reached the conclusion rather than analyzed the problem.

That is an understandable thing that people in public life would do. They want to know, hey, who are these people? Have they ever had any work in this area? Do they know anything about it, or just have axes to grind? A lot do on both sides. So it seems to me that is part of the motive of the Shelby amendment, to get it out on the table in terms of what are the values and what are they leading to, based on the values. Once you get a value set in there, hey, we can all predict the outcome. It doesn't take too many brains to figure that out, if you guys are still talking about brains.

Anyhow, as I listen and think about it, over the last few years we have had a lot of unhappiness by members in both parties and the factions in both parties, depending on what comes out of that study that is used against them in a public policy debate. I think basically we have to face up to that—as to that.

Now, in facing up to that, which I think is what probably motivates some of our colleagues, we don't want to have a problem where we hurt "science," in America—medical science, health science, engineering science, and so forth. So maybe the exemption route is one way.

I would like to hear comments from you. We are not going to close this record for a while. Feel free to write us. We will put it in the record at this point, without objection. But I would appreciate any wisdom that you have of my memory of the 1993–1994 argument. That is what it was all about. Nobody trusted the data that EPA was bringing in. If we were going to give it Cabinet status, we didn't want to have that continue.

As I say, in this room Mr. Conyers was presiding, the Mica-Thurman, Thurman-Mica amendment was part of it. The result was that was the last that we ever saw of it. It is sitting somewhere over in the Capitol.

Any wisdom that anybody has on this, the physical scientists and the social scientists?

Dr. Varmus.

Dr. VARMUS. I agree with your notion that this needs to be narrowed. Watching my colleagues at OMB trying to write a narrowing of the proposal suggests how difficult it is to start from a flawed instrument and design a sharp tool that gets what you all desire—that is, public policy based on the best available evidence. That is why I support Representative Brown's proposal.

I think we should start again. We recognize it as a problem, and we should have an open discussion of the best way to get at the relevant information in a way that serves public policy.

Mr. HORN. Does anybody else want to comment on this?

Mr. Miller.

Mr. MILLER. Well, if you start with the basic premise that the taxpayer pays for the information, it is theirs. You have to have a compelling reason to deny them access to that information. If need be, you might have some clarification that it refers only to published data, that it is data that is used as the basis for policymaking and for rulemaking.

But to echo your concerns, Mr. Chairman, I think it is outrageous for an agency to be able to promulgate regulations in which they simply say, "Trust me, we have a study that supports our point of view." That is so inconsistent with the goals established for open, accountable government, administrative procedures, and so forth.

There also is a danger of delay, delay, delay. Obviously, the Shelby-Aderholt language has brought this issue to a head. If you were to back off now, my suspicion is that nothing would be done.

Mr. HORN. Let me just say, if I might, Dr. Alberts, you have a lot of experience. We ask you for a lot of studies. We have asked you to do a number of studies, et cetera. How do you guard against the biases that can occur in social science research going back to 1863 or 1864 when you started?

Mr. ALBERTS. In the early days, we weren't asked to do much of importance. Now we publish something like 200 reports a year, most of them for government.

The studies are an art form. The first thing we do is set up a committee that contains a wide spectrum of expertise, people with opinions on both sides of the issue. And it is very important to that sort of a committee that brings in everybody's point of view. At the same time, we don't want anybody on the committee who is a public advocate for a position because they can't act as a scientist. They have to be paying attention to their political constituencies. So we limit the extremes of viewpoints to people who say in initial bias discussions that they are free to act as individuals and make their own judgments.

I think we often succeed in getting people with quite diverse viewpoints to come to consensus views. That was the case of my human genome study where we started with two people who sat on opposite sides of the issue; either it was crazy or it was so obvious that we shouldn't even have a meeting. In the end, everybody agreed.

The committee has to educate itself by bringing in all possible outside expertise. Then, after we have the report, we send it out to anonymous review. Now, the names of all the reviewers, as you know, are published along with the report, but not the opinions.

I think there is a lot to be said for the kind of thing that Mr. Hahn was talking about, when you have legislation with great consequences based on a scientific set of findings that would be very serious about reviewing the science that underlines that regulation. I am very sympathetic to that point of view. I think Congress needs to do something about that. I don't think we are set up now to do that adequately.

I do agree with my colleague, Dr. Varmus, that this very hastily written legislation, which has not had the benefit of any hearing

or any normal process of Congress, is not the right way to do it. We have talked here about two different things in fact. We talked about the OMB regulations as if that is the law. But, in fact, the law is the Shelby amendment which, as I have said repeatedly, says nothing about publication, for example; and is, in my mind, fatally flawed.

Congress needs to do something. I don't want this to all be settled in law courts. I think that is a waste of everybody's time.

Mr. HORN. Let me just suggest, as I did a little earlier, that both Democratic and Republican staff will get together a series of questions; if we might send them to you—and we appreciate your thoughtfulness—just give us your best advice.

Now, I want to finish out the panel for Mr. Ose; are you done?

Ms. Biggert, the vice chair, how about it, do you want to let Mr. Ryan go ahead of you?

Mrs. BIGGERT. Just one question. I'm sorry I had to leave. It might have been asked or not.

When you were discussing the different exceptions or the different laws that would apply whether this data was supposed to be made public, who then is going—who decides? Is there anybody overall since this goes to many different agencies?

Probably Mr. O'Reilly again.

Mr. O'REILLY. The mechanics are relatively straightforward. The agency has a Freedom of Information office. Its people are career professionals, many of them with a science background in those scientific agencies. They receive the documents, screen them, and apply the agency's guidelines for personal medical information to be deleted, for aggregatable or disaggregatable information to be identified for commercial or proprietary claims. Then they use the Executive Order 12600 process to determine whether the information has a real commercial value, has been marked as such.

They provide notice for making a disclosure of commercially valuable information. Then they make the decision, which is reviewed typically by the head of the staff of Freedom of Information officers in that agency.

If the agency has a question, it will contact the person who made the submission, in this case, the researcher. The researcher has rights in some situations to appeal within the agency or have a discussion within the agency. In the ultimate case if there are so-called "reverse" Freedom of Information lawsuits, such as the McDonnell Douglas case of June 25, 1989, in which the agency can't agree with the company, in that case a government contractor, those mechanics are relatively simple.

How it plays out, of course, depends on the quality, the resources and the staffing of each individual agency.

Dr. VARMUS. If I could make just one amendment to that. In attempts to solve a problem that you, Mr. Horn, have described very nicely for us, we are putting at risk the proper execution of all of these privacy provisions in enormous amounts of research information. The country is doing a tremendous amount of research in a wide range of fields, some of which includes very sensitive information—confidential information, proprietary information, private medical records—all of which is, in general, irrelevant to the major concern that Mr. Horn has described.

We are opening the door to the possibility that in obtaining information from grantees, agencies get the information and could share it with other agencies. Depending upon people centrally in government to properly redact those records, you change the entire environment in which this very successful enterprise of federally funded research at our universities is carried out.

Mrs. BIGGERT. Thank you. Thank you, Mr. Chairman.

Mr. HORN. I yield now 5 minutes to the gentleman from Wisconsin, Mr. Ryan.

Mr. RYAN. Thank you, Mr. Chairman. This has been a very enlightening panel. It's been a great discussion.

A couple of issues have been coming up repeatedly that I would like to go at a little bit; that is, the published—waiting until the data is published and the release of information data before the work is finished. I was hoping Mr. Holt would be here because he mentioned this quite a few times.

Dr. Varmus, let me ask you. Right now, as it stands—and I just do not know the answer to this question—under current studies funded by the government or current government studies, is it—are researchers required to release the data before the work is finished?

Dr. VARMUS. Under the law that Mr. Shelby has proposed, that would be a requirement. OMB is trying to frame the regulations in such a way that would protect investigators from that kind of intrusion. As you have heard before, some are concerned that this is going to end up in court challenges to the OMB revision, and I don't know where it is going to come out.

Mr. RYAN. If I recall from other testimony, the Shelby amendment didn't speak specifically to that issue.

Dr. VARMUS. It says data, all data. All data, of course, would include data obtained with Federal funds prior to or after publication.

Mr. MILLER. My understanding is, the Shelby language is an admonition in an appropriations bill for the OMB to do certain things. It does not establish a predicate for private litigation.

Mr. RYAN. That is what I am trying to get at. It seems to me, it is an overreaching comment to suggest that this Shelby language in the bill does require the release of data before a work is completed.

OMB is in charge of promulgating the regulation so that it is a workable piece of legislation. As somebody just said, they are going to promulgate this regulation so that it doesn't require the release of data before the work is actually completed.

Dr. VARMUS. That is one aspect of it, and there are many aspects of what the regulation has to achieve that I think present more problems, as in the issue of publication versus nonpublication.

Mr. O'REILLY. I agree with your comment that this is not a self-implementing piece of legislation. This is a direct delegation to an expert administrative agency. In those circumstances, the agency, in this case OMB, would receive much more deference.

Mr. RYAN. So OMB has more latitude to craft that——

Mr. O'REILLY. In the context of the Shelby amendment, yes.

Mr. RYAN. On the published part, some testimony seemed—I just wanted to get at this a little bit more. There was concern that data

would be released after a study is completed, but before a study is published. I noted some of the concern would be, fine, if you released it after it is published. But if you look back over years of data where work has been completed, but years have elapsed between the completion of work and the publishing of that work—and I think it is important to note the consequences of that kind of a system where you have years elapsing between it.

I just had to go back to the National Cancer Institute's atomic fallout study. We just researched this in Congress last year, but we noticed the National Cancer Institute failed to publish a study that tracked the fallout from approximately 100 above-ground explosions in Nevada between 1951 and 1962. This study at the NCI suggested up to 75,000 additional thyroid cancers might result from these tests, mainly in young children exposed at the time.

The study was drafted in 1992, so the study was completed in 1992, suggesting that there would possibly be an additional 75,000 cases of thyroid cancer for young children directly accountable to this testing; however, the study wasn't published until July 1997. This was only after substantial media hype and congressional oversight.

There are literally lives at stake when we move the threshold to "don't release the data until it has been published." if the data has been finished and you wait until it is published, you can see the types of consequences.

I am from Wisconsin. In Wisconsin we had a study—I think it was Dr. White, if I recall, who did a study of our school choice program in Milwaukee. His study concluded, according to his results, that school choice didn't work. From his analysis, he concluded that it brought higher levels of parental involvement and satisfaction, but actually no academic gains. From 1990 to 1995, school choice opponents used that study quite extensively to defeat the school choice arguments. But upon review in 1996 by professors at Harvard and Princeton, they looked at his data and found from his data that the results were quite the opposite, that academic standards and performance actually increased.

So we have found that substantial public policy has been on the line between the elapsed publish of the study and the completion of work and the ability to research the data. So it just seems to me kind of a specious argument to say, let's wait until this stuff is published, because if there is so much time between the publishing of the study and the actual completion of the work, you can see the dire consequences that are involved here.

I would just like each of you to comment about that, if you think that we should wait until it is all published.

Mr. HAHN. I think that you touch on an important issue, Congressman Ryan. Clearly most of us are researchers on this panel. We would be reluctant for a variety of reasons to share our data before a publication. One reason might be that the data set isn't clean.

A second reason is, that we would like to get credit for our findings—for example, if we are interested in getting tenure. I think you have to strike a balance. But I also think that you need to ask yourself the following question as the legislators of the land. Do you want to be in the position of passing regulations or having the

agencies that you oversee enact regulations costing hundreds of billions of dollars without exposing them to sunshine? That is why I had argued that in those cases it is absolutely imperative if the regulatory agency relies on a central study, like the Harvard study, that was one of the motivations for this hearing, that the data be made public if it is going to be relied on for the regulation.

Mr. RYAN. I think this is getting closer to the heart of the issue, which is I clearly understand why the scientific researcher doesn't want it released until after the work is completed, but before it's published for those reasons you just outlined. That is eminently reasonable and within the self-interest of that individual.

But those of us who have to conduct policy and those of us who have to watch out for the concerns of our constituents when we are evaluating promulgation of sweeping regulations have to look at that higher cost, have to look at that broader impact on the entire country. I think that is where these two goals clash. When you examine it in that light, clearly the higher priority should rest with the benefits to the public as a whole rather than that narrow self-interest.

Dr. VARMUS. I am not trying to hide behind this notion of publication. It is not a Holy Grail. In fact, the attempt to modify the Shelby amendment with the term "publication" is one that we at the NIH have criticized in dealing with OMB because the word "publication" itself means many different things. Scientists use websites, they give talks; there are many ways to make data public. The real issue is whether scientists have had a chance to look at the data.

We don't want to confuse this with a failure to publish the radioactivity study, which we acknowledge should have appeared more quickly instead we should recognize the difficulty that we are having in trying to come to terms with an appropriate solution to a problem that I think we all agree about—that public policy should be based on the best available data that should be interpreted as best as possible without making a very broad threat to the entire scientific enterprise.

Mr. RYAN. Let me ask you this, Dr. Varmus. I will just ask you an open-ended question.

It sounds like everybody is pursuing the same goal albeit we have different routes. I agree with you, Mr. Miller, we wouldn't be here if this law hadn't passed; we wouldn't be moving on this if it hadn't passed. The NAS published a study in 1985 suggesting they wanted this to happen, but it is 1999. So it is a good thing that we are here talking about this.

How would you craft data——

Mr. HORN. This will be the last question. Just answer that question and we will move on.

Mr. RYAN. Thank you, Mr. Chairman.

Dr. VARMUS. I wouldn't presume to have an answer to a very difficult question like that, but I do think that some of us here and Members of Congress could, through a series of hearings like this one, come up with some ideas.

In our own work at the NIH, for example, we have data-sharing policies that we use to guide our grantees, who then deposit all of their genomic sequence in a publicly available data base. They de-

posit their crystallographic information from protein structure studies in the public domain. It is publicly accessible.

We have many other means, for example, to allow independent bodies to examine clinical trials information in a way that preserves confidentiality, builds confidence in the results, and allows us to alert physicians if a study is developing a conclusion that forms the basis for a public policy about health care.

So there are ways to do it, but they should be ways that are appropriate to the kinds of solutions we are trying to achieve and not the kind of broad, potentially damaging law that is represented by the Shelby amendment.

Mr. RYAN. It sounds like Mr. O'Reilly sort of answered that question, suggesting that the OMB does have a good degree of latitude in promulgating the regulation and that we are probably going down the right path already.

I notice that my time has expired. I thank you, Mr. Chairman, for extending me great latitude.

Mr. HORN. I would just ask the ranking member, Mr. Turner, if he has a few questions and then we will move to the second panel.

Mr. TURNER. Thank you, Mr. Chairman. I know we need to move along. We have had this panel before us for an extended period now.

I guess after hearing all of you, I am left with the opinion that we do need to provide some mechanism to ensure that when there is research done with Federal dollars, at the time that research enters the public domain that the public has access to all of the underlying data it collects to support the conclusions of that research. I think that can be done and I think the assistance that each of you could give us would allow us to reach that goal.

I personally think it is probably a responsibility that the Congress ought to take, rather than simply allowing it to be done by an administrative agency at the OMB.

So with that, Mr. Chairman, this has been a very informative and helpful panel.

Mr. HORN. I agree with my colleague. I wish that we could have another hour or two, because we have a lot of expertise this morning. We are going to have to get it down to writing, however, just to get the focus. Without objection, those responses would be put at this point in the record.

Thank you for coming on short notice. You have really been an excellent panel. We don't always get that. I think we are going to get it also with the second panel.

Would the second panel come forward, the university panel.

We have Mr. Kovacs, Mr. Shelton, Mr. Obadal, Mr. Thurston, Mr. Gough, Mr. Bass. Gentlemen, I think you know, if you stand up and raise your right hands. If there is anybody advising you that is going to get into the record, please get them to stand up.

[Witnesses sworn.]

Mr. HORN. We have eight. The clerk will make sure that we have the names of all eight that have taken the oath.

So we will start with Mr. William Kovacs, the vice president, Environmental and Regulatory Affairs for the U.S. Chamber of Commerce.

Mr. Kovacs.

STATEMENTS OF WILLIAM L. KOVACS, VICE PRESIDENT, ENVIRONMENT AND REGULATORY AFFAIRS, U.S. CHAMBER OF COMMERCE; DR. ROBERT SHELTON, VICE PROVOST FOR RESEARCH, UNIVERSITY OF CALIFORNIA AND ASSOCIATION OF AMERICAN UNIVERSITIES, NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND GRANT COLLEGES; ANTHONY OBADAL, WASHINGTON COUNSEL, ASSOCIATION OF EQUIPMENT DISTRIBUTORS; DR. GEORGE D. THURSTON, ASSOCIATE PROFESSOR, ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY; MICHAEL GOUGH, ADJUNCT SCHOLAR, THE CATO INSTITUTE; AND DR. GARY D. BASS, EXECUTIVE DIRECTOR, OMB WATCH

Mr. KOVACS. Thank you, Mr. Chairman. It is an honor to be here today to discuss this very significant regulatory reform issue, access to government funded information. The U.S. Chamber opposes H.R. 88, which would attempt to repeal the Shelby amendment.

We have heard a lot of theoretical discussion today. I am probably going to put my comments more in terms of a practical setting.

The Shelby amendment is a practical and reasonable extension of Federal law. Under Circular A–110, the Federal Government has the right to all of the data that is produced under government funded studies upon its first production. This data could be obtained by the Federal agencies today. Federal agencies have used their discretion not to obtain the data and, therefore, the practical need for the Shelby amendment, is that this information has been denied to the American public.

Mr. O'Reilly made an excellent presentation of why FOIA is an appropriate mechanism. It has been around for 34 years. It is not only geared to providing information, but to protecting information. It incorporates numerous Federal statutes from technology transfer acts to the patent act to the copyright act. These protections are all incorporated into Circular A–110. There is a long history on this issue.

But the reason that the Chamber is here, I think was highlighted a little by Congressman Holt when he said that FOIA is a document about political openness. This is really the Chamber's position. When you look at the rules and regulations that we have in this country, a lot of these rules—and we refer to NAAQS, but that is not the only one—use this data to justify the imposition of regulations on business. Those regulations are the same as laws, but let's look at how many regulations there are.

Every year the U.S. Federal Government through its agencies implements 4,000 regulations consisting of over 65,000 pages of text. The cost of these regulations, I believe it was Congressman Ose or Congressman Ryan who mentioned it, is $700 billion.

Last year it was estimated to be $737 billion. This estimate is based on a Competitive Enterprise Study, ''The 10,000 Commandments,'' I had an intern add up all of the regulatory costs from 1977 to 1998. The cost totaled $14.2 trillion. This information puts the Shelby amendment in perspective.

The cost of regulations is literally three times more than all of the corporate taxes paid in the United States on an annual basis. It equals all of the taxes that are paid by individuals in the United

States and exceeds all of the corporate profits paid by all of the companies in the United States by $100 billion. Moreover, it has an effect on small business where the cost of regulation on a small company, 20 employees or less, is literally twice as high on large companies. So when you ask why we are concerned about this data, our concern is simply that it this is used to regulate business.

As Mr. Hahn said, from Brookings, 50 percent of the regulations wouldn't pass a cost-benefit analysis. We are not sitting here saying that it is cost-benefit, but resources are precious. If we are going to spend $1 on a regulation that doesn't have an important effect, then we are not spending $1 on something that does have an important health effect. That is really crucial.

The reason why the private sector is so concerned about the Shelby provision is that there is really no way to check on the Federal regulatory agencies. They have unbridled discretion. If agencies don't ask for the documents, the private sector has no way of getting them from the record.

Several years ago Congress passed the Congressional Review Act, and it was to get regulations before they became effective so that it could review them. Since that time, 8,600 regulations have been sent to Congress, and in not one instance has Congress sent a regulation to the floor for a vote. The private sector, the regulated community, along with the State and local governments, are really the only checks that are left on these regulators, other than congressional oversight. So without getting into the issues of transparency in government or democracy, a lot of the issues that we raise and you made in your opening statement on Madison, are in the record.

I want to make two final points. One is that the data access actually strengthens—and I want to underline the word "strengthens"—the underpinnings of the regulatory process. And at the same time, the failure to provide data undercuts the underpinnings in the regulatory process. The NAAQS regulation is the best example.

We could talk about a horror story where Carol Browner came here and talked about the number of lives saved, but she never released the data. She flip-flopped from $5 billion in cost and 40,000 in lives saved to $50 billion in cost and 10,000 lives saved. But no one has ever seen the life.

The day after the D.C. Circuit ruled, the next day, another panel said, well, the same data was used in the NAAQS rulemaking so we are going to stay that case. We have done an analysis of 11 other rules of the agency. Every one of the rules that relies on the same data that the NAAQS standard relied on is now at risk. EPA has literally gutted its own regulatory program, which is really significant.

My final point is that OMB really is the appropriate mechanism, not Congress. There were 9,200 comments. It is not that the comments came out 55 percent in favor of the Shelby amendment or 37 percent opposed to the Shelby amendment. What is crucial is that 55 percent of the comments were from individuals without a business organization or a business affiliation; 36 percent came from researchers of higher education. That means 91 percent of the

9,200 comments came from individuals. That is an incredible statement.

If we are trying to involve people in democracy, this is what is going to do it because they want to know what is the basis for being regulated. We are strongly opposed to it.

I guess that I want to end with a quote from one of those thousands of individuals. We don't know him and we are going to try to find out where he came from. The example follows the example Congressman Ose used where if you are a small business and a regulator walks in and says, here is your regulation, you have got to follow this, and the business owner says, give me your data.

Mr. Long stated the following. He said, "When I play poker, I am required to show my hand before I claim the pot. Bureaucrats should be held to the same standard."

That is really all we are talking about. Tell us why we are being regulated so that we can begin to understand how we are governed. Thank you very much.

[The prepared statement of Mr. Kovacs follows:]

Statement of the U.S. Chamber of Commerce

ON: THE U.S. CHAMBER'S OPPOSITION TO H.R. 88 AND THE NEED TO ENSURE PUBLIC ACCESS TO PUBLICLY-FUNDED RESEARCH DATA

TO: HOUSE SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY OF THE COMMITTEE ON GOVERNMENT REFORM

BY: WILLIAM L. KOVACS

DATE: JULY 15, 1999

The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

Statement
on
H.R. 88
before the
Subcommittee on Government Management, Information, and Technology
of the
Committee on Government Reform
of the
U.S. House of Representatives
on behalf of the
U.S. Chamber of Commerce
by
William L. Kovacs

July 15, 1999

Good morning, Mr. Chairman and members of the subcommittee. Thank you for this opportunity to testify on H.R. 88, a bill to repeal certain provisions that require the release of information under the Freedom of Information Act. I am William L. Kovacs, Vice President, Environment & Regulatory Affairs for the U.S. Chamber of Commerce. The Chamber is the world's largest business federation, representing more than three million businesses and professional organizations of every size, sector and region. The Chamber serves as the principal voice of the American business community.

I am here today to testify in opposition to H.R. 88. The fundamental objective of the Freedom of Information Act (commonly referred to as "FOIA") is to subject agency actions to public scrutiny so as to provide citizens with information about the operations of their government. If H.R. 88 were to be enacted, the public would, in effect, be denied access to information that forms the basis for rules and policies adopted by federal agencies. This would occur even though such information is developed under a federal grant and agreement with an institution of higher education, a hospital or other non-profit organization, and even though such information is paid for by the American taxpayers. There are many less restrictive alternatives

than the outright repeal of the access called for by H.R. 88. We urge that these hearings examine such alternatives, so that the public is not denied access to the information that forms the basis for the regulations and policies that govern how all Americans live and operate under federal law.

1. The Chamber's Stake In Data Access

Access to publicly-funded research data is critically important for businesses and citizens who want to understand the basis for government regulations. Data derived from government-sponsored research provides the impetus and justification for many government policies, regulations, guidances, risk assessments, interpretive documents, and other findings. Given the significant regulatory burden shouldered by the American public and American businesses, the Chamber is keenly interested in improving the quality of regulation and enhancing public participation in the policymaking process. The Chamber has supported data access for many years.

a. The Extent and Costs of Regulations

The regulations of the federal government pervade every aspect of American life and business. Specifically, government paperwork and the costs and complexity of the regulatory process are among the greatest concerns facing business owners today. Each year, the U.S. government issues approximately 65,000 pages of text representing some 4,000 new rules. As of 1996, there were 132,112 pages, in 204 volumes, of the Code of Federal Regulation ("CFR"). Each sentence of the CFR has the same effect as a law. The regulatory burdens imposed on businesses in the United States are astounding.

Recent studies estimate the overall compliance costs with federal regulations at more than $737 billion annually[1], and project substantial future increases, even without the enactment of any new legislation or regulatory initiatives. The annual cost of regulation in America is roughly

[1] Crews, Clyde Wayne. "Ten Thousand Commandments: An Annual Policymaker's Snapshot of the Federal Regulatory State." Competitive Enterprise Institute, (March 1999).

three times greater than the total amount of all corporate income taxes and is equal to the total amount of all personal income taxes paid. Federal regulatory costs exceed the total amount of corporate profits made by all companies in the United States in 1996, $640 billion. These costs translate to $7, 239 per family and are second only to mortgage payments in annual household expenditures.[2]

b. Impact of Regulatory Process on Small Business

Worse yet, the smaller the business, the more dramatic the cost. According to the U.S. Small Business Administration (the "SBA"), small businesses represent about 99% of all employers. Yet, a 1995 study conducted by renowned economist Thomas Hopkins found that businesses with fewer than 20 employees have almost twice the regulatory costs per employee than operations with 500 or more employees.[3] Small businesses clearly play a key role in our society. According to the SBA, almost 57% of working Americans are employed in small companies, which account for over 52% of national annual sales.

c. Allocation of Resources

The cost of regulatory compliance commits precious resources. Simply, a dollar spent to comply with a poorly designed regulation is a dollar that cannot be spent on more pressing matters. A 1994 Harvard University study concluded that more than 60,000 lives are lost due to misplaced priorities of the current command-and-control regulatory system.[4] The current regulatory system spends billions of dollars on eliminating negligible or nonexistent risks. Meanwhile, regulators fail to protect the public from other risks that are much more defined and serious. An example discussed in the study compared two approaches to preventing cancer. The federal government regulates emissions of the suspected carcinogen benzene during waste management operations at an estimated cost of $19 million per life saved. However, a highly-proven life saving method

[2] *Ibid.* p8,11.
[3] Thomas D. Hopkins, "Profiles of Regulatory Costs," A Report to the U.S. Small Business Administration, November 1995.
[4] Tengs, Tammy O., "Optimizing Societal Investments in the Prevention of Premature Death," doctoral dissertation, School of Public Health, Harvard University, June 1994, p2.

that costs approximately $17,000 per life saved, the mammogram. is not regularly administered to 70 percent of women over the age of fifty. [5]

Because of the impact of federal regulations on our lives, it is essential that the public be allowed access to the information that forms the basis for many rules. Only by being able to evaluate such information can we understand the choices made by our government and assist in setting priorities for the expenditure of the citizens' money.

d. The Congressional Review Act

In addition, public review of the justification offered for regulatory rules is extremely important. While other mechanisms have been established by Congress to ensure integrity in the regulatory process, they have proven to be insufficient in assuring that the information forming the basis of the rule is thoroughly examined in all cases. The Congressional Review Act (the "CRA"), for example, requires agencies to submit regulations to Congress for review before their effective date. A 1998 Heritage Foundation study found that, since CRA's enactment in 1996, over 8,675 regulations have been submitted to Congress, but not one has been voted on by the House.[6]

The Chamber certainly recognizes the complexity of the administrative process and can understand why Congress might not be involved in reviewing the many details that are part of these regulations. Nevertheless. Congress is allowing approximately 4,000 new laws to go into effect each year without review.[7] The only review of these regulations is often by those who participate in the rulemaking process. Therefore, the only check on the regulator is the citizen reviewing the information that forms the basis of these regulations. If Congress, by enacting H.R. 88, denies citizens access to much of the data which serves as the basis for these regulations, the regulators will go unchecked.

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[5] Tengs, Tammy O. and Graham. John D., "The Opportunity Costs of Haphazard Social Investments in Life-Saving," Risk, Costs, and Lives Saved, The AEI Press, Washington, D.C., 1996. p167.

[6] Antonelli, Angela. "Two Years and 8600 Rules: Why Congress Needs an Office of Regulatory Analysis." The Heritage Foundation. (June 26, 1998).

[7] *Ibid.*

The theory underlying the ability of a citizen to have access to government data is to enable that citizen to understand the operation of his or her government. The U.S. Government has itself noted, albeit in a different context, the importance of public access to government-controlled information: "[T]here is little doubt that an aggressive policy is necessary to address the significant problems of lack of accountability and an uninformed citizenry that are created by the current practice of [creating] obstacles to releasing [important] information."[8] Experience has taught us that transparency in government improves the quality of government and leads to more democratic outcomes. Public scrutiny improves the quality of governance and makes government officials more accountable to those who elected or hired them.

a. Better Data Improves Scientific Research

Better data access will also improve the quality of science. Increased data access will allow independent researchers to verify, replicate, or refute the research results – a fundamental step in the scientific process – thereby increasing the public's confidence in the science used in federal rules and policies. Furthermore, providing the public access to research data will encourage research by providing researchers with access to new databases to test hypotheses. For example, a researcher recently retracted his laboratory's well publicized study, which found mixtures of weak estrogens could be much more powerful when combined. Based on the initially published results, many thought the study explained why exposure to low levels of chemicals contributed to breast and testicular cancers. The research results received worldwide attention. Despite joint efforts, at least four laboratories were unable to replicate McLachlin's results.

b. Increasing Data Access Strengthens the Underpinnings of the Regulatory Process

Increasing access to research data can also help to reduce the amount of data fabrication and falsification. The National Institute of Health Office of Science Integrity routinely publishes in the Federal Register notices of Official Findings of Scientific Misconduct. Despite the lack of

[8] Final Report, Assassination Records Review Board. (Sept. 30, 1998). p176.

a systematic approach to identifying and checking for cases of scientific misconduct, these notices show that data fabrication/falsification occurs under government contracts at many of the most prestigious research institutions in the country. For example, a September 26, 1998 front-page article in *The New York Times* outlines, in detail, allegations of scientific misconduct against the head of one of Cornell's largest immunology and AIDS-related research labs, which receives more than $2 million in Federal money. The chief researcher has been accused by a member of his own lab of ordering the falsification of data in grant applications and in a published paper, and of threatening members of the lab who discovered evidence of his misconduct.

Unfortunately, there are instances when agencies do not share the data on which they rely. As a result, significant adverse reactions have occurred to both the regulatory process and the regulated industry. This problem became a national issue after the 1997 debate over mortality estimates from exposure to fine particulate matter (soot) in the air after the Environmental Protection Agency's (the "EPA") proposal to tighten the National Ambient Air Quality Standards ("NAAQS"). The agency originally estimated that the cost of compliance for the revised rule at $5 billion per year. The private sector disagreed, asserting that the annual cost of compliance would range between $50-$150 billion. EPA justified the tightened air standard on epidemiological data, which the agency said showed that as many as 40,000 persons would die prematurely each year from inhaling soot.

EPA was asked by the public and by Congress to release the data supporting that claim, but the agency refused on the ground that it did not have to release the data under FOIA, because it was under the control of outside researchers. The research institution that performed the study also refused to share the data and was not obligated to release the data under FOIA.[9] Ultimately, EPA revised its estimate of the annual cost of compliance with the revised NAAQS standard from $5 billion per year to more than $45 billion, and lowered its mortality estimate (because of a "data glitch") from 40,000 persons per year to 10,000 persons per year. Although under

[9] *Forsham v. Harris*. 445 U.S. (1980). 169, 179-180. (Data that is in the files of a recipient of a federal reward, but not in the files of an agency, are not available through FOIA).

current law EPA has the right to request the research data for public release, the agency has chosen not to do so. To date, the NAAQS data has not been released to the public for review and analysis.

The agency's continuous refusal to give the public access to the epidemiological data not only allowed a $45 - 150 billion rule to be created with only limited public debate, but also spawned controversy and litigation. As a result of the litigation, the process EPA used in revising the NAAQS standards has been found to be unconstitutional by the D.C. Circuit Court of Appeals. The Court found that the agency substituted its judgment for that of the Congress, and acted arbitrarily in accepting some data and rejecting unfavorable data. Thus, the agency did not follow proper procedures and the Court held the new air standards unenforceable.[10] EPA's decision to prevent the disclosure of the data casts serious doubts on the integrity of the rulemaking process. If the agency had opened the data to the public from the start and allowed the data to be scrutinized and debated, the process would have been more transparent, the basis for EPA's decision would have been clearer, and the agency would have been less vulnerable to charges that it abused the rulemaking process.

In contrast to an agency failing to disclose data, there are a number of examples where further analysis of new data has lead to different conclusions. For example, a 1995 study on minimum wage by David Card and Alan Krueger found that minimum wage increases expanded employment. A reanalysis of the raw data uncovered significant errors. When the errors became public, periodicals, such as *The Economist*, among others called the Card-Krueger study "plain wrong."

Just last week, EPA was forced to withdraw its 1998 enforcement accomplishments report because of numerous errors in the data tables on which the report is based.[11] The data errors were discovered pursuant to FOIA requests. If the data had not been obtainable under FOIA, there would have been no way to ascertain that it was filled with errors and was,

[10] *American Trucking Assn. v. EPA*, No. 97-1440, (D.C. Cir., May 14, 1999), slip. op. 48-49.
[11] Inside E.P.A. Weekly Report. Vol. 20, No. 27. (July 9, 1999).

therefore, unreliable. If the public cannot accept the agency's *own* data on faith, it cannot blindly accept data generated by outside sources and shielded from public scrutiny.

c. Support for Data Access

What is most surprising about the controversy over the sharing of data is the fact that most federal agencies and many professional institutions have long supported the principle that the data should be released to the public. For example, the Center for Regulatory Effectiveness, in its "Comments of the Regulatory Effectiveness on Proposed Revisions to OMB Circular A-110," lists many organizations that have pro-data disclosure policies. This list includes 8 federal agencies (including the National Science Foundation and the National Institutes of Health), 15 professional organizations and journals (including the National Research Council and *Journal of the American Medical Association*), and 7 academic and research institutions (including the Massachusetts Institute of Technology and Duke University).[12] Moreover, the federal government, under current OMB regulations, has the right to obtain data produced under an award.[13] This right is seldom, if ever, exercised.

3. What Does The Shelby Amendment Do?

In recognition of public interest in taxpayer funded studies used in a federal rulemaking process, Senators Shelby, Lott, and Campbell placed a provision in the FY 1999 Omnibus Appropriations law allowing the public, for the first time, to obtain and review federally-funded research data collected through grants and agreements with research universities, hospitals, and other non-profit organizations. Prior to the enactment of the Shelby Amendment, it was the practice of federal agencies not to obtain this data from the researcher for the agency record, notwithstanding the fact that the agency had a contractual right to the data. As a result, the agency record was incomplete and the public was limited in its participation in any particular rulemaking to the extent of the agency record. To remedy this deficiency, the Shelby

[12] Center for Regulatory Effectiveness, Comments of the Center for Regulatory Effectiveness on Proposed Revisions to OMB Circular A-110 (April 5, 1999).
[13] OMB Circular A-110, § __36(c). Intangible Property

Amendment recognizes the rights of the public to access research data that is funded by taxpayers and often used to support federal policies, rules and findings. The new law does not apply to research developed under federal contracts.

The Shelby Amendment requires the Director of OMB to amend Circular A-110 to require all federal awarding agencies to ensure that the research data produced under a federal grant or agreement will be made available through procedures under the Freedom of Information Act (FOIA). Federal agencies may require individuals requesting the data to pay the incremental cost of obtaining the data from the federal grantee.

Contrary to stated opposition, the Shelby Amendment is not a radical step, but rather a logical extension of existing policy. Under existing federal policy, federal awarding agencies have the right to obtain, reproduce and publish data first produced under an award. In other words, although often misunderstood, the federal government currently has the right to obtain, reproduce, and publish data produced from federal grants and awards.

This data disclosure issue is, in many ways, very similar to the disclosure laws that impact the business community. Historically, possessors of data, including industry, have opposed new disclosure policies. However, parties have accepted these laws. Furthermore, many have argued that data disclosure is a powerful tool to ensure compliance and engage in a more meaningful debate with government officials and the public. Frankly, many of the complaints from the research community are reminiscent of the concerns industry has expressed with similar laws. Industry's concerns have evolved from opposition to compliance to recognizing that, since data will always be collected by the government, it must be accurate so that government and industry can make the correct decisions based upon that data.

For years, industry has been required to provide the public with steadily increasing amounts of privately-funded data. It's now time for the Federal government and those whose

research is funded by the taxpayer to do the same, especially if that research is used to support a Federal policy or rule.

The Shelby Amendment removes the discretion as to when the federal agency would execute this right on behalf of the American public. In essence, the Shelby Amendment states that if someone submits a Freedom of Information request, the awarding agency must obtain the data and make it available to the public subject to the procedures and safeguards included in the Freedom of Information Act. Simply stated, the Shelby Amendment provides the American people with greater power to access data to which they would like access.

4. **Contrary to Critics of the Shelby Amendment, FOIA is a Tested and Appropriate Mechanism.**

Enacted in 1996, FOIA's purpose is to significantly contribute to the public's understanding of the operations and activities of government. The Shelby Amendment requires the Director of OMB to amend Circular A-110 to require all federal awarding agencies to ensure that the research data produced under a federal grant or agreement will be made available through FOIA. Federal awarding agencies may require individuals requesting the data to pay the incremental cost of obtaining the data from the federal grantee. The Shelby Amendment in no way waives the protections under FOIA or any other information disclosure statutes, for the release of data.

a. FOIA Protects the Release of Certain Types of Information

Under 5 U.S.C. 552 (b), federal research data which meets one of the nine exemptions in FOIA would not have to be produced. Exemptions cover materials relating to national defense, internal personnel rules, matters exempted by statute, trade secrets, and commercial or financial information, inter-agency or intra-agency memoranda, personnel and medical files, and law enforcement records.

FOIA applies to all information in the physical possession or under the control of the Federal government. This includes a significant amount of sensitive, personal information, business confidential, and trade secret information. It also includes direct research conducted by federal agencies in-house. Experience has shown that FOIA has been effective in protecting sensitive information, while providing the public with important information. By relying on FOIA and existing FOIA offices within Federal agencies, we do not need to create a new bureaucracy to implement this provision.

In addition to the many statutes prescribing the release of information, FOIA has been implemented by federal agencies on a daily basis for decades. Most, if not all, federal agencies have FOIA officers that are knowledgeable in the law, and these same agencies have regulations that describe in detail how requests for information are to be handled and how information is to be released.[14]

b. Statutory Protections From the Release of Data

FOIA also is the appropriate mechanism because it works in concert with other existing statutes established to protect information, including the Bayh-Dole, Patent, Privacy, and Technology Transfer Acts.

The Bayh-Dole Act[15] provides that universities and other researchers can retain the title to inventions developed through government funding. This statute contains certain confidentiality provisions for the protection of intellectual property prior to and during the patenting process. Significantly, the Bayh-Dole Act contains a "precedence of chapter" section stating that the Act will take precedence over all future legislation unless the later law expressly overrides Bayh-Dole. The Bayh-Dole Act will continue to provide the same confidentiality and intellectual property protections that were in effect prior to passage of the new data access statute.

[14] 40 CFR §§ 2.208, 2.209.
[15] 35 U.S.C. §§ 200-212.

The Patent Act[16] protects intellectual property rights. The confidentiality protections afforded intellectual property will insulate the commercially valuable materials from disclosure to the extent that university research may lead to a patent application. Patent office regulations[17] explicitly grant secrecy to pending patent applications.[18]

The Privacy Act of 1974[19] provides controls over what type of personal information is collected by the federal government and how it is used. Three "primary rights" are also established by the Act: (1) the right to see records about oneself, subject to the Privacy Act's exemptions; (2) the right to amend that record if it is inaccurate, irrelevant, untimely, or incomplete; and (3) the right to sue the government for violations of the statute, including permitting others to see your records, unless specifically permitted by the act." Further, The Privacy Act places certain limitations on agency information practices, such as requiring that information about an individual be collected from that individual to the greatest extent practicable; requiring agencies to ensure that their records are relevant, accurate, timely, and complete; and prohibiting agencies from maintaining information describing how an individual exercises his or her First Amendment rights unless the individual consents to it, a statute permits it, or it is within the scope of an authorized law enforcement investigation.

The National Technology Transfer Act[20] provides that where the government exercises its license to use an invention, the government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of FOIA.

Underlying FOIA and the numerous statutes that place limits on the types of information that can be disclosed to the public by the federal government are dozens of court cases that make it abundantly clear that the purpose of disclosure is to provide the public with information about

[16] 35 U.S.C. §§ 1-307.
[17] 35 U.S.C. § 122.
[18] 37 C.F.R. § 1.14a.
[19] 5 U.S.C. § 552a.
[20] National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, 110 Stat. 775. (Mar. 7, 1996).

the operation of government, not to provide it with information that invades the privacy of individuals or to release confidential, medical, or trade secret information.

In the trade secret context, the courts prohibit disclosure of any information under FOIA if the release of the information would impair the ability of the government to obtain necessary information in the future or cause substantial harm to a competitive position.

In summary, FOIA is an effective mechanism for handling data requests and safeguarding privacy and confidential materials. There is a workable structure in place within the respective agencies. Using FOIA is the least disruptive way to ensure not only conformity with existing law, but that all materials protected from disclosure in the past are still protected. To take these issues out of FOIA risks upsetting 30 years of knowledge, structure and law for an unknown future.

5. The U.S. Chamber supports the OMB process.

As a first step toward implementing the new law, OMB published in the *Federal Register* on February 4, 1999, a proposed revision to OMB Circular A-110. In response to a request under FOIA, the proposed revision requires federal awarding agencies to obtain federally funded research data and to make that data available to the public through the procedures established under FOIA. The OMB provision only applies to research data from *published* studies that are used to support federal policies or rules. The Chamber views OMB's efforts as consistent with decades of policy implementing FOIA by the federal government.

OMB is now in the process of reviewing over 9,000 comments and is expected to issue another proposal in the near future. Though narrower in scope than the original language in the FY 1999 Omnibus Appropriations Act, the Chamber supports OMB's February 4, 1999 revision. That notice stated, in pertinent part:

> Pursuant to the direction of Pub. L. 105-277, OMB hereby proposes to amend Section ___.36(c) of OMB Circular A-110 to read as follows:

c) The Federal Government has the right to (1) obtain, reproduce, publish or otherwise use the data first produced under an award, and (2) authorize others to receive, reproduce, publish or otherwise use such data for Federal purposes. *In addition, in response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules, the Federal awarding agency shall, within a reasonable time, obtain the requested data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the data. This fee should reflect the costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).*

64 Fed. Reg. 5694-85 (Feb. 4, 1999) (emphasis added). The italicized material above represents new language that OMB proposes to add to the Circular. Significantly, the original (non-italicized) language reserving to the federal government the right to "obtain, reproduce, publish or otherwise use" award data, is not affected by the proposal.

The Chamber believes the OMB process implementing the Shelby Amendment should be allowed to go forward. The process is inclusive and open to the public. OMB has received the comments and the concerns of the American public and is in the process of evaluating them. If there are actual deficiencies in the FOIA process or the real likelihood that confidential, medical or other types of proprietary data would be released, it has the opportunity to protect such data from release as part of its rulemaking. This is significant, because if FOIA is deficient in some respect, it should be amended for the protection of all citizens and businesses, not only researchers who employed by a federal agency to develop information for a federal agency.

6. H.R. 88 and the Scientific Community's Concern for Data Sharing

Since the National Academy of Sciences, National Research Council's (the "Council") Report in 1985 entitled "Sharing Research Data", the position of the Council has been:

1. Sharing data should be a regular practice;
2. Investigators should share their data by the time of publication of initial major results of analyses of the data except in compelling circumstances;
3. Data relevant to public policy should be shared as quickly and widely as possible; and
4. Plans for data sharing should be an integral part of a research plan whenever data sharing is feasible.

The above recommendations were reinforced in 1997 when the National Research Council published " Bits of Power: Issues in Global Access to Scientific Data." In that report, the Council recommended that governmental science agencies and intergovernmental organizations should adopt as a fundamental operating principle the full and open exchange of scientific data. By "full and open exchange" the committee means that the data and information derived from publicly funded research are made available with as few restrictions as possible on a nondiscriminatory basis, for no more than the cost of reproduction and distribution.

Now, the scientific community wants to protect the data that it generates using taxpayers money. There's an old saying: "Be careful what you wish for, you just might get it." H.R. 88 would give the scientific community its wish. If enacted, H.R. 88 may firmly establish a system of secret research in which federal agencies continually refuse to ask for the data and the scientific community does not share data. This situation will be harmful to taxpayers and the regulated community because they will be limited in their ability to understand the operations of government. Those most impacted by H.R. 88 may be the scientific community that will be denied data that is needed for future scientific advancements.

Accordingly, the Chamber urges this Subcommittee and the full Congress to resist efforts to repeal the Shelby Amendment.

7. Conclusion

The Chamber commends the Subcommittee for examining all sides of this issue and for analyzing how the Shelby Amendment or its repeal would impact government accountability and the federal agency decision making process. However, the Subcommittee should work with the OMB to ensure that all of the protections provided by FOIA and the numerous statutes that protect trade secrets, intellectual property, confidential information, medical and personnel information, are incorporated into any final rule. Moreover, if there are deficiencies in FOIA that would result in personal, confidential, or trade secret information being released, FOIA should be amended to protect not only the researcher, but also all other businesses and citizens that would be impacted by a deficiency in FOIA.

By taking the above approach, all of the protections are provided to the interested parties but the information generated by taxpayers' funds is shared with the scientific community and those who wish to examine the operations of their government when it is making the rules and regulations under which we live.

Thank you again for this opportunity to testify.

Mr. HORN. Thank you very much. I will use that analogy around here on a number of things.

I now yield to my colleague, Mr. Ose from California, who is going to introduce our next witness.

Mr. OSE. Thank you, Mr. Chairman. I am pleased today to have the opportunity or briefly to sit here and hear this testimony.

One of those who has joined us today is Dr. Robert Shelton from the premier University of California at Davis, who also happens to be the vice provost in charge of research for the entire UC system. He is here to provide testimony, and we are certainly appreciative of him coming. Dr. Shelton is just one of the many examples of the fine upstanding people working and living in the Third Congressional District of California. He is a physicist——

Mr. SHELTON. That's correct.

Mr. OSE. As Congressman Holt is, I am sure he is smarter than I am, so I am looking forward to his testimony.

Mr. SHELTON. That is a topic that I will not get into. Thank you very much, Congressman Ose.

Mr. Chairman, members of the subcommittee, I really appreciate the opportunity to talk about one university's perspective on H.R. 88 and, in particular, the use of FOIA to provide public access to research data. I have the honor of testifying today on behalf of the University of California, as you have heard, and I am also pleased to testify on behalf of the interests of NASULGC, an association of 203 public universities, and the AAU, which consists of the 62 leading North American research universities.

What I will do is briefly summarize my written statement with some very specific examples from our professional experience at the University of California. We have three basic points that I want to make.

First, the University of California supports H.R. 88 and we do so because, in our opinion, it is not meant to stop efforts to improve access to federally funded research. Rather, it is needed to ensure that these efforts do so in a careful and considered manner rather than in the context of rulemaking with a predetermined outcome.

Second, I want to make clear, as you heard earlier, that universities do not oppose access to federally funded research data. Indeed, the University of California, like others, has policies that emphasize the criticality of publication by researchers and discourage limits on publication. It is anathema to our faculty, to our students, to our research staff to engage in research with restrictions on publication.

Third, we applaud the use of scientific data in Federal policy rulemaking. We believe it is in the public interest that this process be open and informed. Our concern is that the use of FOIA as a mechanism for data access presents some serious potential problems. Let me try to be specific on that point from the perspective and experience of somebody in the University of California.

First, the extension of FOIA to research data will provide an avenue to dissuade research on controversial issues. We heard earlier about some issues with animal rights. We certainly have a number of campaigns of harassment targeted at individual researchers involved in animal rights research, involved in tobacco research, involved in AIDS research. At the present, our campuses are able to

moderate these situations and work with the requesters to limit the potential disruption through a negotiated process that would not exist under FOIA.

Second, the extension of FOIA to research data may have inadvertent consequences for the university's ability to patent research discoveries. As you are aware, premature disclosure of research results can make it impossible to meet the stringent requirements for obtaining a patent. This is particularly true when you are talking about foreign patents and has implications for our global competitiveness for many of our cutting-edge research-based industries, not just in California but throughout the Nation.

Third, the extension of FOIA on the research data may compromise university research partnerships with industry. While FOIA has an exemption for commercially valuable proprietary information, there is case law that suggests that this exemption may not cover information in the possession of not-for-profit institutions like the University of California.

In the last decade, there has been an increasing number of cases where researchers working with data on a project sponsored by a Federal agency and by a private sector sponsor—in fact, many of the programs initiated here through Congress and with the Federal agencies have encouraged such interactions as a way to get research results into the practical arena for the use by the public.

I can tell you from personal experience in negotiating such contracts, there is an extreme sensitivity on the part of industry to intellectual property rights and to the privacy of those materials that they provide in these collaborations.

Fourth, the extension of FOIA to research data may compromise human subject confidentiality. I won't say anything more about that because it's in my testimony and much was made of that by the earlier panel who have more experience than I do.

Finally, we're concerned that the proposed revision could increase the costs to the universities, but I think this is a tertiary consideration. What we now face is the question of how to balance these substantive concerns with the needs for openness and research. I would respectfully suggest that Congress may wish to look at the safeguards provided in the California public records act and other State sunshine laws when dealing with legislation on data access.

As a California public university, we are subject to this act which provides the mechanism for release of university records upon public request. Unlike FOIA, the Public Records Act provides important safeguards for the university in handling information. It enables us and other State agencies to reach a balance in determining whether public interest is best served by the release of the data. Perhaps critically it allows us, California, the University of California or the State agency, to negotiate directly with the requesting parties, as opposed to turning all of the data over to the agency that funded part of the work.

In conclusion, the research partnership between the Federal Government and university serves the Nation in important ways. The direct investment in university-based research promotes the discovery of knowledge, it stimulates technical innovation, it educates our next generation and contributes directly to the Nation's economic

prosperity and quality of life. We urge you to pass H.R. 88 and repeal the FOIA provision, not to bring to an end this discussion but in fact to allow it to take place in a considered legislative forum. We offer our assistance to the authorizing committees and OMB to begin a thoughtful process to review the practices, and I look forward to the question and answer period.

Thank you very much.

Mr. HORN. Thank you.

[The prepared statement of Mr. Shelton follows:]

Testimony of

Robert N. Shelton

Vice Provost for Research
University of California

On behalf of the Association of American Universities and the
National Association of State Universities and Land Grant Colleges

Before the

Subcommittee on Government Management,
Information and Technology

Committee on Government Reform

U.S. House of Representatives

July 15, 1999

Mr. Chairman and Members of the Subcommittee, thank you for inviting me here today to talk about a university's perspective on HR 88 and the use of FOIA to provide public access to research data. I am testifying today on behalf of the University of California, where I serve as the Vice Provost for Research. I am also pleased to testify on behalf of the interests of NASULGC, an association of 203 public universities, land-grant colleges, and state university systems, and the Association of American Universities, which consists of the 62 leading North American research universities.

As Vice Provost, I am responsible for oversight of the University of California's research enterprise that spans nine campuses, three DOE laboratories and a research portfolio that includes over $1.5 billion in research grants and contracts from the federal government. I am also a scientist, continuing my research in the area of experimental condensed

matter physics and supervising the work of three graduate students, two undergraduates, and two research associates.

The University of California supports HR 88.

HR 88 repeals a provision included in the FY 1999 omnibus appropriations act that would make all federally-funded research data subject to disclosure under the Freedom of Information Act. This repeal is not meant to stop efforts to improve access to federally funded research. It is needed to ensure that efforts to do so are done carefully and not in the context of rulemaking with a predetermined outcome.

The significance of this revision was underscored by the huge volume of responses OMB received to their first draft revision of Circular A-110 which governs the Freedom of Information Act. We understand OMB received over 9,000 comments from a wide spectrum of businesses, universities, hospitals and other research interests. Clearly this is an important topic of concern to multiple sectors of our society. Passage of HR 88 will allow those interested parties to come to the table, review the existing underlying policy and determine if there is a better mechanism for making available the scientific data that underlies federal rules and policies.

It is interesting to note that studies have been conducted in the past on the issue of data sharing, including studies by the National Research Council in 1985 and 1997. No study has recommended that the FOIA be made applicable to all federally-funded scientific

research data. Federal science agencies also have been studying data sharing policies to determine appropriate guidelines for the projects they fund, but those efforts were stopped when the FOIA provision was included in the omnibus appropriations act.

The Potential Impact on the Academic Mission

I want to make clear that universities do not oppose access to federally funded research data. Indeed, the University of California's own policies emphasize the importance of publication by researchers and discourage limitations on publication and the dissemination of research findings.

I emphasize publication as the important and normal mechanism for the reporting of scientific findings and the standard for judging the worth and value of the outcome of a study. Publications represent the researchers' own analysis of the meaning of findings and the emphasis that he or she believes should be given to the work. Work that is submitted for publication is reviewed by other experts, who often raise questions and make comments that are answered by the researcher.

We applaud the use of scientific data in federal policy and rulemaking and believe it is in the public interest that this process be open and subject to informed comment and debate. In most cases, such uses of research will involve publication of data with a thorough analysis, not the use of raw research data alone.

In those situations where underlying data are requested, it would be appropriate to provide it, as long as important protections are in place so that other interests of society are maintained. Our concern is that FOIA lacks the necessary protections and is an inappropriate mechanism to provide useful access to this data. FOIA was never meant to apply the research data generated by researchers and research teams. It is a broad law that is aimed at the information produced by agencies, often information that may involve privacy issues affecting individual US citizens in their relationship to government. To apply FOIA to research data can have detrimental consequences for researchers, for research institutions, and for the research enterprise.

The fundamental flaw with this potential use of FOIA is the relationship between the researchers who produce data, the university which supports their work and monitors the contracts with the sponsors of research, and the Federal Agency responding to a FOIA request. Under FOIA, an agency is duty bound to have the university turn over all data to them. The agency then has the responsibility for making important, crucial decisions regarding which data are responsive to the FOIA request and not subject to the important exclusions involving medical privacy, protection of intellectual property and the maintenance of patent rights.

These very issues are often crucial to the ability of researchers to work on important issues in their field. It is also important to the institution to be able to provide support, engage in partnerships with private research sponsors, obtain patent rights, and generate income to fund further research efforts.

Consequences of FOIA

I would like to take this opportunity to point out some potential problems that the use of FOIA could create for research. First, extension of FOIA to research data may provide an avenue to harass researchers and dissuade research on controversial issues. Some literature prepared by those opposing HR 88 indicate they see the provision as a means to stop government regulation by interfering with the independence of research and discouraging research in areas counterproductive to their interests. Our experience in California with animal rights groups speaks to this point. Some animal rights groups have led harassment campaigns targeted against individual researchers and their laboratories. They have made extensive requests for research records as a way to force our campuses to devote inordinate amounts of staff time and resources to fulfill their requests. At present, UC campuses are able to moderate these situations and work with requestors to limit the potential disruption through a negotiation process that does not exist under FOIA.

Unlike the California example, if FOIA is extended to research data, special interest groups could make data requests solely for the purpose creating the costs and disruptions that are inherent in gathering extensive amounts of raw research data. Under FOIA, the requestor would be the agency, not the group leading the campaign. The University would be obligated to undertake extensive work and involve the time of the targeted researchers, which would be the intention of the action, as well as utilize limited resources and staff time in fulfilling these mandated requests.

Second, the extension of FOIA to research data may have inadvertent consequences for the University's ability to secure successfully patents for research discoveries. This is important for the University of California since we lead the nation in the amount of patent income received by an educational institution, which in turn benefits our campuses and helps support the training of students. Premature disclosure of research results can make it impossible to meet the stringent requirements for obtaining a patent. In one situation, the University developed, under NIH funding, an anti-cancer compound that is now covered by five issued patents and numerous pending patent applications. If the Federal agency had decided under a FOIA request to prematurely release the chemical structure and data on the biological activity, which may have suggested potential anti-cancer use, the University would not have been able to secure strong patent protection. Without a strong patent, it would have been impossible to attract a licensee who would be willing to invest the resources and effort to develop the technology and bring it to the marketplace. The anti-tumor compound is currently in multiple Phase 2 clinical trials aimed at several forms of cancer, such as prostate and ovarian cancers.

Third, the extension of FOIA to research data may compromise university research partnerships with industry. While FOIA has an exemption for commercially valuable proprietary information, there is case law that suggests this exemption may not cover information in the possession of not-for-profit institutions. This is important because universities form industrial partnerships for research. This ranges from individual contracts between one sponsor and one researcher to a broader approach such as the UC

Micro program that brings together State government, University and numerous industrial partners to foster research that has a high potential to benefit the California economy.

Thus, where a researcher is working with data that arises from multiple research grants, including federal agency grants and industry-sponsored grants, the industry sponsor's proprietary information could become subject to a FOIA request, including, potentially, requests made by the industry sponsor's competitors.

Fourth, the extension of FOIA to research data may compromise human subject protocols. Universities will need to undertake an extensive reassessment of research confidentiality agreements, and may, in some cases, be compelled temporarily to suspend lines of research or risk abrogating existing agreements. Because the privacy exemption under the FOIA extends only to individuals, it would not adequately protect the rights and anonymity of entities such as community clinics, hospitals, schools, or other institutions participating in critical but sensitive aspects of research, such as mental illness, sexually transmitted diseases, or drug abuse. Again the mechanism of FOIA for data sharing creates the conflict. The FOIA is administered by the federal agency, not by the researcher who compiles the data. Upon request, the researcher would need to turn over all information, including confidential human subject information, to the federal agency so that the agency could determine what information should be released to the public. The very act of turning over the data to the federal agency could violate assurances of confidentiality made by the researcher to human subjects.

The Potential Administrative Impact

We are concerned that the proposed revision could increase the costs of research for universities and other institutions. From the University's perspective, the FOIA process would result in both increased mandates with the resulting increased costs, while potentially preventing us from protecting important University interests. The requirement to respond to FOIA requests will necessitate our increasing staff to handle the legal and administrative burden. We would have to provide extensive data in response to any request, since we would not have the ability to negotiate directly with the requestor and fine-tune the request to provide the actual data needed. This could divert the time and effort of laboratory personnel in complying with potentially extensive requests for data and documentation.

The University would also need to devote time and effort in identifying sensitive information that should be excluded from disclosure under exemptions provided for in FOIA. And yet, we would have no ability to protect such data should an agency choose to release it.

California Public Records Act

In pointing out the flaws in the FOIA requirements affecting data disclosure, I am aware of another law on data disclosure that may be more appropriate when applied to institutions of higher education. As a California public university, we are subject to the

California Public Records Act, which provides mechanisms for the release of University records upon public request. While most requests have involved administrative records, this law has on occasion been used to request research data.

Unlike FOIA, the Public Records Act provides important safeguards for the University in handling information requests. The Act enables the University and other California state agencies to use a balancing test to determine if the public interest is served best by the release of data. [Cal. Gov. Code sec.6255] Naturally, an agency's decision to withhold information for the public interest can be challenged in courts. The California courts have upheld the balancing test on several occasions.

The other advantage of the California Act is that the agency, in our case the University, has the ability to negotiate directly with the requesting parties. Such negotiations need not be adversarial, as often the requestor really is interested in obtaining a limited set of records and does not want the burden and the expense of having thousands of pages of irrelevant records blindly shipped out to them. Such negotiations, while enabling requests to be handled in an efficient manner, would also enable the University to protect sensitive data. The University has the ability and the incentive to protect such data. Agency staff may not have the ability to fulfill data requests while protecting data that preserves patient privacy, is needed to pursue patent claims, or data in joint research projects that is the private intellectual property of industrial partners.

In Conclusion

The partnership between the Federal government and universities serves the nation in important ways. The direct investment in university-based research promotes the discovery of knowledge, stimulates technological innovation, educates our next generation, and contributes directly to the Nation's economic prosperity and quality of life. Federal investments in university-based research are an integral component of the larger research and development enterprise that has enabled approximately half of the Nation's productivity and growth in the last 50 years.[1] The transfer of knowledge and data from federally-funded research is the vital link to the success of this long-standing relationship. Also vital are the safeguards that are in place to protect the conduct of science including the release of sensitive data, as in the case of confidential human subject research and commercially valuable proprietary information. The public interest is served when scientists can provide human subjects with assurances of confidentiality, and when they can participate with industry sponsors in cutting-edge discoveries that will lead to new products and new jobs. The FOIA provides inadequate protection for these types of sensitive data.

We urge Congress to pass HR 88 and repeal the FOIA provision. We offer our assistance to the authorizing committees and OMB to begin a thoughtful process to review current practices for data sharing and to involve all the interested parties in developing any needed remedies.

I would like to thank the committee for holding this hearing on HR 88 and for creating an opportunity for the university community to voice its strong concerns about FOIA. I welcome any questions or comments from the committee.

[1] "Renewing the Federal Government-University Research Partnership for the 21st Century" *NSTC Presidential Review Directive–4*, April 1999

Mr. HORN. And we're delighted to have Mr. Anthony Obadal, the Washington Council of the Associated Equipment Distributors. Mr. Obadal.

Mr. OBADAL. Thank you, Mr. Chairman. I am truly privileged to appear before this committee, and I want to thank you for the invitation.

Mr. HORN. Now, remember you're under oath. Don't go too far.

Mr. OBADAL. And also the staff as well.

I am—our statement contains not only the viewpoint of the Associated Equipment Distributors but also of the major private sector associations and unions engaged in the construction industry. We all belong to a group called the Transportation Construction Coalition, and that is a coalition of roughly 27 associations and three unions.

We are united in our opposition to any attempt to repeal or delay the Shelby amendment. Our organizations support very strongly the principles of open government. We agree with Justices Marshall and Brennan in Forsham when they wrote that providing access to information enables an electorate to govern itself and that the openness required by the FOIA is "vital to the proper operations of democracy."

The Shelby amendment was generated by the refusal of the Environmental Protection Agency to make available—even though it possessed the power to obtain the data, it refused to do so. They prevented us from looking at the clean air standard regulations and the supporting documents and data that underlined it. Really, hundreds of communities have been affected by this regulation. We saw one estimate that there were 167 counties in 42 States which would be unable——

Mr. HORN. Would you repeat that sentence again—167?

Mr. OBADAL. 167 counties and in 42 states that would be unable to comply with EPA's new regulations.

Reference has been made to the fact that the regulations already have been subject to some doubt because of the errors in estimating the health benefits and lives affected that was made by EPA when they considered these regulations. They were roughly I think 25 percent off in their estimates.

It's not the amount. Every life is important. We all recognize that. It's the error. We think we're lucky to catch that error. What other errors exist in the underlying data that has not been subject to critical review by parties who were directly interested in it? Is it too much to ask that, as citizens, we be allowed to examine and criticize alleged facts and theories that underline governmental regulations? We think not.

And we think there is agreement on this panel. I listened to the excellent questions this morning and the wonderful answers. I think everybody recognizes that this is an extremely important area to look at. Shelby has done a great service in closing this loophole. Marshall's—Brennan, Justice Marshall and Brennan predicted that if this loophole back in 1980 were allowed to exist, a bureaucracy desiring to keep its deliberations secret would begin to use outside sources ad nauseum to justify their decisions. And no one would be able to really criticize those sources.

We are also concerned that the ozone mistake was not unique. For example, the Office of Research Integrity of the Public Health Service recently published a report describing its investigation of scientific misconduct between 1993 and 1997. The report focused on 150 cases. In half of them, misconduct was found involving falsification and involving fabrications of the data.

The New York Times recently reported on a for-profit California research company that was engaged in over 170 studies. The investigation turned up the fact that there were fictitious patients, there were fabricated observations, there were substitution of blood and urine samples. In fact, blood and urine samples were kept in the refrigerator in the office and used as substitution.

We think critical public review will help uncover this and will result not only in better regulation but better science. Now, most of the objections to Shelby concern the fear that the FIA provide—FOIA provides inadequate protection in matters of privacy and intellectual property. I think that was really dealt with extensively this morning. I would only point out that, with respect to privacy, the courts under the decisions cited in our statement to you engage in a balancing in which they can balance the individual's right of privacy against the preservation of the basic purposes of the Freedom of Information Act which is to open agency action to the light of public scrutiny.

So what you're dealing with is a rule that decides these issues on a case-by-case basis. I very frankly think that that is the best kind of rule, because these issues are far too complex to provide simply a rigid standard. Justice requires looking at each individual case, and that's what we do.

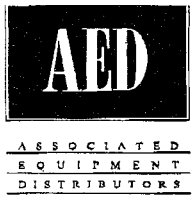
Last, the concern about researchers being beat to the publication table by someone who gets their data early, I think that's a very valid concern. However, I think that the Shelby amendment provides sufficient discretion in the OMB to deal with it and they have tried to with the word "publish" that they're using. Shelby, I notice there was some comment that there was no basis for the OMB latching onto that. I don't think that's correct. To the contrary. Shelby uses the word produce. All data produced under an award.

What does that word mean? Well, when you take a look at Webster's and in Oxford and in Black's Law dictionary and start looking at cases, you mean—it means bringing forth for scrutiny, bringing forth for review. I think until those—the report is brought forth, that the documents can be kept secret.

I know I'm running over my time. But I wanted to thank this committee.

Mr. HORN. Thank you. We appreciate it.

[The prepared statement of Mr. Obadal follows:]



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STATEMENT OF THE ASSOCIATED EQUIPMENT DISTRIBUTORS TO THE UNITED STATES HOUSE OF REPRESENTATIVES GOVERNMENT MANAGEMENT, INFORMATION AND TECHNOLOGY SUBCOMMITTEE

15 July 1999

Chairman Horn, Representative Turner, and other distinguished members of the House Government Management, Information, and Technology Subcommittee, my name is Anthony J. Obadal and I am counsel to the Associated Equipment Distributors. These comments are submitted on behalf of the AED and express the association's concerns about HR 88. AED represents independent, authorized distributors of construction, mining, and forestry equipment. The equipment AED members sell, rent, and service is used to build the infrastructure of this country, from homes to office buildings to roads.

At the request of its chairmen, we are also submitting to you the comments of the Transportation Construction Coalition previously sent to the members of the House Appropriations Committee during their consideration of a measure similar to HR 88. The TCC is a coalition representing 27 construction industry trade associations and labor unions. Its chairmen are Dr. Peter Ruane, president of the American Road and Transportation Builders Association, and Steven Sandherr, executive director of the Associated General Contractors of America. Their statement is attached as Appendix A.

These construction industry representatives are united in their strong opposition to HR 88. They believe that the American people should have access to the data underlying research paid for with taxpayer money and used to develop major government policies and regulations.

In 1997 the Environmental Protection Agency promulgated new National Ambient Air Quality Standards that severely threaten growth in many localities throughout the nation. Despite the massive cost of implementing those regulations – estimated at more than $100 billion per year – EPA has refused to allow the public to examine the research data on which the regulations are based. In response, and to prevent similar refusals from occurring, Senator Richard Shelby authored legislation (enacted last fall) that would require agencies to make available to the public all data produced by federal grantees. That legislation is now under severe attack and would be repealed by HR 88.

We consider the Shelby amendment to be the most important regulatory reform enacted into law in recent memory. It represents a major step forward for the democratic process and for scientific truth and accuracy. It is axiomatic to say that parties affected by government actions should have the right to understand the basis for those actions and the right to challenge them in an intelligent manner. The Shelby amendment was intended to do nothing more than give citizens access to the research data paid for with their tax dollars. Such research data is frequently used to formulate policies and regulations that substantially affect they way we conduct our lives and earn our livelihoods.

Background

The problem before the committee had its inception in 1980 with the Supreme Court's decision in *Forsham v. Harris*.[1] There, the Court was asked to decide the question of whether data generated by a privately controlled organization that received federal grants were "agency records" within the meaning of the Freedom of Information Act.[2] The Court concluded that third party grantees and researchers were not "agencies" under the terms of the law as it was then written and that their records and data could not therefore be reached as "agency records" under the FOIA.

Justices William Brennan and Thurgood Marshall strongly dissented from that decision. Prophetically, they predicted that the Court's decision would result in the growth of the use of grantees by the federal government and that bureaucracies would at the same time seek to protect the basis of their decisions from public scrutiny. Brennan and Marshall wrote that:

> . . . the Court's approach [i.e., the majority's] must inevitably undermine FOIA's great purpose of exposing Government to the people. It is unavoidable that as the work of federal agencies mushrooms both in quantity and complexity the agencies must look to outside organizations to assist in government tasks. Just as the explosion of federal agencies, which are not directly responsible to the electorate, worked to hide the workings of the Federal Government from voters before enactment of FOIA . . . the understandable tendency of agencies to rely on nongovernmental grantees to perform myriad projects distances the electorate from important information by one more step. If the records of such organizations, when drawn directly into the regulatory process, are immune from public inspection, then government by secrecy must surely return.[3]

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[1] 44 U.S. 169 (1980).

[2] 5 U.S.C. § 552.

[3] *Forsham*, 44 U.S. at 191.

The two justices also observed that public, critical evaluation of the data behind research reports relied upon by federal policymakers is essential to the democratic process. The FOIA, they wrote,

> is a broad enactment meant to open the processes of Government to public inspection. It reflects a finding that if left to themselves, agencies would operate in near secrecy. FOIA was, therefore, enacted to provide access to information to enable 'an informed electorate,' so 'vital to the proper operation of a democracy,' to govern itself.[4]

After almost 20 years, the Shelby amendment legislatively overturned the majority's decision in Forsham and the public now has a powerful tool to judge and hold the government accountable for its actions. The check on government authority provided by the Shelby amendment is essential, both to ensure public confidence in the credibility of the government and to ensure sound science. Research work funded by the federal government is of major importance to the nation. But the perceived and highly limited threat to the operations of research institutions must not be allowed to transcend the more important concepts and protections of the democratic process.

Public Oversight is Essential

Although the vast majority of their work is of the highest quality and integrity, research institutions are not free of error or deliberate falsification. After EPA's announcement of the new air standards in late 1996, mistakes were uncovered almost immediately based upon the limited information that had been made public. Statistical errors were discovered by Dr. Kay

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[4] *Id.* at 188 (citing S. Rep. No. 813, 89th Cong., 1st Sess., 3 (1965)).

Jones, a former Carter administration environmental advisor. Having initially claimed that 40,000 lives would be saved by the new standards, following Dr. Jones' criticism, the EPA downgraded that figure to 20,000 by February of 1997 and then to 15,000 two months later. Jones recalculated EPA's statistics and determined that when they were corrected, the number of lives at risk appeared to be fewer than 1,000. Her results were published by the Citizens for a Sound Economy in May, 1997. Any loss of life is significant, but the public has a right to examine what other errors may exist with respect to the EPA findings and EPA has refused to obtain that data from the research institutions it relied upon.

This example is not unique. The Public Health Service's Office of Research Integrity recently released a report describing its investigation of allegations of scientific misconduct between 1993 and 1997. The report focused on 150 scientific misconduct cases closed by the office over the course of this period. According to the ORI, misconduct was found in fully half of those cases. The ORI reported that

> Falsification was the most frequent type of misconduct that resulted in an investigation, it was involved in four of every five investigations either alone or in combination with other types of misconduct, especially fabrication. Fabrication was the second most frequent type of misconduct that resulted in an investigation, plagiarism was third.[5]

Similar evidence of the fallibility of the research process emerged in May of this year, when reports surfaced concerning a prominent West Coast research company that had been engaged in over 170 medical studies. Whistle blowers revealed fraud of auspicious proportions

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[5] Department of Health and Human Services, Office of Research Integrity, *Scientific Misconduct Investigations: 1993-1997*, <http://ori.dhhs.gov/PDF/scientific.pdf>.

involving fictitious patients, fabricated observations and substitutions of blood and urine samples. "Bodily fluids that met certain laboratory values," *The New York Times* reported, "were kept on hand in the office refrigerator, ready to be substituted for the urine or blood of patients who did not qualify for studies."[6] Although this particular case did not involve a federal grantee, it is symptomatic of the type of research fraud that can and, fortunately, only rarely, does occur elsewhere.

The Shelby amendment is a check on such scientific misconduct and increases the likelihood that mistaken or erroneous data that is generated will be detected before it is allowed to work any mischief on the policy process. Scrutiny by the public and by interested parties should provide a healthy and vigorous environment that encourages accuracy and the soundness of scientific research.

Criticism of the Openness Doctrine

Critics of the Shelby amendment express two major concerns: that medical privacy is threatened and that intellectual property rights are jeopardized. While no law is perfect, the Freedom of Information Act certainly is not a "clumsy tool" as some have suggested. Rather, it represents three decades of judicial and legislative thought and adequately addresses these issues.

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[6] Kurt Eichenwalkd and Gina Kolata, *A Doctor's Drug Studies Turn Into Fraud*, N.Y. Times, May 17, 1999, at A1.

Personal Privacy: Exemption 6

Exemption 6 of the FOIA prohibits public disclosure of "personnel and medical files . . . which would constitute a clearly unwarranted invasion of personal privacy."[7] The Supreme Court noted in *Dept. of the Air Force v. Rose*, that Congress' purpose was "to construct an exemption that would require a balancing of the individual's right of privacy against the preservation of the basic purpose of the Freedom of Information Act 'to open agency action to the light of public scrutiny.'"[8] Pursuant to *Rose*, the courts are tasked with determining the existence and degree of privacy intrusion and balancing it against the public's interest in disclosure. Each case is decided on its own merits. A fairer and more reasonable approach to resolving competing interests would be difficult to develop.

Critics also urge that individuals might not participate in federally-funded research studies if they know that their records might be made available to government.[9] However, if such an impact is more than mere speculation, it would obviously impair the government's ability to obtain information necessary for its operations in the future and would therefore likely result in the courts sustaining an agency's decision to withhold data from public scrutiny.[10] But,

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[7] 5 U.S.C. § 552(b)(6).

[8] 425 U.S. 352, 372 (1976).

[9] *See, e.g.*, Statement of the National Academy of Sciences to the Office of Management and Budget regarding modifications to OMB Circular A-110 proposed at 64 Fed. Reg. 5684 (1999).

[10] *See, e.g.*, *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983); *9 to 5 Organization for Women Office Workers v. Federal Reserve System*, 721 F.2d 1 (1st Cir. 1983) (applying this test to business information).

the fact of the matter is that in today's society, waivers are signed by patients, almost as a matter of course, to facilitate insurance coverage or to allow them to participate in private or government-funded research studies. Insurance companies, government service payers, welfare agencies, professional accrediting agencies, licensing agencies, and public health agencies are all involved and can gain access to medical records in the course of their work.[11] There are also an enormous number of situations in which physicians are compelled by law or regulation to reveal information to outside parties. Medical testimony is frequently introduced in criminal cases and in civil cases involving negligence, divorce, child custody, or medical malpractice.

In these circumstances, the possibility of lack of cooperation with federal research work is not substantial. Moreover, under the FOIA, the courts and agencies have been sensitive to matters of medical privacy. *In camera* inspection proceedings may be provided and identifying details are frequently "blacked out" or otherwise not made available.

Trade Secrets and Commercial Information: Exemption 4

Federal law also amply protects intellectual property rights. The FOIA's Exception 4 provides that the Act does not apply to matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[12] The term "trade secret" has been defined by the courts to mean "a secret, commercially valuable plan, formula,

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[11] *See* Evan Hendricks et al., *Your Right to Privacy: A Basic Guide to Legal Rights in an Information Society* (The American Civil Liberties Union 1990).

[12] 5 U.S.C. § 552(b)(4).

process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[13] Commercial or financial matters are considered to be confidential for purposes of FOIA Exemption 4 if "disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained."[14] Critics are concerned that this exemption will not protect not-for-profit grantees because they do not engage in commerce. However, the courts have held that although the non-profit status of the entity from which the information is obtained may be considered, it is "not determinative of the character of the information."[15]

Concern is also expressed that underlying data will be sought before the grantees have the opportunity to analyze and publish their conclusions to the severe "disadvantage [of] federally-funded scientists while providing unreasonable advantages to their competitors."[16] They also suggest that a "researcher's publication prospects" could be harmed by such a

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[13] *Public Citizen*, 704 F.2d at 1288.

[14] *National Parks & Conservation Ass'n. v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).

[15] *Critical Mass Energy Project v. NRC*, 830 F.2d 278, 281 (D.C. Cir. 1987) (Nuclear industry trade association's reports held "commercial" because information would affect profitability of constituent commercial utility companies); *see also American Airlines, Inc. v. National Mediation Board*, 588 F.2d 863, 870 (2nd Cir. 1978) (Information is commercial if it relates to commerce).

[16] National Academy of Sciences statement to OMB, *supra* note 9.

release.[17] This issue clearly may be resolved by the Office of Management and Budget in its proceedings to implement the Shelby amendment. OMB has already proposed that disclosure follow "publication" of research results. The Shelby amendment itself refers to data "produced" under an award. The Concise Oxford Dictionary defines the verb 'produce' to mean to "[b]ring forward for inspection or consideration . . .[or] [b]ring . . . before the public."[18] Blacks Law Dictionary similarly defines the verb 'produce' to mean "[t]o bring forward; to show or exhibit; to bring into view or notice . . .."[19] Thus, under the language of the Shelby amendment, OMB has the discretion to direct agencies to await a researcher's public presentation of their report before making it available under the FOIA.

Other statutes also protect the ownership rights of researchers working under government grants. These include the Trade Secrets Act, the Technology Transfer Act, the Bayh-Dole Act, and the Patent Act. A brief summary of these protections prepared by Charles Fromm, executive director of the Center for Regulatory Effectiveness, is attached to this statement as Appendix B.

Conclusions

The overriding consideration with respect to the Shelby amendment is its direction to make available to the public information essential to an understanding and criticism of governmental action. Such open government is necessary to the success of the democratic

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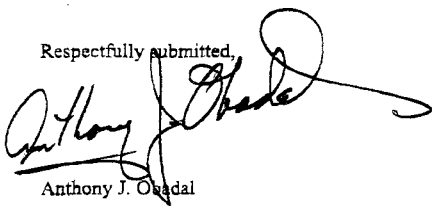
17 *Id.*

18 The Concise Oxford Dictionary 884-885 (6th ed. 1976).

19 Blacks Law Dictionary 1209 (6th ed. 1990).

process and will, in the long pull, enhance and improve scientific research. Government policy and regulation play an increasingly important role in our lives and in the lives of our businesses. The Shelby amendment provides a needed check on the government and prevents abuse of the enormous power vested in the bureaucracy. We therefore request that this committee reject H.R. 88.

Respectfully submitted,



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For More Information:
202/289-4434 (ARTBA)
202/842-2040 (AGC)

May 24, 1999

The Honorable C.W. Young
Chairman
House Appropriations Committee
U. S. House of Representatives
2407 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

We are writing to express the Transportation Construction Coalition's concern regarding efforts to modify or reverse language contained in last year's Omnibus Consolidated Emergency Supplemental Appropriations Act for FY 1999 (PL 105-277). The language in question directed the Office of Management and Budget to amend OMB Circular A-110 to require all data produced under an award or grant from the federal government to be made available to the public through the procedures established under the Freedom of Information Act. We ask that you oppose these efforts and that you protect the progress made last year to promote openness in government and eliminate federally funded "secret science."

Background

Secret science has, over the years, formed the basis of several controversial government policies, including the Environmental Protection Agency's recently-promulgated ambient air quality standards for airborne particulate matter. Because the data on which these policies were based was generated by federal grantees and not by specific federal agencies, the public has been unable to access the underlying data through the Freedom of Information Act. This has prevented an objective review of the data and an independent analysis of the conclusions reached about it by federal agencies.

Last year, following an episode in which they themselves were denied access to the data that forms the basis for EPA's new air quality standards, several lawmakers, led by Senator Richard Shelby (R-AL), secured passage of legislation to require the Office of Management and Budget to make changes to internal government policies regarding access to the information generated by recipients of federal research grants. The statutory language, which was included in the FY 1999 Department of Transportation Appropriations Act (PL 105-277), requires the OMB to modify its Advisory Circular A-110 ("Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations") "to ensure that all data produced under an award will be made available to the public through the procedures established under the [Freedom of Information Act]." OMB published its proposed modification to

A-110 in the *Federal Register* in February and the comment period for the proposal closed on April 5th. At this point, we are waiting to see whether the final OMB policy will fully implement last year's statutory language.

In the meantime, our coalition is very concerned about efforts currently underway to undermine public access to federally-funded research by repealing or modifying last year's statute. Representative George Brown (D-CA) has introduced legislation (HR 88) that would eliminate the Shelby amendment outright and return the veil of secrecy to the public policy formulation process. We are also aware of efforts to use the appropriations process to quietly stay the implementation of the Shelby amendment. We ask that you vigorously oppose both these initiatives.

TRANSPORTATION
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Advocates for a return to secrecy have advanced the position that the Shelby amendment will undermine studies by federal contractors by intruding on the privacy of individuals who are the subject of those studies. These assertions are without merit. The Shelby amendment only requires that federally-funded data be available to the extent required by the FOIA. Since the FOIA's enactment in 1966, several exceptions to it have been carved out by Congress and developed by the courts. Two of the most important of these are the personal privacy and proprietary business information exceptions, which will more than adequately protect the subjects of federally-funded research.

Conclusions

Put simply, closed government is inconsistent with the basic principles of our democracy. *In a free society voters must be permitted access to the information that forms the basis of public policy decisions.* We therefore repeat our request that you oppose any efforts to repeal or stay the implementation of Senator Shelby's secret science amendment and that you support efforts to ensure that the statutory language enacted last year is fully implemented by the OMB.

Thank you for your consideration of our position. If you would like additional information about this important issue, please do not hesitate to contact us.

Sincerely,

The Transportation Construction Coalition

Appendix B

Center for Regulatory Effectiveness

THREE KEY PROTECTIONS FOR INTELLECTUAL PROPERTY UNDER THE NEW FEDERAL DATA ACCESS LAW: FOIA, THE BAYH-DOLE ACT, AND AGENCIES' CONFORMING REGULATIONS

The Center for Regulatory Effectiveness
June 1999

Executive Summary

- *Legislative and Regulatory Status*

  - 1998 legislation ("the Shelby Amendment") directed OMB to revise Circular A-110 to make all data produced under federal awards available to the public through FOIA.

  - OMB is now implementing the new law. OMB published a proposed revision to A-110 in February 1999 and is currently reviewing the comments it received.

  - The Price/Walsh Amendment to FY 2000 Budget would put OMB on hold for one year while the National Academy of Public Administration studies the issue.

- *Opponents claim* public disclosure of data will threaten intellectual property rights.

- ***Three blanket protections*** for intellectual property interests exist, however:

  1. **FOIA Has Specific Non-Disclosure Exemptions for:**

     - Material exempt under other statutes, such as the Patent Act
     - Trade secrets and confidential commercial information

  2. **Bayh-Dole Act**

     - Gives researchers title to inventions created through federal research
     - Contains confidentiality provisions protecting researcher/patent applicants
     - Statutory trump card, takes precedence over new data access law

  3. **Agency Conforming Regulations**

     - Individual agencies conduct rulemaking following OMB's A-110 revision.
     - Regulations can be tailored to address agency-specific issues.
     - Conforming regulations cannot restrict, only expand, A-110's protections.
     - Public has full right of comment and participation at agency level.

- *Contact:* Charles J. Fromm
  Executive Director, CRE
  (202) 265-2383

Mr. HORN. Dr. Thurston. Dr. George D. Thurston is associate professor, Environmental Medicine, New York University. Glad to have you here.

Mr. THURSTON. Thank you.

I'm here today to discuss the many negative consequences of the recent changes made to Circular A–110 provisions regarding the mandated release of government-funded research data.

The Shelby amendments are insidious in that they seem at first glance to be in the public's interest, but they are not. The amendment's stated goal is to make all data from federally funded scientific research readily available to the public, but this new provision will instead most likely be employed by powerful and wealthy special interests in order to squelch government-funded public research results and information that they do not welcome. Thus, the recent revisions will actually hurt the American's public right to know, not enhance it.

Among the specific harms that will be caused by these new regulations and that can be avoided by the passage of H.R. 88 include compromised patient confidentiality. As Mr. O'Reilly earlier stated, the Shelby provision doesn't change the rules of FOIA. Instead, it just adds these to the group that can be FOIA'd. But the rules were not designed to deal with the research data of this type. This is—FOIA is inappropriate for this application.

Another fact is higher research costs, a slowing of scientific progress, and regulatory delay. As Mr. Hahn wrote in his paper, the release of data could slow the development of data and delay the publication of results.

If you look at the Harvard six-city study that's been bantered about here, and misrepresented I might say, there are over 100 publications that have come from that study, not 1. And if all that data were released after the first publication, that would have been a taking of property from those researchers who did all the work, decades of work. They would have had to give up that data, and other researchers would have had open access to that. So they would have lost, basically, their property. Their intellectual property and academic freedom is really infringed.

So Mr. Miller's danger of delay is really applied to delay of regulation. The Chamber of Commerce on their webpage points out that agencies will have a much harder time imposing regulations on the business community as a result of Circular A–110. This Circular A–110 provision is not going to speed things up. It's going to, as the Chamber of Commerce points out, delay regulations. This isn't regulatory reform. This is much more than that. It's regulatory annihilation, I think, in some cases. They're just going to be able to take regulations and stop them in their tracks, at will.

Researcher harassment is another problem. By making research data subject to inquiries, vested interests can easily tie up researchers' time and energy by filing endless requests for data. Additionally, once they have the data in hand, past experience with State open records and Freedom of Information Act laws indicates that vested interests will aim to discredit the data and/or its analysis, irrespective of its merits.

Based on my investigation into this issue, I conclude that it will be impossible to craft limitations that can overcome the inherent

flaw of using FOIA procedures to achieve broader access to Federal funded research data.

As Mr. Miller said in the last panel, it's the summary of the data that's important. But the Shelby provision sets no such limit. As was discussed, the OMB regulations will likely be thrown out in court. So we're really dealing with what's in the law, which has no limits. Thus, FOIA is not an appropriate mechanism for assuring the proper sharing and testing of scientific data.

But let me discuss how I came to these conclusions. In late 1997, I was asked to write an article for the Tulane Environmental Law Journal on the issue of the forcing of scientists to give unrestricted release of their health research data. As I started out the research I, like most people, first thought a requirement for the release of data from government-funded research was not unreasonable. However, as I investigated the past history of cases in which data had been released to special interests, my eyes were opened to the intractable problems and grave dangers of such a requirement.

In my article, I summarize the case of Dr. Herb Needleman and his research on adverse effects of lead exposures on children. As part of a government lawsuit against polluters, Dr. Needleman had to make his research records available for examination by the lead industry. While the case was eventually settled out of court, a lengthy document accusing Dr. Needleman of scientific misconduct was forwarded to the NIH based on these data.

After an NIH hearing, Dr. Needleman was finally cleared. But he concluded, "If my case illuminates anything, it shows that the Federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time while defending himself."

Another case is that of Dr. Paul Fisher, who investigated the effects of tobacco company advertising on children. RJ Reynolds responded to his research by hiring consultants to analyze the studies and subpoenaed the research data. Because of State open records regulations, the Medical College of Georgia turned over the documents. Consultants to the cigarette industry then started criticizing his research, even though his research results were later independently confirmed. Dr. Fisher resigned in disgust and entered private practice in medicine. So researchers can be driven out of this practice by these freedom of information rules.

Ironically, documents uncovered, in the Attorney General's tobacco settlement clearly shows that the tobacco industry had specifically designed their advertising to get kids smoking, just what Dr. Fisher had said years before.

As recently noted by Deyo and colleagues in an article in the New England Journal of Medicine on this issue using yet other cases, "the common theme in these examples is an attack through marketing, professional, media, legal, administrative or political channels on scientific results that ran counter to financial interests and strong beliefs. Freedom of Information requests, subpoenas and complaints to the Office of Research Integrity were analogous to SLAPP suits."

Thus, policies as democratic and important as the Freedom of Information requirements can be and have been employed as mechanisms for vested interests to attack the messenger when the message is financially or politically unwelcome to the interest group involved.

It's inevitable that the same things will happen if the Shelby amendment is allowed to be implemented. The amendment purports to be a public right-to-know provision, but it is in fact quite the opposite. The Shelby Circular A–110 provisions will open the gate to special interests to destroy government funded research in the United States at will. This will allow them to once again set the research agenda by controlling publicly funded research the way they have controlled and hidden their own industry research from the public in the past, such as asbestos and lead effects.

Before the Federal Government started doing research into these areas, the public never knew. Industry did their research, they knew of their effects, they put it in a file drawer and locked it. And now we have federally funded research to let people know. This will give industry special interests the chance to undermine federally funded research that informs people about the adverse effects of pollutants and other hazards in their lives.

If the Congress passes——

Mr. HORN. I am going to have to interrupt on that.

Mr. THURSTON. I'm almost done.

Mr. HORN. What do you mean undermine? Explain it to me.

Mr. THURSTON. Well, you won't be able to use it, and people won't be able to do their research. Because they'll raise questions. It will come up for regulation. They'll get the data. They'll raise questions. You won't be able to go forward with the regulatory process. And, meanwhile, the researchers won't be doing any research because they'll be spending all their time——

Mr. HORN. Isn't that the way the scientific method operates anyhow? You have colleagues that review the data see if they can replicate it?

Mr. THURSTON. No, that isn't really exactly how it works. Other researchers generate their own data, and they see if they can replicate the results. There are situations, such as the Harvard data, where they did give up their data. I don't know what all this talk is about that they won't give up their data. EPA did request their data. They did give their data up to the Health Effects Institute in an agreement, and the Health Effects Institute reviewed that data and redid their analysis and confirmed every aspect, as far as I know, of the results of that study.

That's an excellent example for showing how the Circular A–110 provisions aren't needed, not the other way around.

Everybody seems to be using this Harvard six-city study as an example. It's an excellent study. It was also subject of an OSI investigation a number of years ago. As I reported in my paper, the OSI came out and said not only did they do the things right, this is almost a textbook case of the way one should do a study. So this is an excellent study in that they have provided their data. They just didn't want to hand it over because patient confidentiality is crucial, and that was what they stood on.

Mr. HORN. I think we all agree on that.

Mr. THURSTON. Thank you. So I feel that Congress, if it passes H.R. 88, will be properly acting to protect the public's primary source of unbiased scientific information, government-funded, peer-reviewed research.

And, last, I would just like to say that if you have any questions about this Harvard study, I do work in that field so I am familiar with what has happened with that, and with these air pollution regulations, which no one has been damaged by. They haven't been implemented. I mean, the way the administration wrote it, there is over a decade before the States really have to implement it. So no one has been harmed by that regulation.

And the error that Mr. Obadal was talking about it, was by EPA. They misread the paper. When someone went through and carefully read the paper, they found that the EPA had used median value and interpreted that as a mean. But when they carefully read the paper, it was all right there. There was no reason to request the data. The correct information was included in the paper. EPA just merely failed to read the paper correctly.

Mr. HORN. Thank you very much.

[The prepared statement of Mr. Thurston follows:]

STATEMENT OF DR. GEORGE D. THURSTON, Sc. D.

TO THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON

GOVERNMENT MANAGEMENT, INFORMATION AND TECHNOLOGY

OF THE U.S. HOUSE OF REPRESENTATIVES

RE: THE MANDATED RELEASE OF GOVERNMENT-FUNDED RESEARCH DATA

JULY 15, 1999

I am George D. Thurston, a tenured Associate Professor of Environmental Medicine at the New York University (NYU) School of Medicine.

I am also the Director of the National Institute of Environmental Health Sciences' (NIEHS) Community Outreach and Education Program at NYU. One goal of this program is to provide an informational resource on science issues to decision-makers, and that is my goal in testifying to you. Today, I am here to discuss the many negative consequences of the recent changes made to the Circular A-110 provisions regarding the mandated release of government funded research data.

The Shelby amendments to Circular A-110 are insidious in that they seem at first glance to be in the public's interest, but they are not. The amendment's stated goal is to make all data from federally funded scientific research readily available to the public. As a recent Washington Post article[1] that reported on the potential problems of the Shelby provision rhetorically asked: "How could anyone, especially scientists, be against openness and the public's right to examine or better understand science?" (Article attached). But as I shall discuss, this provision (that was slipped into the 1999 Appropriations Bill at the last minute without the benefit of hearings or debate) will, in all likelihood, not usually be invoked by members of the general public. This new provision will instead most likely be employed almost exclusively by powerful and wealthy special interests in order to squelch government-funded public research results and information that they do not welcome. Thus, the recent revisions will actually hurt the American public's right-to-know, not enhance it.

Among the specific harms that will be caused by these new regulations, and that can be avoided by the passage of H.R. 88, include:

- Compromised Patient Confidentiality -- Giving anyone access to original research data will violate confidentiality given to people who participate in clinical studies and epidemiological field studies. It will also make people less willing to participate in future research projects.
- Higher Research Costs -- The Circular A-110 provision would require duplicative copies of data sets that will increase costs for the researchers. Additionally, the federal granting agency would have the additional costly responsibility for keeping data and evaluating public requests for data.
- Researcher Harassment -- By making research data subject to inquiries, vested interests can easily tie up researchers' time and energy by filing endless requests for data. Additionally, once they have the data in hand, past experience with state open-records or Freedom of Information Act (FOIA) laws indicates that vested interests will aim to discredit the data and/or its

analysis, irrespective of its merits. This will force researchers to expend significant additional time, energy, and resources to defend the validity of their data and analyses, all at the expense of productive research efforts to meet the aims of the affected scientists and their research sponsors.

Based upon my investigation into this issue, I conclude that it will be impossible to craft limitations that can overcome the inherent flaw of using FOIA procedures to achieve broader access to federal funded research data. FOIA is not an appropriate mechanism for assuring the appropriate sharing and testing of scientific data.

But let me discuss the history behind the Shelby Amendment, and how I came to these conclusions.

In late 1997, I was asked by the Tulane Law School Review to write an article for the Tulane Environmental Law Journal on the issue of the forcing of scientists to give unrestricted release of their health research data. This request was prompted by 1997 Congressional hearings regarding the science behind the latest Clean Air Act standards set by the U.S. EPA, as well as by a previous controversial research data release amendment to a 1998 Appropriations bill in the U.S. House of Representatives that was proposed in July, 1997 by Representative Robert Aderholt.[2] If passed, the Aderholdt amendment would have required researchers with government grants to make their raw medical and scientific data publicly available within 90 days after the first public reporting of any study results. No hearings were held on the implications of such a step.

According to the journal Science, the data release amendment proposed by Representative Robert Aderholt of Alabama was, in part, a response by the Congress "to industry demands for data from a Harvard University air pollution study",[3] the results of which were at the center of proposed new air pollution regulations. The study's authors had objected that making their raw research data publicly available would violate the crucial confidentiality agreements they had made with study subjects to protect their individual privacy. Although these Harvard researchers were willing to share their data with other scientists when that confidentiality could be protected, they were not willing to capitulate to unrestricted release of their research participants' personal health records.[4]

In the days that followed Mr. Aderholt's Congressional proposal, numerous confidentiality, logistical, and fairness objections came to light from

other legislators, the Clinton Administration, and from the nation's research universities.[4] Representative George Brown, ranking minority member of the House's Science Committee, expressed his "deep concern", and that "the amendment as drafted would create significant legal uncertainties and substantial and unnecessary costs for scientists, research universities, high tech industries, and federal agencies."[5] In addition, the White House Office of Management and Budget enumerated potential problems, including the impeding of commercial agreements and the risk of problems if the data were not analyzed correctly by others unfamiliar with the data collection process.[5]

In the end, this particular Congressional amendment was defeated by a vote of 19 to 34[6], but it was expected that this issue would surface again as demands for Congressional action were deemed likely to continue due to other regulatory measures being questioned by special interests. As a result, and since I was familiar with both the scientific and policy aspects of this issue, the Tulane Law Journal editors contacted me to write an article on this issue. A copy of the resulting article is attached to this testimony.[7]

As I started my research into this issue, I, like most people, first thought that a requirement for the release of data from government funded research was not unreasonable. However, as I investigated the past history of cases in which data had been released to special interests, my eyes were opened to the intractable problems of such a requirement, and of the grave dangers that are part and parcel of any such scientific data release measure.

I quickly learned that it is not necessary to speculate what might occur if these recent Circular A-110 revisions are allowed to stand. Past experience tells us much about the negative consequences that result when health researchers are forced to give open access to their data.

In my article, I summarize the case of Dr. Herb Needleman and his research on the adverse effects of lead exposure on children that provides one relevant case in point.[8] As part of a lawsuit brought by the Department of Justice against three lead polluters, Dr. Needleman had to make his research records available for examination in 1990 to witnesses on behalf of the lead industry. While the case was eventually settled out of court, a lengthy document critiquing Needleman and his research was forwarded to the National Institutes of Health based on these data.

As reported by Dr. Needleman[8]:

> "These kinds of issues are generally considered methodological disagreements and are fought out in the pages of journals; I could not understand why they were defined by my critics as scientific misconduct. Similar criticisms were raised before the EPA in 1982 and dismissed. These facts not withstanding, in October of 1991, I was notified by the Dean of my medical school that an inquiry into charges of misconduct was being done at the instruction of NIH..."

Months after the hearing, Dr. Needleman was finally cleared, but he concluded that[8]:

> "If my case illuminates anything, it shows that the federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time, while defending himself."

Dr. Needleman's situation was also reported in an article in The Chronicle of Higher Education, along with that of a researcher who investigated the effects of tobacco company advertising on children, Dr. Paul Fischer[9]. Dr. Fischer's research was one of several studies published in the Journal of the American Medical Association that indicated children's attraction to the Camel cigarette "Joe Camel" advertising character.[11] R.J. Reynolds (RJR) responded to the research by hiring consultants to analyze the studies and subpoenaed the research data supporting each of the studies. The company demands reportedly included that "the researchers supply the names and telephone numbers of all of the children who had participated in the studies". As described by the Chronicle [9]:

> "Paul Fischer expected his college to back him. The request, he says, violated 'the principles of confidentiality and academic freedom.' Instead, the Medical College of Georgia sided with the tobacco company. Last year, it turned over the documents...Consultants to the cigarette industry then started criticizing his research. In disgust over the

college's response, Dr. Fischer resigned and entered private practice in medicine."

Since then, the substance of Dr. Fischer's research has been verified by others, while R.J. Reynolds memoranda have recently been made public which indicate that the company had indeed specifically targeted children in their advertising[10].

The Needleman and Fischer experiences are hardly unique, as the financial incentives to interest groups for such attacks on researchers are large. For example, another recent case of researcher harassment was documented in a May, 1998 Associated Press story about Deborah Swackhamer of the University of Minnesota (see attached copy)[11].

As recently noted by Deyo and colleagues in an article in the New England Journal of Medicine[12]:

> "Attacks on health researchers are not new. Pierre Louis, for example, was vilified nearly two centuries ago for suggesting that bloodletting was an ineffectual therapy. In an open society such as ours, controversy is common and often socially useful. The fact that scientists are sometimes challenged by special-interest groups should be no surprise. However, with widening media coverage of health research, growing public interest in health hazards, and expanding research on the outcomes of clinical care, such attacks may become more frequent and acrimonious. The huge financial implications of many research studies invite vigorous attack."

Deyo and colleagues go on to discuss three cases in other disciplines illustrating "how vituperative such attacks may be and the range of tactics employed", including: spinal-fusion surgery; multiple chemical sensitivity; and, pharmaceuticals. The authors conclude that[12]:

> "The common theme in these examples is an attack - through marketing, professional, media, legal, administrative, or political channels - on scientific results that ran counter to financial interests and strong beliefs. In each case, funding for the research involved peer

> review and the offending results were published in peer-reviewed journals. The interested parties had financial stakes in maintaining their market share or the legitimacy of a model of illness or a particular treatment. Their responses, which by-passed peer-reviewed scientific debate and further research, were nonscientific and aimed at discrediting the findings, investigators, or funding agencies. In each case, the attacks intimidated investigators, discouraged others from taking up the same lines of investigation, and took up the time of investigators and staff with legal, professional, and media responses.
>
> The intent is to turn the tables on claimants, force them from a political to a judicial forum, and cast them as defendants. In our cases, freedom-of-information requests, subpoenas, and complaints to the Office of Research Integrity were analogous to SLAPP (strategic lawsuits against public participation) suits."

Thus, policies as democratic and important as the Freedom-of-Information requirements can be subverted and employed as mechanisms for vested interests to "attack the messenger" when the message is financially or politically unwelcome to the interest group involved.

It is inevitable that the same things will happen if the Shelby amendments to Circular A-110 are allowed to be implemented. The amendment purports to be a public "right-to-know" provision, but it is in fact quite the opposite. The Shelby Circular A-110 provisions will open the gate to special interests to destroy government funded research in the U.S. at will, allowing them to once again set the nation's research agenda by controlling publicly funded research the way they have controlled and hidden their own industry research from the public in the past. If the Congress passes H.R. 88, it will be properly acting to protect the public's primary source of unbiased scientific information: government funded, peer-reviewed research.

Thank you for this opportunity to speak to you regarding this issue of importance to the scientific community, and to the nation.

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Research Law Fight: Right to Know, or to Squelch?

By John Schwartz
Washington Post Staff Writer

It seemed like such a simple idea at first: Make all data from federally funded scientific research more available to the public. How could anyone, especially scientists, be against openness and the public's right to examine or better understand science?

But it has turned out to be far from simple. The federal law intended to make that happen has triggered loud and angry opposition from the scientific community.

"This is a meat-ax approach to access to data when it's actually a fine scalpel that's required," said Mary Ellen Sheridan of the University of Chicago at a recent forum on the issue held at the American Association for the Advancement of Science.

Scientists and the institutions they work for say the law will add to the costs of research, will be used to harass and intimidate researchers whose work angers powerful interest groups and companies, and could expose their work to the prying eyes of potential academic and commercial competitors. They contend that it will even imperil the privacy of people who volunteer for research projects.

Sen. Richard C. Shelby (R-Ala.) said he sponsored the bill, passed by Congress at the end of last year, after he was refused access to Harvard School of Public Health studies that the Environmental Protection Agency used to develop controversial new air pollution rules.

EPA Administrator Carol M. Browner said she could not release the data because it belonged to Harvard; the university had refused to hand the data over to critical industry groups such as the American Petroleum Institute. The Harvard researchers eventually turned the data over to a third party for review, but Shelby wasn't mollified.

"The taxpayers are paying billions of dollars for scientific research that they have a right to have access to," Shelby said. "Any study ought to be able to be defended, if it's worth publishing, if it's worth making policies over. . . . I think that's just common sense."

Now some lawmakers are trying to repeal the law, which makes federally funded research subject to the Freedom of Information Act (FOIA).

"This is clearly one of those things that becomes more complicated the more we look at it," said Jean Fruci, an aide to Rep. George E. Brown Jr. (D-Calif.), who has introduced a repeal bill. "You spend a little bit of time up here on the Hill, when something looks too good to be true, you know you're in trouble," Fruci said.

Brown does not question Shelby's motives in passing the original bill, and Fruci noted that Congress passed the law and President Clinton signed it. "If it's a mistake, it's a bipartisan mistake."

But drug companies, too, have expressed reservations about the law. It is "potentially chilling on the conduct of clinical trials—which is certainly not good public policy," said Chuck Ludlam, vice president for government relations at the Biotechnology Industry Association. The Pharmaceutical Research and Manufacturers of America has voiced similar worries about patient confidentiality and trade secrets.

The Office of Management and Budget (OMB) has made an initial attempt to draft regulations based on the new law, narrowing its scope to apply only to published research and to research that is used as the basis for making federal policy or rules. But those who oppose the law say it cannot be tinkered into better shape.

"FOIA is really a blunt instrument when it comes to striking the right balance" between the need to share data and to protect researchers and their work, said Nils Hasselmo, president of the American Association of University Professors. In a recent letter to the OMB, Hasselmo wrote: "We do not believe it is possible for OMB to allay these concerns given the problems inherent in the underlying statute."

Shelby staff members said FOIA has exceptions to protect commercially sensitive information and confidential medical information.

Scientists and institutions opposing the new law say their fears that the law will be used to harass are not idle speculation: State open records laws, they say, have already been used to punish researchers whose results anger powerful companies and patient-advocacy groups.

Oregon drug researcher Bruce Psaty, for example, contends that his work on the health risks of drugs known as calcium channel blockers was met with harassing investigations by drug companies. "These public records laws that were supposed to protect the public were really subverted in behalf of private interests," he said.

Similarly, Paul Fisher, a Georgia-based doctor, said his state's laws helped drive him out of research altogether. He published an influential 1991 article that found that more than half of children between the ages of 3 and 8 recognized R.J. Reynolds Tobacco Co.'s cartoon camel character and identified "Old Joe" with cigarettes.

The company vigorously attacked the studies, and R.J. Reynolds lawyers used Georgia's open records acts to demand access to "everything in my office," even the names of the children Fisher interviewed, he said.

"Their goal was harassment of me," Fisher said, "and that has nothing to do with science." The open records law, he said, protects companies that want to harass scientists and keep them from doing commercially sensitive research.

"What their lawyer said in court was that they were going to knock on the children's doors and ask them if they actually said what I claimed they said in my study" more than two years after the fact, he said. Fisher, who had promised the families confidentiality, refused. His university sided with the company, however, and Fisher left academia for the private practice of medicine. "I didn't feel it was reasonable to continue on as a faculty member" considering the school's position, Fisher said.

Guy M. Blynn, a deputy general counsel for R.J. Reynolds, said that "as soon as the objection was raised, everybody recognized that we didn't need and didn't want to bother the parents and these 3- and 5-year-old children." Officials initially simply wanted to confirm that Fisher had actually performed interviews. "This comes down to a very, very simple issue," Blynn said. "If Fisher and other researchers have nothing to hide, then why do they try to hide their data?"

Blynn said Fisher's work was deeply flawed because the children were not asked their attitudes about smoking; the company's own research suggests that children with the highest Old Joe recognition disliked smoking most.

George Thurston, an associate professor at the New York University School of Medicine, said the threat to patient privacy could have the most far-reaching effects. Patients, he said, may refuse to participate in studies "because they know someone can force us to turn over the data. So what's the result? You don't do the research, which I think is one of the intents of the law."

BY PATTERSON CLARK — THE WASHINGTON POST

AP 05-19-98 04:10 PMT

Environmental professor investigated after probing toxin

MINNEAPOLIS (AP) It's a case of the investigator being investigated. For more than 12 years, Deborah Swackhamer of the University of Minnesota has been scouring the Great Lakes for an outlaw pesticide called toxaphene, one of the most dangerous environmental toxins since DDT. She has found the toxin, in some cases at far higher levels than anyone expected.

But now, someone has hired a prominent New York law firm to investigate Swackhamer, 43, a nationally known environmental chemist, and her husband, David DeVault, a biologist formerly with the U.S. Environmental Protection Agency.

The lawyers are acting on behalf of an anonymous client, the Star Tribune reported. They have asked the university and the EPA to turn over copies of virtually every document written by or about the two scientists since 1984.

Using federal freedom-of-information and state open-records laws, the lawyers have sought thousands of memos, phone logs, financial records and even information about the couple's "familial relationship."

The requests are perfectly legal. But their mysterious origins and their sweeping, personal nature have alarmed many scientists who fear that anyone could use the laws to harass scientists and undermine their research.

"I feel like I'm in the middle of a Grisham novel," said Swackhamer, an associate professor of environmental health. "I just feel at the mercy of... this giant law firm."

Swackhamer and her colleagues believe it's most likely the pulp and paper industry that's behind the probe. Her research has prompted questions about whether paper mills could be a source of toxaphene. The industry says it has never created toxaphene.

The law firm that filed the requests, Cravath Swaine & Moore, isn't talking and isn't required to reveal its client. However, Georgia Pacific Corp., the nation's second-largest paper company, is one of its regular clients.

A spokesman for Atlanta-based Georgia Pacific refused to confirm or deny any involvement in the investigation Tuesday.

"We just as a matter of policy don't disclose use of a FOIA (Freedom of Information Act) in this or any other matter," said spokesman Ken Haldin.

But the company released a statement that said, "To suggest that we would do anything other than encourage and foster sound scientific research at universities is baseless."

Other industry officials have been quick to distance themselves from the investigation.

Almost any researcher who receives public money may be subject to requests under open-records laws. Exceptions are made for privacy and confidentiality.

The university has refused to provide Swackhamer's unpublished data, which it considers a trade secret. Still, Swackhamer has shipped off thousands of other records to the New York law firm. The EPA has sent only some of the requested documents, saying many records already have been destroyed.

Toxaphene is a suspected carcinogen and has been shown in lab tests to cause birth defects in wildlife. Experts fear that it could do the same to humans if they eat enough contaminated fish.

Swackhamer discovered in the mid-1990s that the levels were even higher than expected in Lake Superior water and the sediment of northern Lake Michigan.

Her research didn't pinpoint any source, and she's never claimed it was the paper industry. But when her husband was with the EPA, he thought it was worth exploring.

The paper industry, of course, isn't the only possible explanation.

"When you look at the details, there's just no convincing science or data to support that hypothesis," said Jay Unwin, a regional manager of the industry's scientific arm, the National Council of the Paper Industry for Air and Stream Improvement Inc.

EPA official Frank Anscombe says he "would be surprised if it was not a paper company," but he also said he has no problem sharing "the information with the public."

In the meantime, Swackhamer says she hasn't given up her toxaphene research.

"My husband has said, `Are you sure you want to submit that proposal? Maybe you don't want to do toxaphene research for a few years,'" she said, laughing. "No, they're not going to do that to me."

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MANDATING THE
RELEASE OF HEALTH RESEARCH DATA:
ISSUES AND IMPLICATIONS

GEORGE D. THURSTON

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Mandating the Release of Health Research Data: Issues and Implications

George D. Thurston*

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I. INTRODUCTION

"Show me the data!" sounds a lot like a soundbite from a Hollywood movie, but it accurately characterizes the demands that U.S. industry representatives and legislators on Capitol Hill have in recent years been making of researchers who study environmental and occupational health problems. Indeed, in July 1997, an amendment to a 1998 appropriations bill in the U.S. House of Representatives was proposed that, if passed, would have required researchers with government grants to make their raw medical and scientific data publicly available within ninety days after the first public reporting of any study results.[1] No hearings were held on the implications of such a step. Only defense-related research and cases in which "adverse economic harm to

* © 1998 George D. Thurston. Associate Professor of Environmental Medicine; Director, Community Outreach, Institute of Environmental Medicine, New York University School of Medicine. Dr. Thurston testified before both the U.S. Senate and the U.S. House of Representatives in 1997, regarding air quality regulations in the United States. He serves as an advisor to the State of New York on air quality matters, having served on the Department of Environmental Conservation's Air Management Advisory Committee since its inception in 1991. He presently serves on the National Academy of Science's Committee on Health Effects of Incineration, and was Chairman of Canada's Health and Environment Panel for the Health Canada Sulfur in Gasoline Study in 1997. A.B., Sc.B. Envtl. Engineering 1974, Brown University; M.S. Envtl. Health Science 1978, Harvard University; Sc.D. Envtl. Health Science 1983, Harvard University.

1. *See* Jocelyn Kaiser, *Data Release Proposal Raises Alarm*, 277 SCIENCE 627 (1997).

commercial proprietary interests . . . would result" would have been exempted from this blanket data release mandate.[2] Is this proposal to mandate a blanket release of federally funded research data a necessary and worthwhile solution to a real problem that is impeding the advance of scientific knowledge? Or, alternatively, are the cries for Congress to take such an action merely a manifestation of vested interests' attempts at undermining the credibility of researchers who publish results that run counter to their financial interests?

According to the journal *Science*, the data release amendment proposed by Representative Robert B. Aderholt (R-AL) was, in part, a response by Congress to industry demands for data from Harvard School of Public Health air pollution studies, the results of which were at the center of proposed new air pollution regulations.[3] The studies' authors objected to making their raw research data publicly available because it would violate the crucial confidentiality agreements they had made with study subjects to protect their individual privacy.[4] Although these Harvard researchers were willing to share the data with other scientists when that confidentiality could be protected, they were not willing to capitulate to unrestricted release of the personal health records.[5] In the end, this particular congressional amendment was defeated by a vote of nineteen to thirty-four.[6] Discussion of such a measure, however, will no doubt surface on the Hill again in the near future, as demands for congressional action are likely to continue due to other regulatory measures being questioned by industry. It is therefore important to air both the issues involved in, and the implications of, such a mandate for the release of federally funded health effects research data.

At first glance, this proposal may seem to be a simple and straightforward idea. The basic logic behind the proposal, apparently, was that the data collection was paid for, at least in part, by the government, therefore it should be available to the public and to anyone else who wishes to evaluate it further. In a cover letter to his colleagues in the House, the sponsor of the amendment stated that "the federal government does not have a standardized government-wide process for making research data available for independent review. My amendment seeks to remedy this while still allowing for a limited number of

2. *Amendment to Treasury, Postal Service, and General Government Appropriations Bill, 1998* (offered by Rep. Robert B. Aderholt (R-AL), July 25, 1997) (rejected July 31, 1997) [hereinafter *Amendment to Treasury Bill*].

3. *See* Jocelyn Kaiser, *Government Grants: Academia Wins a Round on Raw Data*, 277 SCIENCE 758 (1997).

4. *See id.*

5. *See id.*

6. *See* H.R. REP. No. 105-240 (1997).

exceptions . . . . I strongly believe that sunshine is the best antiseptic."[7] In addition, the argument has been made that government regulations that are based upon federally funded health research might cost billions of dollars to affected businesses and industries.[8] Accordingly, it is important to make doubly sure that the research is right. Thus, there were some seemingly plausible rationales for such a measure, however, practicality and ethical concerns quickly arose.

In the days that followed the congressional proposal, numerous confidentiality, logistical, and fairness objections came to light from other legislators, the Clinton Administration, and the nation's research universities.[9] Representative George E. Brown, Jr. (D-CA), ranking minority member of the House's Science Committee, expressed his "deep concern" that "the amendment as drafted would create significant legal uncertainties and substantial and unnecessary costs for scientists, research universities, high tech industries, and federal agencies."[10] In addition, the White House Office of Management and Budget enumerated potential problems, including the impeding of commercial agreements and the risk of problems if the data were not analyzed correctly by others unfamiliar with the data collection process.[11]

This Article provides a detailed consideration of the ongoing data access debate in the context of the United States Environmental Protection Agency's (EPA or the Agency) recent air pollution regulations and the research upon which they are based, followed by a discussion of the key issues surrounding the data access debate in general. These key issues include the potential effects of a mandate requiring the release of health research data on: (1) the scientific credibility of the research involved, (2) the confidentiality of research participants' medical records, (3) the intellectual ownership of research ideas and their results, and (4) the speed of research progress in the medical and public health fields. Information from past cases of data release demands and their aftermath are supplied as examples. Consideration is then given to whether there are sufficient deficiencies in the current practices of scientific assessment and data sharing that warrant such government mandated intervention

7. Letter from Rep. Robert B. Aderholt (R-AL) to the House of Representatives (July 24, 1997) (on file with author).

8. *See* Madeleine Jacobs, *EPA Should Take a Breather*, CHEM. & ENG. NEWS, Apr. 14, 1997, at 5; *see also* Philip H. Abelson, *Proposed Air Pollutant Standards*, 277 SCIENCE 15 (1997); Jocelyn Kaiser, *Showdown Over Clean Air Standards*, 277 SCIENCE 466 (1997).

9. *See* Kaiser, *supra* note 3, at 758.

10. Letter from Rep. George E. Brown, Jr. (D-CA), Ranking Minority Member, House of Representatives Science Committee, to Rep. Bob Livingston (R-LA), Chairman, House Committee on Appropriations (July 28, 1997) (on file with author) [hereinafter Brown Letter].

11. *See* Kaiser, *supra* note 3, at 758.

into medical and public health research, or whether the side-effects of this proposed solution are worse than the initially perceived problems. Finally, alternative approaches to addressing the question of the validity of published scientific research are also proposed.

II. THE CASE AT HAND: AIR POLLUTION EPIDEMIOLOGY

The National Ambient Air Quality Standards (NAAQS), the cornerstone of the nation's air pollution control program, are aimed at establishing air quality requirements sufficient to protect public health and welfare.[12] The Clean Air Act (CAA)[13] and its Amendments[14] require that these national air quality standards be set at a level stringent enough to protect the health of the public, with an adequate margin of safety.[15] The CAA Amendment of 1977, as adopted by Congress, requires that each of the NAAQS be reviewed by the EPA at least every five years in order to determine whether the NAAQS are still appropriately protective of public health and welfare based on the most recent research information.[16] Revisions of the NAAQS by the EPA Administrator are based upon scientific air quality criteria documents that are prepared by the EPA for the air pollutant under review and subsequently reviewed by an independent scientific advisory panel, the Clean Air Scientific Advisory Committee (CASAC).[17]

In 1979, upon review of the nation's photochemical oxidants standard, the EPA relaxed the ozone (O_3) NAAQS from a once-per-year, one-hour maximum of 80 parts per billion (ppb) up to 120 ppb, due to a lack of published information supporting the then existing standard.[18] Ozone is a secondary pollutant, or one that is formed in the atmosphere in the presence of sunlight from precursor pollutants, most notably nitrogen oxides and hydrocarbons that are emitted by a variety of sources, including automobiles, coal-fired power plants, and industry.[19] This

12. *See* Clean Air Act § 109, 42 U.S.C. § 7409 (1994).
13. *See* CAA §§ 101-618, 42 U.S.C. §§ 7401-7671*q*.
14. *See* Clean Air Act Amendments of 1966, Pub. L. 89-675, 80 Stat. 954; Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676; Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685; Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399 (codified as amended in scattered sections of 42 U.S.C.).
15. *See* CAA § 109(d), 42 U.S.C. § 7409(d).
16. *See* CAA Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 385 (codified as amended in scattered sections of 42 U.S.C.).
17. *See* CAA § 109(d), 42 U.S.C. § 7409(d).
18. *See* National Ambient Air Quality Standards for Ozone, 44 Fed. Reg. 8201, 8204 (1979).
19. *See Review of EPA's Proposed Ozone and Particulate Matter NAAQS Revisions—Part 2 Before the Subcomm. on Health and Environment and the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 105th Cong. 146 (1997) (prepared statement

standard remained in effect until 1997, when the EPA, after a long and extensive review of both new epidemiological and controlled pollutant exposure health studies, determined that the ozone NAAQS should be tightened back to a value of 80 ppb, but averaged over eight hours and allowing as many as three violations per year.[20] This new standard is therefore less protective than the once-per-year 80 ppb one-hour maximum standard in effect before 1979, but somewhat more protective than the pre-1997, 120 ppb one-hour maximum standard.

In 1997, the EPA also determined, after a similar extensive scientific review process, that the particulate matter (PM) NAAQS should also be modified to better protect the public health.[21] Fine PM (i.e., small particulate matter) is primarily composed of two components: carbonaceous primary particles, or soot, emitted directly from combustion sources such as diesel buses, coal and oil-fired power plants, and other industries; and, secondary particles formed in the atmosphere from gaseous pollutants such as sulfur dioxide and nitrogen oxides emitted from sources such as coal-fired power plants, automobiles, and industry.[22] In the case of PM, it was decided that a new standard was needed which focused on fine particles less than 2.5 micrometers in diameter ($PM_{2.5}$), which are particles small enough to reach deep into the human lung and most likely to have the highest concentrations of especially toxic PM components (e.g., acids, lead, arsenic, etc.).[23]

The implementation of these new air quality standards will require various businesses and industries to control their companies' air pollution emissions of gases and particles that some fear may cost large sums of money. This fear has caused those potentially affected parties to scrutinize the new standards intensely, and many of them have collectively or individually objected to the standards.[24] Partially in response to these industry concerns, Congress held numerous hearings on the new standards, including the consideration of bills to block the new standards.[25] However, no Congressional action has been taken to date to reverse the new air quality standards.

of Dr. George D. Thurston, Assoc. Prof., Dep't of Envtl. Medicine, New York University School of Medicine) [hereinafter *Thurston Testimony*].
20. *See* National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,856-96 (1997) (to be codified at 40 C.F.R. pt. 50).
21. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,652-711 (1997) (to be codified at 40 C.F.R. pt. 51).
22. *See Thurston Testimony*, *supra* note 19, at 146.
23. *See Clean Air Act: Ozone and Particulate Matter Standards, Hearings Before the Subcomm. on Clean Air, Wetlands, Private Property, and Nuclear Safety and the Comm. of Environment and Public Works*, 105th Cong. 138 (1997) [hereinafter *Hearings*].
24. *See* Air Quality Standard Coalition, News Release (Nov. 25, 1996).
25. *See* S. 1084, 105th Cong. (1997); H.R. 1984, 105th Cong. (1997).

During the period when the EPA developed the new standards, demands surfaced for the release of the underlying health and scientific data upon which the key epidemiological pollution-health effects studies were based to set the new standards. In particular, in May 1994, Dr. George T. Wolff, a scientist for General Motors and the Chair of CASAC at that time, and Dr. Roger O. McClellan, the President of the Chemical Industry Institute of Toxicology (CIIT) and a former chair of CASAC, sent a letter to EPA Administrator Carol Browner asking that the EPA make demands for data and for data reanalyses.[26] However, neither Wolff nor McClellan indicated any scientific wrong-doing on the part of investigators in their letter.[27] Although this issue and the sending of a letter were discussed at a CASAC meeting, the Wolff and McClellan letter was not sent as a result of a consensus of the entire CASAC panel that the EPA should request such data, but at the initiative of these two specific CASAC panel members.[28] During congressional hearings in early 1997, these two scientists testified in opposition to the EPA's proposed $PM_{2.5}$ standard, with Wolff stating that "I can't endorse the present proposal,"[29] and McClellan stating that "the serious shortcomings in the scientific data on $PM_{2.5}$ and PM_{10} led me to not support the promulgation of either an annual or a 24-hour $PM_{2.5}$ standard."[30] The Wolff and McClellan letter to the EPA stated that:

> several recent published reports have indicated effects on both morbidity and mortality at about the level of the current PM_{10} standard. In some cases, the analyses are extremely complex because of the need to correct a wide range of potential confounders, such as temperature, cigarette smoking and other pollutants .... It is crucial that two or more groups analyze the same key data sets linking exposure and morbidity/mortality response to verify the adequacy of the complex analyses and that different analysts using the same data reach similar conclusions .... The EPA should take the lead in requesting that investigators make available the primary data sets being analyzed so that others can validate the analyses.[31]

In 1997, the Air Quality Standards Coalition (AQSC), in a submission to the EPA during the proposed O_3 and $PM_{2.5}$ NAAQS

26. *See* Letter from George T. Wolff, Ph.D., Chair, Clean Air Scientific Advisory Committee, and Roger O. McClellan, D.V.M., Past Chair, Clean Air Scientific Advisory Committee, to Carol Browner, Administrator, EPA (May 16, 1994) (on file with author) [hereinafter Wolff Letter].

27. *See id.*

28. EPA SCIENCE ADVISORY BOARD, CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE, SO_2 CLOSURE & PARTICULATE MATTER, TRANSCRIPT OF PROCEEDINGS 169-70 (Apr. 12, 1994) (on file with author).

29. *Hearings*, *supra* note 23, at 38 (testimony of Dr. George T. Wolff).

30. *Id.* at 139 (testimony of Dr. Roger O. McClellan).

31. Wolff Letter, *supra* note 26.

comment period, cited the letter from Drs. Wolff and McClellan as a basis for requesting the data from the key Harvard "Six Cities" Studies. The AQSC submission requested that the studies be made "available in the rulemaking docket for assessment by other investigators and request EPA to reaffirm the existing PM standards until such time that these assessments are completed."[32] In its literature, the AQSC describes itself as "a broad-based coalition whose membership includes more than 500 corporations, associations and interest groups," whose goal is "to assure that the ... [EPA] makes scientifically ... sound decisions as it reviews the National Ambient Air Quality Standards for ozone and particulate matter."[33] However, the AQSC is described elsewhere as "a group of oil, steel, trucking, agricultural and auto companies, formed last July [1996] to fight the EPA's newly proposed air quality standards."[34] Thus, among the members of the AQSC are auto manufacturers, an industry group that includes General Motors, as well as oil companies and chemical manufacturers, two sectors well represented in the list of companies supporting the CIIT.[35] Indeed, CIIT's financial supporters include the Chemical Manufacturers Association, Chevron Corporation, Ethyl Corporation, Exxon Corporation, Texaco Inc., and Unocal Corporation.[36] In addition, the Mobil Corporation ran advertisements on the editorial pages of U.S. newspapers critical of the EPA proposal, including one ad stating that "data from a key study—the Harvard 'Six Cities'—has never been made public, despite repeated requests from scientists over a three-year period."[37] Thus, the most pointed demands for these studies' data have most often come from individuals and organizations either directly or indirectly supported by companies expected to be adversely affected by the new air standards based on those studies.

These recent demands for data release and reanalysis of the Harvard work have largely ignored the fact that these same Harvard researchers and their data have previously been reviewed for scientific integrity by the National Institutes of Health (NIH), Office of Scientific Integrity

32. Letter from Charles J. DiBona, President, American Petroleum Institute, and Andrew Card, President, American Automobile Manufacturers Association, Air Quality Standards Coalition Co-Chairs, to EPA Air Docket Section, Docket No. A-95-54(PM) (Mar. 12, 1997) <http://www.nam.org/bulletin/RER/rercmt.html>.

33. Air Quality Standard Coalition, News Release (Nov. 25, 1996).

34. Hanna Rosin, *Shades of Gray: St. Boyden's Unholy Money Trail*, 216 THE NEW REPUBLIC 21 (1997).

35. *See* National Association of Manufacturers Air Quality Standards Coalition (1998) (visited Apr. 29, 1998) <http://www.nam.org/air.html>.

36. *See* Chemical Industry Institute of Toxicology Supporting Companies (1998) (visited Apr. 29, 1998) <http://www.ciit.org/SUPPC/suppc.html>.

37. Mobil Corporation, *EPA: Let Science Do Its Job* (visited May 15, 1997) <http://www.mobil.com/this/news/opeds/970515_oped.html>.

(OSI), and the Health Effects Institute (HEI) and were cleared of any misconduct or scientifically inappropriate analyses.[38] The OSI investigation, which was the result of separate accusations raised in the mid-1980s, found that "there is no basis whatsoever for the allegations of serious errors and gaps in the database," and that "the quality control program of the Six Cities Studies considerably surpasses that of most continuously operating monitoring programs."[39] Furthermore, the HEI, which receives one-half of its fiscal support from the automotive industry and one-half from the U.S. government, subsequently commissioned an extensive reevaluation of the data and research methods of the Harvard team in conducting time-series analyses of various U.S. cities' daily records of mortality and PM pollution.[40] The HEI review found that the reanalysis results "agree closely with the earlier conclusions that particulate air pollution is tied to increased risk of death, even when weather and other pollutants are taken into account."[41] Thus, the Harvard researchers have in fact provided their data for evaluations in the past, and these previous evaluations have consistently confirmed the validity of their data and analytical methods.

However, in response to the continuing demands for the Harvard researchers' air pollution studies' data, Mary Nichols, then the EPA's Assistant Administrator for Air and Radiation, sent letters to Drs. Joel Schwartz and Douglas Dockery of the Harvard School of Public Health, as well as to Dr. Arden Pope, the lead author of another key PM study, stating that:

> there has been considerable interest in your research on the health effects of air pollution, including requests by members of Congress, governors of several states, and others for the raw data underlying your published research .... EPA is confident of the scientific integrity of your studies and their appropriateness for purposes of consideration in the Agency's present rulemaking on particulate matter without a separate or additional review of the underlying data. Nevertheless, given the strong interest in your research, EPA would encourage reasonable accommodations within the scientific and governmental community that would permit other interested scientists and agencies to understand fully the basis for your

38. Letter from Suzanne W. Hadley, Ph.D., Deputy Director, Office of Scientific Integrity, Department of Health & Human Services, to Michael W. Roberts, Esq., Office of the General Counsel, Harvard University (Nov. 15, 1990) (on file with author) [hereinafter Hadley Letter].

39. *Id.*; *see also NIH Clears Harvard Researchers*, WALL ST. J., Dec. 7, 1990, at A3.

40. Letter from James H. Ware, Dean for Academic Affairs, Harvard School of Public Health, to Mary D. Nichols, Assistant Administrator for Air and Radiation, EPA, (Apr. 8, 1997) (on file with author) [hereinafter Ware Letter].

41. Pamela Zurer, *Air Pollution Link to Rise in Deaths Confirmed*, CHEM. & ENG. NEWS, Apr. 8, 1997, at 9.

> work. We therefore request that you make data associated with your published studies available to interested parties as rapidly as possible.[42]

Dr. James H. Ware, the Dean of the Harvard School of Public Health, subsequently recommended to Ms. Nichols that the Harvard "Six Cities" data be reviewed and tested by the HEI. Dr. Ware wrote "[w]e believe that HEI is well qualified to conduct a review process that will be thorough and fair, without jeopardizing confidentiality concerns."[43] This review is presently in progress. Thus, in this case, the concerns raised by industry and industry-funded groups concerning the results of this research are being addressed, without the need for a public release of the research health data.

In promulgating the new $PM_{2.5}$ air quality standards in the Federal Register, the EPA summarized the comments that it received during the NAAQS comment period regarding the issue of raw data availability.

> Several commenters questioned EPA's ability to rely on studies demonstrating an association between PM and excess mortality without obtaining and disclosing the raw "data" underlying these studies for public review and comment. In particular, a number of commenters cited Dockery, D.W., et al. 1993 and Pope, C.A. III, et al., 1995, as studies upon which EPA relied without obtaining and disclosing the underlying raw data .... A few commenters argued that section 307(d) of the [Clean Air] Act requires that EPA obtain the raw data underlying these studies and that a failure to do so contradicts the plain language of section 307(d)(3) of the Act, which requires EPA to place in the docket any "factual data on which the proposed rule is based." Other commenters argued that under section 307(d)(8) of the Act, a failure to obtain and disclose the underlying raw data used in the studies would constitute an error "so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made." According to one commenter, without the raw data and an opportunity for an analysis of it, "EPA has no legal alternative other than to conclude that no new air quality standard would be appropriate within the meaning of CAA section 109(a)(1)(B)." Finally, a number of commenters have argued that recent caselaw under the Clean Air Act and other statutes makes clear that EPA has a legal obligation to obtain and disclose the data used in these studies.[44]

In that same preamble, the EPA responded to those comments:

42. Letter from Mary D. Nichols, Assistant Administrator for Air and Radiation, EPA, to Dr. Douglas Dockery, Harvard School of Public Health (Jan. 31, 1997) (on file with author).

43. Ware Letter, *supra* note 40.

44. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (1997).

> In developing the proposed revisions to the PM NAAQS, the Administrator relied on the scientific studies cited in the rulemaking record, rather than on the raw data underlying them. In this case, the raw data consists of responses to health questionnaires based on information supplied by individual citizens, or computer tabulations of this information, which remains confidential, and air quality and monitoring data, most of which is now publicly available. EPA does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process. Only in extreme cases—for example where there are credible allegations of fraud, abuse or misconduct—would a review of raw data be warranted. It would be impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard. If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.[45]

Thus, while the EPA did request that the researchers in specific cases release their data for review, the Agency refused to require the release of such data as a requirement for a study's inclusion in the standard setting process.

III. Issues and Implications

A. *Research Credibility*

While the EPA ruled that there is no need for peer-reviewed, health study raw data to be released as a routine part of the NAAQS process, industry's public demands for the raw air pollution-health data in the case of the CAA standard setting process succeeded in generating skepticism in the press regarding the credibility of air pollution epidemiology results.[46] Thus, an unrestricted public release of such studies' subject health data would indeed provide one means for the researchers to allay any concerns that they are trying to hide something. Once the data were examined by all interest groups and reanalyzed by others, it would have the benefit of removing even the most remote possibility that the researchers are hiding anything, but at what cost?

The open and informed discussion of scientific issues and protections against biased analyses or reporting of scientific results are

45. *Id.* at 38,689 (citations omitted).

46. *See* Laura Johannes, *Pollution Study Sparks Debate Over Secret Data*, WALL ST. J., Apr. 7, 1997, at B1; Scott Allen, *Clean-Air Researchers Pressured to Show Data*, BOSTON GLOBE, Mar. 4, 1997, at A1.

indeed important to an informed debate regarding scientific issues. But, a key question about any policy mandating a blanket release of data as a means to advance debate on a scientific issue is: who is most likely to reexamine the publicly released data, and with what goal(s)? The three major groups that spring to mind are: (1) competing researchers wishing to capitalize on the more expensive and time-intensive work already done by the original researchers, by analyzing aspects of the data that the original authors have not yet had an opportunity to investigate;[47] (2) regulatory agencies wishing to verify the research results before relying on the studies for regulatory decision-making; and (3) vested interest groups that would be adversely affected by regulations, laws, or lawsuits based upon the published research.[48]

However, it is not necessary to speculate what might occur because past experience tells us much about what happens when health researchers allow open access to their data. The case of Dr. Herb Needleman and his research on the adverse effects of lead exposure on children provides one relevant case in point.[49] Dr. Needleman wrote:

> [H]aving satisfied myself that the tooth was a valid marker of past [lead] exposure . . . I studied a sample of children who were asymptomatic for lead, classifying them by dentine lead levels. The data showed that after controlling for a number of covariates, children with elevated lead in their teeth scored lower on tests of psychometric IQ, speech and language function, and on measures of attention . . . . The lead industry, in the form of the International Lead Zinc Research Organization . . . began to call for copies of my original data. I declined. I had seen what had happened to good data when massaged and distorted by industry technicians, and while I was happy to share my data with any bona fide scientist—and did—I was not willing to include the lead industry.[50]

As part of a lawsuit brought by the Department of Justice against three lead polluters, Dr. Needleman did ultimately have to make his records available for examination to witnesses on behalf of the lead industry, including a grantee of the International Lead Zinc Research Organization and someone who had appeared in testimony for Lead Industry Associates.[51] While the case was eventually settled out of court,

47. *See* Allen, *supra* note 46, at A1. Indeed, multiple analysis and publications often result from a single data set, and this step would deprive the original authors the opportunity to further "mine" their data set.

48. It might be well worth the expense to such vested interests to extensively investigate whether any conflicting conclusions could be derived from the same data.

49. *See* Herbert L. Needleman, *Salem Comes to the National Insitutes of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977 (1992).

50. *Id.* at 977-78.

51. *See id.* at 978.

Dr. Needleman indicated that these witnesses had written a lengthy document critiquing Needleman and his research that was forwarded to the National Institutes of Health by a law firm.[52]

As reported by Dr. Needleman:

> These kinds of issues are generally considered methodological disagreements and are fought out in the pages of journals; I could not understand why they were defined by my critics as scientific misconduct. Similar criticisms were raised before the EPA in 1982 and dismissed. These facts notwithstanding, in October of 1991, I was notified by the Dean of my medical school that an inquiry into charges of misconduct was being done at the instruction of NIH's Office of Scientific Integrity.[53]

Months after the hearing, Dr. Needleman was finally cleared, but he concluded that:

> If my case illuminates anything, it shows that the federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time, while defending himself.[54]

Dr. Needleman's situation was also reported in an article in *The Chronicle of Higher Education* (*Chronicle*), along with that of a researcher who investigated the effects of tobacco company advertising on children, Dr. Paul Fischer.[55] Dr. Fischer's research was one of several studies published in the *Journal of the American Medical Association* (*JAMA*) that indicated children's attraction to the Camel cigarette "Joe Camel" advertising character.[56] R.J. Reynolds (RJR) responded by hiring consultants to analyze the studies and subpoenaed the research data supporting each of the studies.[57] The company's demands reportedly included that "the researchers supply the names and telephone numbers of all of the children who had participated in the studies."[58] As described by the *Chronicle*:

> Paul Fischer expected his college to back him. The request, he says, violated "the principles of confidentiality and academic freedom." Instead, the Medical College of Georgia sided with the tobacco company. Last

52. *See id.*
53. *Id.*
54. *Id.* at 980.
55. *See* Stephen Burd, *Scientists See Big Business on the Offensive*, THE CHRON. OF HIGHER EDUC., Dec. 14, 1994, at A26-A31.
56. Paul M. Fischer, M.D., et al., *Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991).
57. *See* Burd, *supra* note 55, at A27.
58. *Id.* at A30.

> year, it turned over the documents .... Consultants to the cigarette industry then started criticizing his research. In disgust over the college's response, Dr. Fischer resigned and entered private practice in medicine.[59]

Since then, the substance of Dr. Fischer's research was subsequently verified by others,[60] including RJR itself in a memoranda that recently acknowledged that the company specifically targeted children in their advertising.[61] As reported by Dr. Fischer in a letter to *JAMA*:

> Our findings have been validated by other investigators. Henke studied 83 children aged 3 to 8 years using a similar board-game design and found a 54% recognition rate for Joe Camel, compared with 51% in our study. In a study funded by RJR, Mizerski looked at recognition rates among 790 children aged 3 to 6 years and found that 52% of all subjects could match Joe Camel with a cigarette and that an additional 8% associated him with a lit match, for an overall recognition rate of 60%. A third study, also funded by RJR and conducted by the Roper Group, surveyed 1,117 children aged 10 to 17 years and found a total awareness rate of the Joe Camel logo of 86%. The consistency of the findings across age groups, geographic populations, and various study designs validates the findings in our first report.
>
> Based on an estimated rate of 3,000 new teenage smokers per day, more than 5 million US teenagers have become regular smokers since the publication of our study. The most recent research not only confirms that advertising affects smoking rates, but also indicates that this effect is 3 times greater for teenagers than adults. Given the health consequences of cigarettes, tobacco industry advertising should be viewed as a major public health risk.[62]

More recently, Dr. John P. Pierce and colleagues have provided further confirmation, publishing the first longitudinal study (i.e., following subjects over time) indicating that tobacco company ads and promotional activities are indeed causally related to the initiation of smoking among adolescents.[63]

Ironically, on January 14, 1998, internal RJR memoranda were released that, according to the *Washington Post*, indicate that the company:

> sought for decades to reverse the declining sales of its brands by developing aggressive marketing proposals to reach adolescents as young

59. *Id.* at A26.
60. *See* Paul M. Fischer, M.D., *Recognition of Cigarette Advertisement Product Logos*, 277 JAMA 532 (1997) (citation omitted).
61. *See* John Mintz & Saundra Torry, *Internal R.J. Reynolds Documents Detail Cigarette Marketing Aimed at Children*, WASH. POST, Jan. 15, 1998, at A01.
62. Fischer, *supra* note 60 (citations omitted).
63. John P. Pierce et al., *Tobacco Industry Promotion of Cigarettes and Adolescent Smoking*, 279 JAMA 511 (1998).

> as 14 years old.... The 81 documents contrast sharply with the company's repeated public declarations that it does not target young people, collectively sketching a picture of a company that seemed decades ago to determine that its financial future depended on recruiting a new generation of smokers. Many of the documents outline RJR's thinking that led up to the 1988 launch of its controversial Joe Camel cartoon advertising campaign.[64]

Thus, the criticized researcher was proven correct, and the vested interest company that attacked him was apparently seeking to discredit research findings that some individuals in that company must have known to have merit.

The Needleman and Fischer experiences are hardly unique, as the financial incentives to interest groups for such attacks on researchers are large. As recently noted by Dr. Richard A. Deyo in the *New England Journal of Medicine*:

> Attacks on health researchers are not new. Pierre Louis, for example, was vilified nearly two centuries ago for suggesting that bloodletting was an ineffectual therapy. In an open society such as ours, controversy is common and often socially useful. The fact that scientists are sometimes challenged by special-interest groups should be no surprise. However, with widening media coverage of health research, growing public interest in health hazards, and expanding research on the outcomes of clinical care, such attacks may become more frequent and acrimonious. The huge financial implications of many research studies invite vigorous attack.[65]

Dr. Deyo and colleagues go on to discuss three cases in other disciplines illustrating "how vituperative such attacks may be and the range of tactics employed," including: spinal-fusion surgery, multiple chemical sensitivity, and pharmaceuticals.[66] The authors conclude that:

> The common theme in these examples is an attack—through marketing, professional, media, legal, administrative, or political channels—on scientific results that ran counter to financial interests and strong beliefs. In each case, funding for the research involved peer review and the offending results were published in peer-reviewed journals. The interested parties had financial stakes in maintaining their market share or the legitimacy of a model of illness or a particular treatment. Their responses, which by-passed peer-reviewed scientific debate and further research, were nonscientific and aimed at discrediting the findings, investigators, or funding agencies. In each case, the attacks intimidated investigators, discouraged others from taking up the same lines of investigation, and took

64. Mintz & Torry, *supra* note 61, at A01.
65. Richard A. Deyo et al., *The Messenger Under Attack—Intimidation of Researchers by Special-Interest Groups*, 336 NEW ENG. J. MED. 1176 (1997).
66. *Id.* at 1176-77.

> up the time of investigators and staff with legal, professional, and media responses.... The intent is to turn the tables on claimants, force them from a political to a judicial forum, and cast them as defendants.... In our cases, freedom-of-information requests, subpoenas, and complaints to the Office of Research Integrity were analogous to SLAPP [strategic lawsuits against public participation] suits.[67]

Thus, policies as democratic and important as the Freedom of Information Act requirements can be subverted and employed as mechanisms for vested interests to "attack the messenger" when the message is financially or politically unwelcome to the interest group involved. It seems inevitable that the same things would have happened with Representative Aderholt's "Sunshine" amendment, despite its well intentioned goals.

Therefore, while there may be the initial benefit to researchers' credibility if they are willing to release all their underlying health data, past experience tells us that interest groups with a financial stake in the research outcome will likely be the primary user of that released data. These interest groups may use the data in order to further their own interests, irrespective of the merits of the original research, with little public health assessment benefit, and with the potential of significant public health disbenefit if appropriate public health measures are delayed by such tactics.

B. *Confidentiality of Participant Medical Records*

In March and April of 1997, as the pressure grew on the Harvard School of Public Health researchers to address the industry demands for their data, stories appeared in the *Wall Street Journal* and the *Boston Globe* on the topic.[68] In the *Wall Street Journal* article, one of the researchers pointed out that "giving up this data in violation of our agreements would completely cripple our ability to go out and do epidemiological studies of any type."[69]

Similarly, in the preamble of the Federal Register promulgation of the new PM standard, the EPA also pointed out that:

> such data are often the property of scientific investigators and are often not readily available because of ... arrangements made to maintain confidentiality regarding personal health status and lifestyle information of individuals included in such data. Without provisions of confidentiality,

67. *Id.* at 1177-78.
68. *See* sources cited *supra* note 46.
69. Johannes, *supra* note 46, at B1.

the possibility of conducting such studies could be severely compromised.[70]

Thus, the mandated release of health data collected in confidence during a research study, as proposed during the 105th Congress, would force researchers to violate the confidentiality agreements made with study participants at the start of the research years before. Retrospectively obtaining each subject's permission to release those data could be an onerous task, and may not be possible at all, in those cases where the subject has since died without designating responsible next-of-kin.

Moreover, when conducting new studies, investigators would have to tell subjects that their data would be publicly available at the end of the study, which could severely hamper researchers' ability to recruit new study populations. Thus, even if such data release mandates were to be applied only to new studies, one effect of the proposed data release mandate would be to stifle new research efforts funded by the federal government.

Ironically, these data release requirements would not apply to privately funded research, such as that funded by regulated industries, who have been among the most reticent in the past to make all of their private research data available to others. This bias in the data release requirement would be as unjustified as the present requirements in the House of Representatives that witnesses testifying before a committee must reveal their past government funding, but need not reveal past funding by interest groups that may have a vested interest in the outcome of the hearing.[71] Thus, under proposals such as Representative Aderholt's, vested interest groups will still be free to selectively publish research that supports their positions, while only government funded research will be encumbered by the data release requirements that, as will be shown below, will hamper its ability to expeditiously obtain research independent of special interest group influence upon which to base scientific assessments of health risks.

In light of these important concerns, and to at least partially offset the onerous effects of such a data release mandate, it seems possible that Congress might instead set up a new governmental agency, or assign an existing agency, with the task of collecting the data from researchers, and then releasing it to qualified parties on a limited basis, in order to at least partially protect the privacy rights of individuals. For example, this is presently done by the National Center for Health Statistics (NCHS) for

70. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (1997) (to be codified at 40 C.F.R. pt. 51).

71. *See* Rules for the Comm. on Commerce: Rule 4(b)(2), 143 CONG. REC. H368-01, H369 (1997).

certain proprietary death certificate information, such as the date of death.[72] However, such a proposal for government control of data releases would raise the question of who is more appropriate to make decisions about sharing original research data: the individuals who collected it and were given permission to access the personal information by the subjects in question, or a government bureaucracy?

C. *Intellectual Ownership Rights*

A scientific data set often represents years of effort by a researcher and his or her colleagues, including: the conception of a research idea; the preparation of a research proposal for submission to a granting agency; obtaining institutional scientific Internal Review Board (IRB) approval to ethically collect the data; obtaining permission from each study participant; the collection, quality assurance, and statistical analysis of the data; and the preparation of reports documenting the work in the peer-reviewed literature. Usually, more than one publication results from a single data set, as there are multiple aspects of a data set that can be investigated. In the case of the Harvard Six Cities Studies, more than 100 research publications have resulted from this single data set. Oftentimes, further funding for support from agencies is obtained to investigate the many other scientific aspects of the data records. If the data were released after the first public use, then others could use the data to seek that funding to analyze and publish these further findings before the original researchers. In the case of the Six Cities Studies, the numerous publications and hundreds of thousands of dollars in research moneys that the researchers have accumulated for their institutions could have been lost to other competing researchers and institutions eager to get their hands on the Harvard data sets. Thus, a mandated "taking" of a data set from an original investigator shortly after the first public presentation of results from the study, as proposed in the 105th Congress,[73] and making it available to others for free, could represent a major loss, professionally and financially, to that investigator and his or her research institution.

If research is funded by a federal grant, does the government maintain any rights to demand access to those data beyond its rights to obtain data sets collected without federal funding? Congressman Brown, in his letter to the House Committee on Appropriations at the time of the Aderholt amendment, discussed this issue.

72. *See* National Center for Health Statistics, Centers for Disease Control and Prevention (last modified Mar. 3, 1998) <http://www.cdc.gov/nchswww/index.htm>.

73. *See Amendment to Treasury Bill*, *supra* note 2.

> [I]t is important to understand that the federal government usually supports research through grants, not through contracts. The distinction is significant. The purpose of a grant is to support or stimulate activity which serves the public good, such as the increase and diffusion of scientific knowledge. Unlike a contract, a grant does *not* purchase the product of the grantee's work. (See Government Accounting Office, *Principles of Federal Appropriation Law* (2d Ed.) pages 10-3 through 10-10.)
>
> For this reason, it has traditionally been understood that researchers receiving federal grants nevertheless retain significant property interests in their research. Congress has explicitly recognized and even recently expanded those property rights. For example, grantees have the right to copyright documents they produce with grant support, and can own and patent intellectual property created under the grant. (See Office of Management and Budget Circular A-110.) Just last year, Congress passed the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), which expanded the rights of persons receiving federal research support to own and license intellectual property created with federal support.[74]

Thus, the government apparently has no more right to insist that researchers who have collected scientific data as part of a federally funded grant release their data than it has to make the same demands of private industry funded research. As a result, any such mandates for the public release of data sets underlying published research results should apply equally to both industry and government funded research, and should be viewed as a "taking" of property from those investigators.

D. *Effect on Scientific Progress*

The proposed mandate to require raw data release upon first public use of results from those data, although aimed at advancing scientific knowledge, would undoubtedly have the reverse effect in many ways. As previously noted, a researcher in the Six Cities Studies, Dr. Douglas Dockery, pointed out in a *Wall Street Journal* article that violating their subject agreements would cripple their ability to do new epidemiological studies.[75] Potential subjects would be less likely to participate in research where their personal medical data will be made public. In addition, Dr. Joel Schwartz, another Six Cities data researcher, also noted in that same article that "[n]o epidemiologist can afford to be buried in so much time-consuming controversy for every study, yet that is what industry promises for every data set they get their hands on."[76] Dr. Needleman's experience

74. Brown Letter, *supra* note 10.
75. *See* Johannes, *supra* note 46, at B1.
76. *Id.*

is confirmation of the real-world potential for a realization of Dr. Schwartz's concerns. In addition, there would likely be a reluctance on the part of researchers to publicly release any research results from a study until all possible research opportunities are exhausted, if they must release their data after doing so. Financial considerations would likely ensure that the first completed results from a data set might well be used solely as justification in subsequent grant applications for further funding, rather than expeditiously published, and would therefore not be available to the public, the research community, or regulatory agencies until years later, when all further research avenues had been exhausted. In other words, the requirements for public release of data would have the overall effect of inhibiting, not enhancing, scientific progress and would thereby also have the effect of inhibiting governmental agencies from being fully informed about the most up-to-date state of scientific knowledge when making regulatory decisions.

E. *Unfunded Mandates*

Among the less politically popular things that Congress can do is to impose an "unfunded mandate," or a requirement for individuals to do things without providing any financial support to address these new requirements—which is exactly what these data release mandates represent. As noted in Representative Brown's letter to the Appropriations Committee:

> The Aderholt amendment would impose a significant unfunded mandate on individual researchers and universities—including state universities. To comply, universities would have to maintain a central repository of all of the raw data produced by all of its federally-supported researchers, respond to all public requests for documents at its own cost, and review all of the material before disclosure for potential legal liability for disclosure of sensitive personal or business information.[77]

F. *Are Existing Mechanisms Sufficient?*

Certainly important among the issues raised by data release mandates is the question as to whether the scope of the "solution" advanced is consistent with the "problem" it proposes to address. As stated by Representative Brown in his letter to the Appropriations Committee:

> Before we impose these costly burdens, we ought to ask ourselves what is the problem? As the ranking minority Member of the Science Committee,

77. Brown Letter, *supra* note 10.

> I am unaware that there is any general problem with federally-funded scientists failing to publish research results in public, peer-reviewed journals. I suspect that federally-funded scientists are no different than their colleagues in wanting to publish their work in respected scientific journals and to have a wide distribution of their research results.
>
> Nor am I aware that there is a general concern about the integrity of federally-funded research. The peer-review process, while not perfect, does a pretty good job of weeding out flawed research. In that regard, requiring the mandatory disclosure of raw research data would be overkill.[78]

Indeed, of the roughly 28,000 biomedical articles published each year by researchers in the United States,[79] only a small percentage have letters written to the journal editor about them, and only a handful of those are controversial enough to warrant requesting their data for reanalysis. Clearly, the requiring of tens of thousands of researchers to prepare their data in a form appropriate for public release and the setting up of a bureaucracy (or bureaucracies) to handle these data and their dissemination is regulatory overkill for a perceived problem involving such a very small percentage of these researchers.

Thus, there is no pervasive scientific credibility problem in federally-funded research that justifies the global mandates called for in Congress during 1997. A focused approach would seem much more commensurate with the scale of the perceived problem.

But what about those specific cases in which real scientific controversy does exist? Representative Brown, in his letter to the Appropriations Committee, goes on to address this point, stating:

> There may, of course, be isolated instances where there are problems . . . . Those instances need to be addressed on a case-by-case basis to ensure the careful consideration of all factors, including the confidentiality of patient and medical records. Agencies have adequate existing legal authority to obtain research results and data for federal purposes in such instances. There is no need for the sweeping across-the-board approach proposed in the Aderholt amendment.[80]

Available mechanisms used in the past to address specific concerns include an evaluation of the data integrity by a disinterested third party. In the case of the Harvard study data sets, even though there were no charges of any scientific misconduct, the HEI has again stepped in to

78. *Id.*
79. *See* National Science Board, *Science and Engineering Indicators* (1996) (visited May 28, 1998) <http://www.nsf.gov/sbe/srs/seind96/start.htm>.
80. Brown Letter, *supra* note 10.

address demands for a reexamination of the data and its analysis.[81] HEI will provide a neutral party to evaluate the scientific integrity of the data and the research that led to the important Six Cities Studies finding, without the need for the Harvard researchers to make their data publicly available.

In cases where scientific controversy surrounds a published research document that an Administrator has relied upon in making a regulatory ruling, the courts also provide an existing avenue to address concerns. A comprehensive discussion of the legal precedents surrounding the issue of research data availability is presented by the EPA in the preamble to the recent PM standard revision. One example where the courts interceded in the process is provided in *Endangered Species Committee v. Babbitt*[82] (*Gnatcatcher*), which involved the range of the coastal California gnatcatcher. In its Final Rule of the Particulate Matter NAAQS, the EPA stated that:

> the *Gnatcatcher* opinion itself notes, "courts have generally allowed agencies to rely on scientific reports." Thus, the question at issue in *Gnatcatcher* was whether specific circumstances exist in which an agency may not be entitled to rely on studies alone. In the *Gnatcatcher* case, a single author had published two directly contradictory studies on the same issue, while relying on the same data. In light of this clear contradiction, commenters in that rulemaking argued that without the underlying data it was impossible to determine whether the conclusions in either study were correct. The district court noted that:
>
> "The Secretary had before him a report by an author who, two years before had analyzed the same data and come to an opposite conclusion. It is the disputed nature of this report that distinguishes this from other cases where a scientific report alone has been considered sufficient for ESA purposes."
>
> . . . Thus, according to the court: "While courts have generally allowed agencies to rely on scientific reports * * * this is not sufficient in this case because the report itself is under serious question."[83]

In this case, the court concluded that, in the specific situation in which the author published conflicting results, the data should be made public, and this was required of the Department of the Interior.[84] This opinion appears to support the EPA's position in issuing the new $PM_{2.5}$

81. *See generally* Hadley Letter, *supra* note 38.
82. 852 F. Supp. 32 (D.D.C. 1994) [hereinafter *Gnatcatcher*] (cited in National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,692 (1997)).
83. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,692 (1997) (quoting *Gnatcatcher*, 852 F. Supp. at 37).
84. *See Gnatcatcher*, 852 F. Supp. at 43.

standard that only in extreme cases is the review of raw scientific data warranted.[85] Clearly, the courts provide a working and viable mechanism to address concerns about scientific research in those situations.

Thus, there does not appear to be a pervasive problem with the integrity of peer review literature results that calls out for the type of regulatory intervention being proposed on Capitol Hill. Moreover, in the rare cases in which the integrity of peer reviewed published research is credibly questioned, not just because the results are undesirable to vested interests, there are existing mechanisms in place to address and resolve those concerns.

IV. Discussion and Recommendations

Overall, it should be apparent from the considerations presented that the recent proposal to mandate the immediate and unrestricted release of raw health research data underlying federally-funded medical and public health research is an overly heavy-handed and burdensome solution to the infrequent problems that arise regarding limitations in access to published research data. Moreover, such an unrestricted data-release policy has the major drawback that it will undoubtedly worsen the very real and serious present-day problem of unwarranted attacks on scientists and physicians who publish research with conclusions that run counter to vested interests.

Qualified researchers who have published research results potentially damaging to vested interests have come under intensive attacks in the media through the initiation of scientific misconduct charges, via legal actions, and by the influencing of government agencies to demand specific studies' data release. Many of these attacks have come even when no scientific misconduct is suspected. These researchers have generally been ill-prepared to defend themselves. The attacks cause them to spend a great deal of time and money in defense of charges initiated or encouraged by vested interest groups having far "deeper pockets" and significant financial incentives to relentlessly pursue the attacks. The result is extremely detrimental to the scientists involved, both financially and professionally, and in one case documented here, has actually caused a researcher to leave the field of health research, despite the fact that the substance of his research results were later confirmed by others.[86] It may also have slowed the speed at which regulators took action in the cases where scientific integrity was questioned. A data release mandate would provide vested interest groups with even more "fodder" with which to attack the research upon which federal regulations

85. *See supra* text accompanying note 45.
86. *See supra* text accompanying notes 59-61.

unfavorable to their financial interests are based. Thus, in addition to slowing scientific progress, the legal and financial burdens on research institutions, and the undermining of research subject privacy, it seems very clear that a mandate to release the underlying data behind all published, federally-funded research would greatly exacerbate the problem of unwarranted attacks on researchers.

However, in the face of inevitable, future, contentious public policy debates, how can we best ensure that the important processes of information exchange, data-sharing, and validation of results are carried out without unwittingly making the affected researchers the target of unfair criticism and harassment by vested interests? Clearly, to avoid being onerous, any solution involving data release by researchers must be focused specifically on the critical issues and results, rather than a global release of all raw data. The solution will also need to provide a structured framework for the conscientious handling of data transfer, protection, and evaluation. This might involve the designation of rules and funding for the establishment of a deliberative entity to serve the role played so well by the HEI in the case of the Harvard air pollution research results. Perhaps the National Academy of Sciences could be funded to provide a forum for the design and implementation of such a deliberative body. The key interested parties will need to be involved, or at least considered, in designing such a mechanism, including: the scientists and/or physicians conducting the research; the editors of the journals that publish such research; the potentially affected vested interest groups and industries; and the governmental agencies involved in promulgating regulations based upon the research.

The editors of the various scientific journals that publish this research have an especially important responsibility to play a larger role in setting up a mechanism to address this issue. To date, the role of these journals has largely been limited to having scientific papers carefully reviewed before publication, rejecting inadequate papers, and/or passing along major and minor revisions suggested by scientific reviewers. After that, the journals basically "wash their hands" of any subsequent problems, merely publishing any substantive letters sent in to the journal criticizing a published paper. This seems an inadequate role in today's world of scientific debate in which the stakes can be so high, and in which researchers largely are left to fend for themselves, many times not even being supported by their own research institutions. Once a journal publishes an article, it must shoulder a responsibility for that work that goes beyond the mere publishing of letters to the editor and their responses. The *New England Journal of Medicine* (*NEJM*) has taken an aggressive stand on the issue of editorial writers and potential financial

conflicts of interest.[87] However, the *NEJM* has not yet "weighed in" on the issue of the independent evaluation of the scientific merits of already published research, even though it published a controversial air pollution study by Dr. Douglas Dockery et al.[88] Prominent journals, such as the *NEJM*, should consider setting up a review panel comprised of representatives, such as the editors from each journal, that would organize a second, more extensive, peer-review of especially controversial papers. This might be analogous to the Committee on Publication Ethics recently set up by editors of prominent British journals such as the *British Medical Journal* and *Lancet*.[89] Through a scientific journal "court of appeals," expeditious and fair re-reviews of contentious results might be conducted.

Whether these suggestions are followed, or some alternative mechanism is adopted, it seems imperative that the scientific journals and the scientific community "face-up" to the issues of peer-reviewed and published research method evaluation and data access. Otherwise, Congress may in fact take it upon itself to impose a remedy that will likely be far worse for science and policy-making than the perceived problem it proposes to cure.

87. Marcia Angell & Jerome P. Kassirer, *Editorials and Conflicts of Interest*, 335 NEW ENG. J. MED. 1055 (1996).

88. Douglas W. Dockery, Sc.D., et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENG. J. MED. 1753 (1993).

89. Jocelyn Kaiser, *British Editors Form Misconduct Panel*, 277 SCIENCE 627 (1997).

Mr. HORN. Mr. Gough is an adjunct scholar at the Cato Institute. Welcome.

Mr. GOUGH. Thank you, Mr. Horn and members of the committee for the opportunity to address you.

In my written testimony I comment on the importance of review and attempted replication of data for the advancement of science. I will limit my oral testimony to scientific data used for the development of laws, rules, regulations, risk assessments and other government guidance documents; and I will divide those data into two types.

Laboratory experiments and replication of laboratory data can be attempted in other laboratories and access to experimental data isn't so important as information about how the experiments were done.

Significantly, I do not include data from routine toxicity tests when I say experimental data. Those tests can cost millions of dollars, take years to complete, produce thousands of tissue samples and result in reams of data. Such tests are often the basis of Federal action, and access to the data from them is fundamental to understanding what the tests mean.

Epidemiologic studies to examine the health of a population of people cannot be replicated. The data are collected on a unique set of people, circumstances, and time.

In large part we are here today because of such a study. C.A. Pope and others who wrote a paper which is a primary basis for EPA's air pollution regulations initially refused a congressional request to release their data. After much pressure they released the data only to a committee of the jointly industry-EPA-funded Health Effects Institute.

In May, Steve Malloy and I wrote the EPA and requested the Pope study data which are also the basis for EPA's proposed tier 2 gasoline sulfur regulations. EPA replied in a letter, "We are not providing the health survey date you seek because these data are not in the Agency's possession. The data you seek are contained in a data base that is proprietary with the American Cancer Society. The EPA has never had access to this data base."

Evidently it's not only critics of EPA's regulations who have not seen the data, not even EPA has seen them. I question whether billions of dollars in regulatory costs should be heaped on American industry, cities and consumers on the basis of data that have not been examined by the regulatory agency.

Pope and his colleagues objected to releasing their data because they said it would compromise the privacy of individuals in the study. That is an overblown concern. For 5 years I chaired the committee that advised the U.S. Air Force's study of the health of the 1,200 Air Force personnel who sprayed 90 percent of the Agent Orange used in Vietnam. There are few more newsworthy or politically sensitive epidemiology studies.

In 1990 or 1991, Air Force scientists told the advisory committee that they had received some requests for data. After a few minutes' conversation about whether access to the data should be restricted in any way, we agreed to make the data—we agreed to make the data available to anyone who requested it. The data were scrubbed

of all personal identifiers and released. Scrubbing isn't a trivial exercise, but it can be done.

My final examples concern the most widely used herbicide in this country, 2,4-D. EPA has declared that there is no evidence to support even the possibility that 2,4-D causes cancer, but the National Cancer Institute has made several epidemiologic investigations of it. Those investigations have been marred by mistakes that came to light only when the NCI data were independently reviewed.

One NCI study included a table that indicated exposure to 2,4-D increased the risk of cancer. Inspection of the data showed that NCI scientists had never asked a question about 2,4-D use. Instead, they asked questions about all herbicides. The origin of the mistake that transformed herbicides into 2,4-D is not known.

Subsequently, NCI scientists failed to report a survey of farm workers in Iowa and Minnesota that showed no association between 2,4-D and cancer.

NCI published a study which received a great deal of publicity that associated cancer in dogs with 2,4-D. Although the dog owners' names had been removed from the data, NCI continued to stonewall release of data from the study for more than 18 months because it was concerned that industry would use information about the breeds of dogs and zip codes to track down and harass the dog owners.

When NCI did release the data, independent analysis revealed flaws in it, in the study. Correction of those flaws eliminated the association between 2,4-D and cancer. The 2,4-D saga shows the importance of citizens having access to data to check on the work of government scientists and their grantees.

The science used to support regulation and taxes must be based on publicly available data. Otherwise, government, simply by calling any collection of data, conclusions, and conjecture science and refusing to let others see the data, has a free hand to impose taxes and regulations.

Regulations always generate antagonisms. People in organizations that stand to gain or lose stature or resources or money will look most seriously at those data. They are the ones most interested. Their involvement in review of data is a quicker way to get to the truth than the use of non-biased or "philosopher-king agencies" of the government.

Thank you.

Mr. HORN. Thank you.

[The prepared statement of Mr. Gough follows:]

The Importance of Data Access for Science and Governance

Testimony before the
Subcommittee on Government Management, Information, and Technology
U.S. House of Representatives

by
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Washington, DC
July 15, 1999

Mr. Horn and Members of the Committee, thank you for this opportunity to address you. I am here as a scientist and a citizen to testify that regulation and taxes that are promulgated as being based on science should not be shrouded in mystery because the underlying data are not available to the regulated and taxed.

Karl Popper, an English philosopher, inquired as deeply as anyone into questions about what is science and how does science work. He concluded that the scientific process, for all its accouterments of math, instrumentation, and specialized knowledge, can be divided into two parts. The first part is the formulation of an idea or a hypothesis or theory, the words are used somewhat interchangeably, about how some part of the physical universe works. The second part is the design and execution of an experiment or a test to examine whether or not the idea or hypothesis or theory is correct. And, of course, if it is correct, the idea or hypothesis becomes incorporated into scientists' knowledge of the universe, and it can be used in the construction of other ideas and hypotheses.

Ideas, hypotheses, and theories are the stuff of all human inquiry, but the requirement of having to devise a test for an idea or hypothesis and demonstrating that the idea or hypothesis survived the test is the hallmark of science. An essential part of the testing process is review of ideas and hypothesis, tests and experiments and studies by other scientists. It's necessary because all people can make mistakes, and scientists who investigate the unknown are in areas without guideposts or milemarkers. There's nothing shameful about a mistake, but it's inefficient and costly when mistakes are incorporated into accepted science. Additional ideas and hypotheses that are based on the mistake are almost certain to be wrong, and the time and effort expended on developing them and testing them is lost. Far better to review, analyze, and attempt to replicate a new finding before accepting it.

Scientists have developed myriad methods for review. Scientists are expected to present talks to their peers in seminars and meetings of all kinds. Most scientists

welcome the opportunity to talk about their results and insights; after all, scientists who don't talk can pass into obscurity and their work go unnoticed. Scientists tend to be pretty good listeners. They like to learn about what's new even if it sometimes includes protracted periods of boredom. It's not all sunny and serene, however. I think every practicing scientist can recall when a question from the audience opened a huge hole in the speaker's logic or experimentation.

Beyond oral presentations, scientists, to obtain attention for their results and to be successful, have to publish their findings. Scientific journals have varying standards for review of papers submitted for publication, and scientists know that the journals with the most rigorous review are also the most prestigious.

One of the problems faced by scientists and journals is that the data that go into describing an experiment or a study can be such a bulky package that it won't fit into a paper of any reasonable length. Some journals in economics and political science have responded to that problem by requiring that authors inform the readers about where the complete set of data is available and how to obtain it.

More informally, scientists make personal contact by phone or email to obtain additional data, or they visit each others' laboratories. There are no rules for such requests or visits, but it's generally understood that it's okay to ask for data that are necessary for complete understanding of a published paper and not okay to ask for data that are still being examined before publication.

Good science requires that observations and analyses be repeatable and repeated. Given information about technique and procedure by the scientist who made the observation or analysis, other competent scientists should be able to replicate the observation or analysis. Reproducibility distinguishes science from another human activity called magic. For centuries, magicians claimed "special powers" that couldn't be taught to others who lacked the power. Now, we know that magic is tricks, and that the tricks are necessarily kept secret so that non-magicians can't learn them. Science, on the contrary, works best when it's open to skepticism, review, and attempts at replication.

I am going to focus on scientific data are used for the development of laws, rules, and regulations, risk assessments and other government guidance documents, and I am going to divide those data into two types. Laboratory experiments and replication of laboratory data can be attempted in other laboratories. Most everyone can remember about a decade ago, when cold fusion burst into the news. The hypotheses underlying cold fusion and the explanations for how it could produce wondrous worlds of energy in an open glass beaker on a laboratory workbench at room temperature were contradicted by much of physical theory, but cold fusion didn't fade away because of theory. It faded away because other scientists tried and failed and failed repeatedly to replicate the results.

There is a similar story of laboratory mistake (or worse) that has contributed to what are likely to be billions of dollars spent on largely or completely wasted toxicity tests. In 1996, scientists from Tulane University published a paper in *Science* magazine,

one of the most respected scientific journals in the world with a reputation for rigorous review of papers before publication. The Tulane scientists reported that tiny amounts of pesticides, present at concentrations that are now permitted under stringent Environment Protection Agency regulations, could interact and unleash a plethora of adverse biological events. Their report, which was leaked to EPA before it was published in *Science* was instrumental in the passage of the Food Quality Protection Act of 1996 and especially important in Congress' directing EPA to require new tests of commercial chemicals. The Tulane results attracted major press and TV and political attention, they have had lasting impact, and they are wrong.

Competent scientists in laboratories in universities, the federal government, and industry tried and failed to replicate the Tulane results. Initially, the Tulane scientists stuck to their guns and suggested that special conditions in their laboratory that weren't exactly replicated in the other laboratories explained the discrepancy. These "special conditions" sound a lot like the "special powers" involved in magic that I mentioned earlier, and few scientists accepted them as the explanation. About a year after the publication of their results, the Tulane scientists threw in the towel, and published a letter in *Science* that acknowledged that no one, not even they, had been able to replicate their original findings.

Science worked. Even though the faulty (or fraudulent) science was not caught by the reviewers for *Science*, the requirement that scientists describe their experiments in enough detail so that others can try to replicate them led to the debunking of the mistake. Even so, American industry remains burdened with expensive and unnecessary testing requirements that will drive up consumer costs and almost certainly reduce consumer choice.

That ends what I have to say about data from laboratories that other scientists can attempt to replicate. I am now going to turn to epidemiologic studies that examine the health of populations of people with particular exposure histories or the histories of people with specific diseases. Such studies cannot be replicated. The data are collected on a unique set of people under unique conditions over a unique time period.

In large part, we are here today because of such a study. A study done by C.A. Pope and others[1] is a primary basis for EPA's stringent air pollution regulations announced in November 1996. At the heart of the Pope study is information about a million volunteers who participated in an American Cancer Society and supplied information about their habits, workplace and environmental exposures, and health. That data set is unique, and it cannot be replicated.

EPA's air pollution regulations are very expensive – tens of billions of dollars a year – and some scientists question whether they will produce the health benefits claimed by EPA. Congress requested that the health data from the Pope study be made available

[1] Pope, C.A., M.J. Thun, M.M. Namboordiri, D.W. Docery, J.S. Evans, F.E. Speizer, and C.W. Health. Particulate matter as a predictor of mortality in a prospective study of United States adults. *American Journal of Respiratory and Critical Care Medicine 151*: 669-674.

to independent scientists, which would include industry scientists, for review and analysis. The scientists involved in the Pope study refused to release the data, and initially EPA backed them up. When EPA changed its mind and said the data should be made available for review, it was announced that the data really belonged to the American Cancer Society, and that EPA couldn't release them. Pope and his colleagues eventually agreed to release all their data to a committee of the jointly industry-EPA funded Health Effects Institute, which is supposed to report its analysis of the data in 2000, years after the air regulations went into effect.

The Shelby Amendment that directed the Office of Management and Budget to establish procedures for access to federally generated data was one upshot of the attempt to get those data. In February, OMB published a proposal for the implementation of that amendment. In May, Steve Milloy and I wrote the EPA and requested the data that went into the Pope study because the same study is the basis for the calculation of most of the benefits EPA expects from its proposed Tier 2/Gasoline Sulfur regulation. EPA replied in a letter and supplied us data about air pollution, but stated, "We are not providing the health survey data you seek, because these data are not in the Agency's possession.... Since the records were not produced under an EPA award, the Public Law cited as authority for your request is also not applicable."[2]

As a citizen, I am very disturbed by other information in the EPA letter. "The health study data you seek are contained in a data base that is proprietary with the American Cancer Society (ACS). The EPA has never had access to this database...."[3] Evidently, it's not only critics of EPA's regulations that have not seen the data. Not even EPA has seen them. I question whether billions of dollars in regulatory costs should be heaped on American industry, cities, and consumers on the bases of data that have not been examined by the regulatory agency.

Pope and his colleagues objected to releasing the health data because they said it would compromise the privacy of individuals in the study and make it impossible for Pope and his colleagues to do additional epidemiologic studies. That is an overblown concern.

For five years, I chaired the Department of Health and Human Services committee that advised the United States Air Force's study of the health of the 1200 Air Force personnel who sprayed 90 percent of the Agent Orange used in Vietnam. There are few more newsworthy or politically sensitive epidemiologic studies.

It's an immense study, involving extensive physical and psychological examinations of the 1200 men who sprayed Agent Orange and a comparison group of 1200 men who flew and serviced similar airplanes during the Vietnam War but who did not spray Agent Orange. The study began in 1982 and will end with the examination in 2002. The Air Force has contracted with famous and competent medical institutions such

[2] Wegman, L.N., Director, Air Quality Strategies and Standards Division, U.S. Environmental Protection Agency. Letter to Steven J. Milloy, June 9, 1999.
[3] Ditto.

as the Lovelace Clinic in New Mexico and the Scripps Clinic in California for the conduct of the examinations, and the examination records and statistical analyses fill many data tapes and books.

In 1990 or 91, the Air Force scientists told the advisory committee that they had received some requests for data. I remember that there was a few minutes' conversation about whether access to the data should be restricted in any way, but that was replaced with agreement that the data should be made available to anyone who requested it. I also recall comments that taxpayers had paid for the data and were entitled to it and that independent analyses of the data would strengthen the conclusions that the Air Force had drawn and that the committee accepted or those analyses would show where mistakes had been made.

The Air Force and the advisory committee were very concerned to protect the privacy of the study participants. An office at the National Center for Health Statistics is skilled in "scrubbing" data so that personal identifiers are removed, and such identifiers were removed. Releasing data was and is not a trivial affair, but I think that the Air Force experience demonstrates that confidentiality can be preserved.

My final example of the importance of access to data is concerned with the herbicide, 2,4-D (2,4-dichlorophenoxyacetic acid), the most widely used herbicide in the country. It has been thoroughly tested for toxicity, and EPA has declared that there is no evidence to support even the possibility that it causes cancer.

But 2,4-D has been the target of epidemiologic investigations by the National Cancer Institute (NCI), and those investigations have been marred by mistakes that would never have come to light without persistent requests for data collected by NCI. In 1986, NCI published a study of Kansas farm workers that included a table that indicated that exposure to 2,4-D increased the risk for cancer, and NCI scientists concluded that 2,4-D was a likely cause of cancer. This widely reported conclusion frightened farmers and other users of 2,4-D and raised concerns among consumers who worried about eating food that was contaminated with the herbicide.

Manufacturers of 2,4-D were finally able to obtain a copy of the questionnaire used by NCI in its study. The NCI scientists had never asked a question about 2,4-D use; instead they'd asked questions about uses of all herbicides. The origin of the mistake that transformed "herbicides" into "2,4-D," is not known, but NCI published a correction. In a subsequent study of farm workers in Iowa and Minnesota, NCI completed its study without asking about 2,4-D use. Then it went back and resurveyed study participants and their relatives about 2,4-D use. The resurvey delayed the publication of the study by two years, and when the study appeared, there was no mention of 2,4-D.

Again, industry officials requested and obtained information from NCI, and the resurvey data showed no association between 2,4-D use and increased cancer risk. NCI scientists never released those data. Those data, of course, undermined any connection that could be drawn between 2,4-D and cancer, which they persisted in suggesting.

Each of the NCI studies was released with great fanfare that produced a lot of press coverage about the risks from 2,4-D. The corrections that showed no evidence of risk attracted far less attention.

In 1991, NCI published a study that showed an association between cancer in dogs and the dog owners' use of 2,4-D.[4] Like the NCI studies of farmers, the dog study attracted a lot of attention, and editorials drew attention to the similarities of the cancers reported in the farmers and in the dogs.

Industry officials had some doubts about the methods of analysis used by the authors of the dog study, and they requested the underlying data from NCI. NCI stonewalled release of the data for more than 18 months. Although the dog owners' names had already been removed from the data, NCI said that they were concerned that "industry" would use information about the breeds of the dogs and ZIP locations to track down and harass the dog owners.

Eventually, NCI released the data, and scientists at Michigan State University reanalyzed the data. Their reanalysis revealed several flaws in the NCI dog study, and when those flaws were corrected, the association between 2,4-D and cancer in dogs disappeared.[5] The 2,4-D saga shows the importance of citizens having access to data to check on the work of government scientists.

Science depends on skepticism, review, criticism, and replication. Good science and good scientists thrive under those conditions.

The science used to support regulations and taxes must be based on publicly available data for review and analysis. Otherwise, government, simply by calling any collection of data, conclusion, and conjecture "science" and refusing to let others see the data, has a free hand to impose taxes and regulations.

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[4] H.M Haynes, R.E. Tarone, K.P. Cantor, et al. 1991. Case-control study of canine malignant lymphoma: Positive association with dog owner's use of 2,4-dichlophenoxyacetic acid herbicides. *Journal of the National Cancer Institute 83*: 1226-1231.

[5] J.B. Kaneene and RA Miller. 1999. Re-analysis of 2,4-D use and the occurrence of canine maliginant lymphoma. *Veterinary and Human Toxicology 41*:164-170.

Mr. HORN. And we turn to our last witness, which is Dr. Gary D. Bass, the executive director of OMB Watch.

Mr. BASS. Thank you, Mr. Chairman. I guess it's helpful to go last because you get to hear all the commentary beforehand.

Let me just say that OMB Watch has as its primary mission public access to government information. In fact, OMB Watch has testified before this committee repeatedly on electronic FOIA issues; and we also worked back in the early 1990's on the EPA Cabinet-level bill with both Mr. Horton and Mr. Conyers to put a right-to-know provision, which also didn't go through, and have worked all the way into the early 1980's on right to know.

With that background, it is striking that OMB Watch concludes that the Shelby amendment is the wrong way—wrong way to proceed in making information available that grantees have. I would like to highlight five points in coming to that conclusion.

First, since the passage of the Shelby bill—or Shelby amendment—and all the way through this hearing today, I am still uncertain what the problem is we're trying to resolve. I thought we were dealing with open government and public access. On the other hand, in listening to the panelists today, I'm somewhat like the magistrate from Casablanca saying to Humphrey Bogart, "I'm shocked, absolutely shocked." It's now about reg reform, it isn't just simply the Chamber of Commerce website that has it about reg reform—and by the way, I'll add to Dr. Thurston's comment. The issues that are highlighted on that website are clean air, environmental justice, ergonomic regulations, secondhand smoke, breast implants. These are public protections that we rely on.

No, it's not just simply that. It's not about open government. It's now become a partisan attack.

How do we get these comments that came into OMB that Mr. Kovacs referred to? I went to another website called junkscience.org. You can win an award if you send to OMB your comments. There are five awards that were going to be given if you could get your comments in about how problematic the existing system is and how good the Shelby amendment is.

Well, let me say that I am still uncertain what we're trying to fix. Once I better understand it, then I would like to engage in a serious discussion about fixing it.

The second point I would make consistent with that which you pointed out and others have pointed out in this panel, there were no hearings. There were no hearings on a major substantive piece of legislation. And I thank you, Mr. Chairman, for having these de facto hearings on the subject, even though it's really about H.R. 88.

The third point I would make is this really was a back-door amendment to the Freedom of Information Act. Mr. O'Reilly testified that the scope of FOIA has been expanded. That is a back-door amendment to FOIA. We now have a greater coverage of who is included.

The Shelby amendment, by the way, says "procedures of FOIA." Now, I don't know what that means. I'm assuming that Mr. O'Reilly is correct that the exemptions under FOIA would then apply and, therefore, the confidentiality issue, exemption 6, would apply. But then again, does predecisional exemptions apply? The Freedom of Information Act, as you know, in terms of agencies, al-

lows for agency communications to be exempt from FOIA. Are we going to apply that to nonprofit grantees, to the Federal grantees? Where does the exemption list go and how far does it extend?

Well, more importantly, what we have just done, by-passing the Shelby amendment without any hearings, is reverse 20 years of case law including, as Mr. O'Reilly pointed out, the Forsham case.

Fourth point I would make, if there is a problem, if there is a problem, why would we fit it in the manner of the Shelby amendment? It has already been said by Mr. Kovacs that OMB's Circular A–110 provides for the opportunity for the agency to request this type of information. Section 53(d) specifically allows an agency to do that. In addition, section 36(c) allows for the agency to not only collect but to reuse that information.

My fifth point: there are many substantive concerns that we have with the Shelby amendment, not the least of which is it does not deal solely with research. It deals with "all data." That means that all Federal grantees, including those that provide services, whether it be institutions or homes with disabled kids, you name it, whatever the service provision is, this applies to them.

The second concern I have is, really, this is an attack reminiscent of the attack on the advocacy voice of nonprofits. This does not cover, critically, money that goes to contractors, nor that which goes to State and local governments. If you will refer to page 8 of my testimony, there is a graphic, a chart that demonstrates exactly that State and local governments as well as contractor funding is roughly about eight times the scope of grants that would be covered under the Shelby amendment.

One last point I would make under substantive concerns and that is the hefty discussion that has occurred not only on this panel but the previous panel about privacy. Clearly exemption 6 applies, according to Mr. O'Reilly. The issue isn't exactly that. The issue is more complex. It really gets to data quality and to the researcher capability.

In today's era it is possible to take a small data set—and I'll take hypothetically research dealing with kids with AIDS. Hypothetically, it is quite possible to redact all the names. And because it's done in a small community or because it's a small subset of a population, computer matching would provide the capability, the possibility of identifying who those people are. In such a case, the researcher must make sure that the human subject pool is aware that the potential exists. That puts in a situation that you may not get the subject pool that you originally deemed possible.

And let me say, Mr. Chairman, you had commented on your prior life as a dean of research, I will be committing heresy, but there may be no truth in research. There is often a lot of politics surrounding the research.

And so it is with that I conclude that I think the Shelby amendment is unwarranted, unnecessary, and unwise and we strongly support H.R. 88.

Thank you.

Mr. HORN. Thank you very much.

[The prepared statement of Mr. Bass follows:]

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Statement of
Gary D. Bass, Ph.D.
Executive Director
OMB Watch

Before the House Committee on Government Reform,
Government Management Information and Technology Subcommittee

On
H.R. 88
July 15, 1999

Thank you for the opportunity to testify today regarding H.R. 88, a bill to repeal a provision that extends the Freedom of Information Act (FOIA) to data collected by federal grantees.

My name is Gary Bass, and I am the executive director of OMB Watch, a nonprofit research and advocacy organization formed in 1983. OMB Watch does not have any grant, subgrant or contract with the Federal government this fiscal year, nor the past two fiscal years. A key component of our work is assisting national, state, and community nonprofit groups in complying with federal grant rules. OMB Watch also has a rich history in promoting the public's right to know about government information. We have assessed government-wide policies and practices to promote public access and have advocated for changes in laws and regulations that will help the public achieve equal and equitable access.

Accordingly, we have followed with great interest the amendment to the Treasury and General Government Appropriations Act of 1999 that requires the Office of Management and Budget (OMB) to modify Circular A-110 to allow data collected by nonprofit federal grantees to be subject to FOIA. More specifically, the amendment (herewith called the Shelby amendment after its sponsor) requires "Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." The provision also states "that if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equalling the incremental cost of obtaining the data."

When OMB proposed language to modify Circular A-110 to comply with the Shelby amendment, we distributed information about it to nonprofits around the country and received a number of comments raising many concerns. Our testimony today is framed in part by the comments we received.

While OMB Watch strongly supports the public's right to know, we believe subjecting nonprofit grantees to FOIA is the wrong approach. To the extent that there is a demand for federally funded "data," we believe agencies could stipulate that grantees and contractors provide the government with the underlying data as part of grant and contract agreements. In this manner, the "data" would then be considered a government record, and subject to the procedures of FOIA. This approach fulfills the

objective of meeting the public's right to know without overturning court decisions on FOIA or subjecting recipients of federal funds to new requirements.

OMB Watch strongly supports H.R. 88's repeal of the Shelby amendment for the following reasons:

- **It is unclear what the Shelby amendment is attempting to fix.** There is no real evidence of a government-wide problem obtaining underlying data from grantees. It appears that the rider simply addresses specific difficulties that some may have had in obtaining data on a specific EPA clean air issue. In that case, the National Institutes of Health had funded Harvard University to research certain health issues. EPA used the research findings in justifying regulations dealing with air quality. But the regulated community opposed the EPA regulations and wanted the underlying Harvard data in order to frame arguments against EPA. Since EPA did not have the underlying data, those in opposition could not FOIA the information. While the merits of this example can be debated, it is very dangerous to formulate far-reaching legislation based on one anecdotal problem.

- **There was no debate on the merits of the Shelby amendment, which is buried in an omnibus appropriations bill.** While there was a short colloquy, there was no floor debate in the Senate and nothing in the House. There were no hearings on the rider, and the hearings on H.R. 88 are serving as *de facto* hearings on the rider.

- **The Shelby rider may not be the right way to deal with the problem of public access, if the problem exists at all.** If the objective is to obtain underlying research data, why not use existing authority under Circular A-110? Under Circular A-110, agencies have the authority to request "records pertinent to an award" from any grantee. Section _.53(d) states "The Federal awarding agency shall request transfer of certain records to its custody from recipients when it determines that the records possess long term retention value." Moreover, Section _.36(c) states, "Unless waived by the Federal awarding agency, the Federal Government has the right to (1) and (2). (1) Obtain, reproduce, publish or otherwise use the data first produced under an award. (2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes." Once the federal government has custody of the information, it can be subjected to FOIA if it is determined to be a "record" and not exempt from one of the nine FOIA exemptions. Why is legislation needed?

- **The Shelby amendment is a back door amendment to FOIA, yet it was not reviewed by the committees with jurisdiction.** FOIA law is very complex, and changes should be reviewed by those with responsibility for it. Because there were no hearings, expert opinion was never considered, and the relevant committees were not able to add their input. Today's hearing is helpful to address issues in grants management, but there also need to be hearings with FOIA experts in the appropriate committees.

- **There are many substantive concerns we have with the amendment, not the least of which is that it only applies to federal grantees, usually nonprofit organizations, and not to contractors, usually for-profit organizations.** This bias is reminiscent of the attack on the advocacy voice of charities that was launched in 1995. The Shelby amendment does not deal with contract or grants to state and local governments, where the largest share of federal funds go.

The remainder of this testimony addresses the specific substantive concerns we have with the Shelby amendment and OMB's proposed regulation.

1. The Freedom of Information Act (FOIA) Should Not Apply to Nonprofit Grantees. The FOIA defines the term "agency" to include any "executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch . . . , or any independent regulatory agency." 5 U.S.C. '552(f). The courts have identified certain factors to consider in determining whether an entity should be regarded as an "agency" for purposes of federal law. In *United States v. Orleans*, 425 U.S. 807 (1976), a case which involved a statute other than the FOIA, the Supreme Court defined the conditions under which a private organization must be considered a federal agency as follows: "[T]he question here is not whether the . . . agency receives federal money and must comply with federal standards and regulations, but whether its day-to-day operations are supervised by the Federal Government." Id. at 815.

In other words, an organization will be considered a federal agency only when its structure and daily operations are subject to substantial federal control. See *Ciba-Geigy Corp. v. Matthews*, 428 F. Supp. 523, 528 (S.D.N.Y. 1977). Subsequently, the Supreme Court ruled that the *Orleans* standard provides the appropriate basis for ascertaining whether an organization is an "agency" in the context of a FOIA request for "agency records." *Forsham v. Harris*, 445 U.S. 169, 180 (1980) (Forsham). See also *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 168 (1975); *Rocap v. Indiek*, 539 F.2d 174 (D.C. Cir. 1976); *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971). In 1975, the D.C. Circuit indicated that the most important characteristic of an "agency" is that the entity must have the "authority in law to make decisions." *Washington Research Project v. HEW*, 504 F.2d 238, 248 (D.C. Cir. 1974), cert. denied, 421 U.S. 963 (1975).

Even this fact, however, is not always determinative. *Public Citizen Health Group v. HEW*, 668 F.2d 533 (D.C.Cir. 1981). The National Capital Medical Foundation, Inc. (NCMF) was the entity under consideration in *Public Citizens Health Research Group v. HEW*, supra. The NCMF owed certain statutory obligations to HEW, having been designated by HEW as a Professional Standards Review Organization. As such, it was required to review health care provided to hospital patients covered by Medicaid and Medicare and to make final and binding determinations as to whether the care rendered was necessary and therefore qualified for federal reimbursement. The court concluded that NCMF had authority in law to make decisions and exercised it daily. The court also proceeded to identify other factors that helped it determine that NCMF is an "agency," such as that it was financed by the United States, was a creature of statute, performed an executive function, and operated under

"direct, pervasive, continuous regulatory control affecting even minutia of the procedures and functions." Id. at 941.

The characteristics of an "agency," however, are not always clear. The D.C. Circuit also held that the Vice President's Task Force on Regulatory Reform, later renamed the Council on Competitiveness, was not an agency because its sole function was to advise the President and Vice President. A dissenting judge pointed out that the Task Force had been created by Executive Order and had administrative support functions and that, no matter what it appeared to have been used for, it had been created as if it were an agency. *Meyer v. Bush*, 981 F.2d 1288 (D.C. Cir. 1993). Thus, even though it has been given authority to make decisions, an entity may, at times, not be considered an "agency" for purposes of FOIA.

An entity may receive funds from the federal government, and even perform work for it, without becoming an agency. In *St. Michael's Convalescent Hosp. v. State of Cal.*, 643 F.2d 1369, 1379 (9th Cir. 1981), the court rejected the argument that "the federal funds received through the Medicaid program and Medicaid's pervasive statutory and regulatory scheme necessarily" transformed the recipient state agencies into federal ones for purposes of the FOIA. The court relied on *Forsham v. Harris*, supra, to hold that there must be extensive control by the grantor agency over the recipient's day-to-day operations before it could be transformed into an agency. According to the Supreme Court in *Forsham v. Harris*, "Data generated by a privately controlled organization which has received federal grants (grantee), but which data has not at any time been obtained by the agency, are not 'agency records' accessible under the FOIA." Federal agencies do have the right to collect underlying data currently, by stipulating the collection as a condition of the grant. Once the Agency has the data, it is then considered an "agency record" and is subject to public access.

This question of control has also been emphasized by the 9th Circuit Court in holding that the American Red Cross was not an agency. "It is the existence of this element of substantial federal control that distinguishes those entities that can be fairly denominated as federal agencies under the FOIA from the organizations whose activities may be described as merely quasi-public or quasi-governmental." *Irwin Memorial, Etc. v. American Red Cross*, 640 F.2d 1051, 1055 (9th Cir. 1981). The court recognized that the government exercised a certain degree of control over the Red Cross, but held that it was not sufficient to transform that organization into an agency.

Most recently, in *Chicago Tribune Co. v. U.S. Dept. of Health & Human Services*, (April 30, 1999) the court identified four factors that it said should be considered when deciding whether a judgment under FOIA can be enforced against a private third party: (1) the degree of control or participation in the FOIA litigation; (2) deliberate maneuvering to avoid disclosure under FOIA; (3) the degree of relationship between the agency and the third party; and (4) whether the prior relationship between the third party and the agency justifies binding it to the judgment under FOIA.

The Shelby amendment undermines this rich body of law, changing the standards under which FOIA applies to one type of private third party -- a federal grantee. It has done this

without adequately amending FOIA and will complicate matters. To what extent do all FOIA exemptions (e.g., pre-decisional exemptions) apply to the federal grantees? Does it apply to subawards, such as those from state and local governments, especially since Circular A-110 would apply to nonprofits? If so, does that mean nonprofits would be subject to FOIA requests without having any knowledge of it?

Without properly modifying FOIA in an open process, we must oppose the Shelby amendment. To the extent that a federal agency chooses to make information collected by entities that receive federal financial assistance publicly available, it can stipulate that the recipient must provide the information to the agency as a condition of receiving the assistance. Once the information is in a federal agency's possession, it would be deemed "agency records" and subject to the FOIA procedures. *Department of Justice v. Tax Analysts*, 492 U.S. 136, 144-46 (1989); see also *Kissinger v. Reporters Comm. for Freedom of the Press*, 445 U.S. 136 (1980); *Forsham*, 445 U.S. at 182.

2. There Are No Clear Definitions in the Shelby Amendment. The Shelby amendment does not include any definitions of key terms, which makes it nearly impossible for OMB to proceed with developing appropriate regulations. For example, "data" could be anything from empirical data, to tissue samples, to a researcher's personal lab notebook or phone records.

OMB relied on commentary from supporters to narrow the scope to research data. Senator Shelby stated the rider "represents a first step in ensuring that the public has access to all studies used by the Federal Government to develop Federal policy." Senator Lott concurred by indicating that public access should be "to federally funded research data." Senator Nighthorse Campbell added that the disclosure "shall apply to all Federal funded research..."

However, nothing in the statutory language would limit the definition of "data' to research data. This will allow the Shelby amendment to be used to harass, intimidate or burden many grantees by those who oppose their work (e.g., smoking control, population control, etc.). Even if limited to research data, there are many questions as to which federal grants would be considered "research."

Without a clear definition of "data," it is likely that substantial legal activity will have to occur to arrive at definitions. Such activity would unfairly burden grantees.

There is also no clarification of what format data must be in. It is possible that some data may be completely indecipherable to anyone but the researcher, either due to its complexity, or due to its format. For example, some data may be stored on a proprietary computer program. Is the researcher obligated to provide the data in a format that is commonly useable, or can he or she simply hand over disks that contain the data, but are useless with any other program? Most software licenses would not allow the researcher to include a copy of the program with the data.

To use a more absurd example: if a researcher with illegible handwriting must provide personal notes, is he or she under an obligation to transcribe the notes so that they are readable?

3. The Reimbursement Schedule in the Shelby Amendment is Very Unclear. The rider states that "If the agency obtains the data solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data." No mechanism for determining the user fee is mentioned. There is no clarification of what exactly is covered by this fee. There is no mention of exactly who is reimbursed. The rider only states that the agency may charge the requester for collection of the data, but offers no mechanism or timetable for distribution of the fee. Does the federal agency collect the money and then divide it between itself and the grantee? Does the grantee get any of the money? If the Treasury collects the money and reimburses the agency and the grantee, does it do so on a regular basis, or does it become a yearly budget line item for each agency? Moreover, what happens when the grant expires, but the grantee is still subject to FOIA requests? Is there a mechanism for providing reimbursements to the grantee?

Surprisingly, there is no mention of the rights of a grantee to request reimbursement. The absence of this authority raises questions about burdens placed on the grantee. It is likely that an agency will not know the exact cost of obtaining data from a grantee. Can the grantee request reimbursement from the agency in response to a FOIA request? Is expenditure of grant funds to comply with FOIA requests an allowable expense under OMB cost principles? It is especially important that the grantee be able to request reimbursement if the agency is seeking "data" from the grantee or that the cost of such a transfer be considered when preparing the cost of the grant.

If the grantee cannot be reimbursed quickly (or at all), it may be impossible to comply with a FOIA request, which could subject the grantee to legal or other penalties. Without clearly defining a fee and penalty structure, it is impossible for a grantee to know the consequences of non-compliance with a FOIA request, as this is the first time data that is not a direct agency record is covered under FOIA.

4. The Shelby Amendment Raises Concerns Over Privacy and Quality of Research and Service Delivery. The changes to Circular A-110 cause concern that privacy will not be adequately protected, even with the FOIA exemptions in place. While the FOIA exemptions may protect the privacy of records/data about individuals held by nonprofit grantees, their exact application may involve litigation. For example, if a grantee does clinical trials of small, defined populations (e.g., minority children under five with HIV), can the identity of the participants be recognized through computer matching services? Would that constitute an "unwarranted invasion of personal privacy" (under Exemption 6). It is likely that the answers to these concerns will come in the form of litigation. There is also no guarantee that the exemptions will be applied perfectly and consistently.

Even if private information is protected, most human subject review panels would require researchers to notify subjects of the possibility that personal information about them might

become public. Potential subjects may be reluctant to give personal information if it is to become the property of the federal government or the public at large. For example, it may become harder to conduct clinical studies of those who use illegal substances, especially because the granting agency applies the FOIA exemptions, not the grantee. A subject may be less inclined to participate in studies on drug use, alcoholism, or similar studies if he or she knows that a government agency may obtain records with their personal information. There are also forms of data that make it extremely difficult to protect privacy, such as videotaped interview or interaction sessions used in social science.

It is also possible that the changes to Circular A-110 would make it more difficult for nonprofit organizations to provide service under a federal grant. The possibility of the public release of records may frighten people from AIDS clinics, shelters for abused women, and similar services. Inevitably, the fear of possible breaches in privacy will have a chilling impact on subject participation and research quality.

5. **The Shelby Amendment Raises Concerns Over Timing of FOIA Requests.** The rider states that "data produced under an award will be made available to the public." The language does not define when the data is to become available to the public. Interpretation and publication of research in peer reviewed journals is one of the most important elements of research, and publication is a major incentive for many to conduct research. The possibility of a researcher's data being open to the public before analysis is completed could serve as a disincentive to research.

There is also a concern that a lack of a clear timetable could result in theft of intellectual property. If data is available before the grant recipient is completely finished with it, there is an opportunity for others to profit from the research. Without such a timetable, statutes that protect the intellectual property rights of researchers receiving federal money, such as the Bayh-Dole Act (which clearly states that universities may elect to retain title to inventions developed through government funding), could be undermined. It will become increasingly difficult to find private funding to use in conjunction with federal funding because research that is solely privately funded is not covered, and there is no chance of theft of intellectual property. It is clear that it is not in the interest of private companies to co-fund research that can be used for the profit of others.

It is also unclear under the Shelby amendment whether the new regulations will be retroactive. It is unreasonable to apply these regulations to any research ever conducted under a federal grant. It is likely that much of the underlying data from past studies is not accessible, whether it has been lost, destroyed, or is on antiquated media (punch cards, COBOL tape reels, etc.). Any entity that would be forced to provide the underlying data from a project that happened 40 years ago would incur tremendous cost in finding the data and providing it in some useful fashion.

A mechanism must be included that deals with data under currently ongoing research projects, as well. Many studies, especially in social science, take many years to complete.

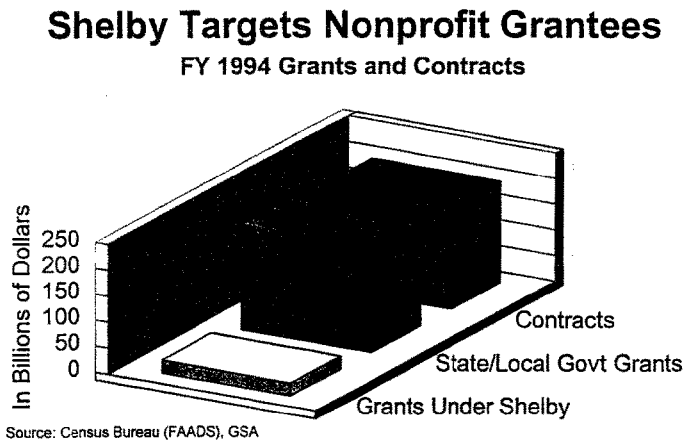
Unless there is such a mechanism, unfinished studies that have been ongoing for years may have to use substantial resources to prepare their past data for public accessibility.

The absence of clarifications in these areas will likely result in substantial litigation.

6. The Shelby Amendment Raises Cost Sharing Concerns. The rider's changes to Circular A-110 will likely have a chilling impact on research that is jointly funded from federal and private sources. On the Senate floor, Senator Ben Nighthorse Campbell stated that "the amended Circular shall apply to all Federally funded research, regardless of the level of funding or whether the award recipient is also using non-Federal funds." This issue is not addressed directly in language of the rider. Does this mean that the public can obtain data that was paid for in part (or almost completely) by private funds? To avoid this, will researchers be forced to compartmentalize their research, and state explicitly which part of the research is being conducted using federal money and which part is not (possibly down to the individual experiment)? A stratification such as this may make the research less useful to the granting agency.

If this issue is not addressed, it is almost a certainty that researchers will have difficulty raising any private funds for a project that also uses federal funds.

7. The Shelby Amendment Unfairly Targets Nonprofits. The Shelby amendment modifies Circular A-110, which only applies to institutions of higher education, hospitals, and other nonprofits that receive awards (e.g., grants and cooperative agreements) from the federal



government. The amendment does not apply to entities that receive contracts. Thus, it applies to a YMCA that receives a federal grant, but not to Boeing that is doing a range of research through contracts.

It is interesting to note that the largest portion of federal grants go to state, local, and tribal governments, which are exempt from the Shelby amendment. Additionally, the amount of money spent on federal contracts is roughly eight times the amount of money that would be covered by the Shelby amendment. But it too would not be covered. (See Attached Table, which provides FY 1994 data from the Census Bureau's Federal Awards Data System and the General Services Administration. Also see chart on previous page.)

To the extent that Congress is changing the definition of "agency" for FOIA consideration, then it should not limit it to just federal grantees. It should also include state, local and tribal governments that receive grants. Furthermore, those entities that receive federal contracts also should be considered "agencies" for FOIA purposes. This seems to be the principle that Congress intended when passing the legislative rider. Senator Shelby stated the rider "represents a first step in ensuring that the public has access to *all studies used by the Federal Government* to develop Federal policy." (emphasis added) Senator Lott concurred by indicating that public access should be "to federally funded research data," not just those supported by grants. Senator Nighthorse Campbell (R-CO) added that the disclosure "shall apply to *all Federally funded research...*" (emphasis added)

Conclusion

We believe the legislative rider to amend Circular A-110 in P.L. 105-277 is unwarranted, unnecessary, and unwise. We strongly support H.R. 88's repeal of the legislation. This should be a high priority for Congress as the changes to Circular A-110 set a dangerous precedent and could dramatically affect the quality of research in this country.

Thank you for giving me the opportunity to testify on this important issue.

FY 1994 FEDERAL GRANTS
(grants in millions of dollars)

	Formula Grants		Block Grants		Project Grants		Cooperative Agreements		TOTAL GRANTS	
	$ millions	# grants	$ millions	# grants	$ millions	# grants	$ millions	# grants	$ millions	# grants
Grants to state, local and tribal governments	$157,344.4	108,109	$4,644.9	696	$39,053.9	202,140	$844.9	2,900	**$201,888**	**313,845**
Grants to higher education organizations	$654.4	4,686	$2.0	15	$11,687.4	75,203	$752.8	2,169	**$13,096**	**82,073**
Grants to other nonprofits	$467.0	2,575	$1.9	5	$6,611.4	27,066	$664.0	977	**$7,744**	**30,624**
Grants to taxable organizations	$116.3	179	$0.2	1	$1,267.0	6,612	$947.2	804	**$2,331**	**7,596**
Grants to individuals	<$0.1	6	$0.0	0	$1,313.4	7,823	$0.9	340	**$1,314**	**8,169**
TOTAL	**$158,582.2**	**115,555**	**$4,648.9**	**717**	**$59,933.1**	**318,844**	**$3,209.9**	**7,190**	**$226,373**	**442,307**

NOTES

(1) Grants to higher education organizations include public and private universities. Some public universities may be exempt under the Istook amendment since they may be organized as part of the state government.

(2) Total direct grants to entities covered by the Istook amendment is no more than $24.5 billion (total grants minus grants to state, local and tribal governments). In fact, the actual number is probably significantly lower since many public universities and individuals may be exempt.

SOURCE: Census Bureau, Federal Awards Data System

Mr. HORN. I now yield 5 minutes to the gentleman from Texas, Mr. Turner, the ranking member. And after him we'll welcome Mrs. Biggert, the vice chair; and she'll adjourn the meeting. I have to be somewhere at 1, and I'm sorry about that. But the previous panel took a little more time than we thought. But I thank you all for coming.

Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman.

Obviously we've heard a diversity of opinion today, have been very helpful. The resolution before us simply repeals the Shelby amendment, and I guess it would be appropriate to ask even those of you who oppose the Shelby amendment whether or not you think it would be possible to craft some language that would appropriately address the concerns that have been expressed about access to data which in my opinion should be accessed after the research enters the public domain so as not to have a chilling effect upon academic freedom and inquiry.

But, Dr. Bass, would you have a suggestion that you could offer us that would allow us to address the issue but to do it in a more responsible way?

Mr. BASS. If the issue is solely as you just described it, Congressman, of gaining access to data from selected research that was used in hypothetically a particular case, OMB's Circular A–110 already provides the ability to make that happen.

As Mr. Kovacs pointed out earlier, agencies are not utilizing that to the maximum effect. That would suggest, as Congress, your oversight responsibility may prove even more useful through that route of identifying where you believe that agency should be collecting the underlying data. I'm yet to be—I'm yet to be convinced that new legislation is needed. If legislation were needed, I would not use—I would not attempt to use FOIA in this manner. In some respects the Shelby amendment is like a caveman using the tools of that time to do brain surgery today. It is the wrong vehicle to achieve what you're saying.

Mr. TURNER. Maybe I misunderstood what the current law is, but, as I understand it, agencies, you're telling us agencies have access to this data.

Mr. BASS. What I'm saying is the existing—the administrative requirements which are authored under Circular A–110 prescriptively state that the agency may request certain data from the Federal grantee. Not only does it state that, it also states that the Federal agency cannot only use it but reuse it and give it to others.

Mr. TURNER. Well, I thought that the proponents of the Shelby amendment here were trying to ensure that third parties who may be affected by the recommendations of the research also had access to the underlying data. It would appear to me that they do not under the current law.

Mr. BASS. Under Circular A–110 if the agency chose to put under its grant agreement with the Federal grantee the exercise of that authority of taking the data, it then becomes an agency record which would then be potentially subject to FOIA and go through the process that Mr. O'Reilly described, in the last panel, of the procedures established within the agency for review to determine whether it should be made publicly available.

In other words, we already have in place a structure for addressing some of these issues. The problem, if it is dealing with academic research, is that Circular A–110 does not prescriptively deal with the words "Federal research data." And there may be more work that needs to be done in modifying A–110 to deal with that specific concern.

Mr. TURNER. I notice Mr. O'Reilly shaking his head.

Mr. O'REILLY. I concur.

Mr. TURNER. So you're saying that it is true that under current law that third parties do have access.

Mr. O'REILLY. Let me clarify. Third parties who have access to the agency record once it's in the agency can use the Freedom of Information Act. The Shelby amendment afforded an opportunity for a third party to have the agency bring into the agency, pieces of data that the agency did not currently possess, and which the agency on its own would not have taken into its control.

Mr. TURNER. And, Dr. Bass, you oppose.

Mr. BASS. My point is that the ability to bring in the data and to make it a record as Mr. O'Reilly just described, already there are tools in place for the agency to seek that, to make that occur under the existing A–110. However, there may need to be some greater modification to A–110 to deal specifically with the research data that has been talked about today.

Mr. TURNER. So you are saying to us you have no objection to a third party requiring disclosure of the underlying data.

Mr. BASS. No, that is not what I'm saying. What I am saying is that I have no problem with the government collecting the information that it deems necessary; and, therefore, that data does become subject to the Freedom of Information if the Federal agency has already collected it.

I do not agree to extend the Freedom of Information Act to nonprofit organizations or to Federal grantees. I think that would be an incredible burden. It will be used in a way to harass agencies dealing with everything from smoking to reproductive grants, to you name it. There is always an opposite side on every issue, and the opposite side will use every vehicle possible.

Mr. TURNER. Would it be helpful if there was some limitation on when that data was available to those third parties?

Mr. BASS. Absolutely. That needs to be considered.

Mr. TURNER. Would that remedy your objection if you required access to be limited to a time after publication?

Mr. THURSTON. After which publication? I mean, the Harvard six-city study actually has 100 publications. If those data were released after the first one, those researchers would have lost all those publications. Other researchers like me would have scarfed up their data and published it for them. That's a taking of property.

There isn't just one publication. You look at the Framingham study: many, many publications. You know what's going to happen is that they'll say, OK, we won't publish that first paper. We'll wait 10 years until we get all of our publications ready, and then we'll put them out the door. Because I want tenure. I want to protect my rights to these data. So we won't publish that first paper.

It will cause delay. People will protect their property, and they won't publish that first paper because they won't want to give it all away. And they certainly wouldn't want to open themselves up to the kinds of attacks Dr. Needleman has had.

But in answer to your question, I guess your question really is, if we don't do the Circular A–110 revisions Mr. Shelby has done, what should we do? But I'm left to reiterate Dr. Bass' question, what's the problem? Why do we have to do something about this? The research we do, represents tens of billions of dollars of federally funded research every year. Mr. Obadal's research says in over 5 years there were 150 scientific misconduct cases out of all of that money, half of them were groundless. Quality research is coming out of this.

If there is a problem, it's with privately funded research. The example he gives of West Coast Research Co., that's private research.

And the New York Times—I can put this in the record. The New York Times had an article yesterday that U.S. officials are examining clinical trials, ones run by private companies. This is the problem. It says that problems exist in the recruitment practices in research sponsored by the drug industry and the system of oversight used to detect possible fraud. These examinations come on the heel of drastic changes in the clinical trial system which, in just the last decade, was largely based in the academic medical institutions doing like this federally funded research and conducted by professional researchers. But now it's become a multi-billion-dollar industry with hundreds of testing and drug companies working with thousands of private doctors who mine their patient lists for test subjects. You want a problem, look into this private research—but what we're talking about here, federally funded, peer-reviewed research, this is what the American people need. They don't need it to be subjected to these kind of unneeded regulations. There is no need for this regulation I agree with Dr. Bass.

Mr. TURNER. I think my time is up, Mr. Chairman, but if you would like to allow us——

Mrs. BIGGERT [presiding]. Why don't you have—Mr. Gough would you like to address that issue.

Mr. GOUGH. A couple of comments.

Well over 50 percent of the research in this country is funded by private sources in industry. To demean it all and toss it all in the wastebasket, I don't think is an advantage to anybody's interest.

The Pope study became important not when it was first published, but when it was the basis of EPA regulations. That's what opened the doors to the questions. And the questions are pretty straightforward. It depends on a survey of volunteers by the American Cancer Society, how well was that done, how were the questions asked, so forth. Those are legitimate research questions. And that's—to respond to Mr. Bass—or Dr. Bass's issue, I mean, that's what nobody's been able to obtain. I think that's strictly public information, and it should be obtained by people who are going to be affected by the regulation either positively or negatively.

Mr. BASS. Could I just add to that? Dr. Gough raised the issue of public versus private research. In passage of the Shelby amendment there was a colloquy involving several of the major players on the Senate side. Senator Nighthorse Campbell had stated,

quote, the amended circular shall apply to all federally funded research regardless of the level of funding or whether the award recipient is also using non-Federal funds.

This is the discussion that occurred in the last panel about commingling of funds. Will private research dollars be willing to be commingled with Federal dollars if potentially their data is suddenly going to be made public? There are a lot of concerns that the Shelby amendment raises in this regard that could be quite problematic.

Mr. TURNER. Thank you.

Mrs. BIGGERT. Thank you. I have just one question, and I'm afraid we're going to have to adjourn since we're an hour and a half over our time limit. And you have all been very patient.

Since neither the Shelby amendment nor the proposed revisions to the Office of Management and Budget Circular A–110 addressed the mechanism for Federal grant and award recipients to offset the administrative cost of the policy change, how would they be reimbursed for the cost of collecting the data? Does anybody have an answer to that?

Mr. SHELTON. Could I speak to that?

I think the simple answer is that there probably would not be a mechanism. You know that the indirect cost for administrative purposes at universities is capped at I think 26 percent. One can argue up and down about indirect costs, as many of you have. But this would fall clearly under an administrative responsibility. And since all of the major research universities are already collecting that 26 percent for the administrative components of their indirect cost base, I don't see how it could be accommodated.

Mrs. BIGGERT. So that would have to be.

Mr. SHELTON. That is a factor, and I mention that. But I think more critically—if I'm getting a take-home message—because I've learned a lot today as well—more critically what we're seeing here is just how complex this issue is. You've got the issue of private and public funds coming together. And that's increasing. If you look at the University of California we have huge growth in the area of private sector funding of our projects, and very often that's combined with Federal funds simply because it's a very important problem that is of interest to both the public and the private sector. That factor could be harmed irreparably if we go this route of the Shelby amendment.

There are other issues of harassment. You have heard issues of patents. What this tells me at these hearings is that this matter is sufficiently complex that we all need to take a very serious look at it before implementing the Shelby amendment. And that's why we favor H.R. 88 because—not because it eliminates the problem or eliminates our ability to discuss, but in fact the opposite. It gives us an opportunity in the sunshine of the day to go and discuss, as we have today, the pros and cons and come up with something that's both workable and gets at the real needs.

Mrs. BIGGERT. Thank you.

Mr. Obadal.

Mr. OBADAL. Yes, the costs of accumulating the data are currently covered by the current FOIA which could require parties to

pay for those costs. And indeed I have been in a number of instances which we've had to do that.

Second, the importance of the regulations and their impact on our society I think transcends the objections that we've been hearing today, many of which I believe are without merit.

So if this committee is going to consider some sort of legislation, we certainly would urge you not in the interim to suspend the Shelby amendment or the OMB action under the Shelby amendment, which is sorely needed. I put a proviso to that, unless you're willing to freeze all regulation during the process until you come out with a solution.

Mrs. BIGGERT. Thank you.

Mr. Kovacs.

Mr. KOVACS. It's been interesting going last and listening because I want to address the cost issue.

One, I don't think you've heard anyone from the pro-Shelby side in any way state that they didn't want to reimburse the costs. That, No. 1, it is in FOIA; and, two, OMB, from what I am hearing, is going to have a cost reimbursement provision. That is not an issue.

The second issue is, as part of the process, we need to move away from the academic to the practical world. In the practical world the FOIA request is made to the agency, not to the researcher. This idea of being harassed, is not the issue. The request is going to go to the agency. The agency is going to ask for the data. Under existing A–110 this data has to be managed anyway. So it's already in some form to be provided to the Federal Government.

And to turn to Mr. Turner for a second, because, Congressman, when you had asked the question, what does Shelby really do, the reason Shelby was important was not because under existing law the agencies can't get title to the information, they can, and that is fully provided. They intentionally did not get it. So that this data was not available.

Our central contention is that when the government implements a rule or a regulation, the data needs to be provided in ample time so that the public can analyze what the impact of the rule is going to be on them. And that's why, finally, OMB is so important, because OMB is taking these 9,100 or 9,200 comments and it's beginning to narrow them in a practical way. It's beginning to develop in definitions of what is "published," what is "data," and what does it apply to. It applies to a rule or regulation.

So a lot of the stuff that you're hearing about is really theoretical. No one is objecting to protecting private or confidential information. We represent the business community. We want the confidential information, the trade secrets, all of that, protected. So what you're hearing is a theoretical argument versus a practical. OMB and the rulemaking process is moving in a practical way to release information. Everything else is theoretical.

Mr. BASS. Madam Chairman, could I respond to the cost issue?

Mrs. BIGGERT. Yes, quickly.

Mr. BASS. My understanding of the way this would be implemented is that a requester would not file a FOIA request to the nonprofit grantee. It would go to the agency. The agency in turn would go select or request the information from the grantee. The

FOIA fees are the agency's costs that would have to be dealt with. That's why the Shelby amendment added an extra clause that there could be other fees that are levied. The problem in it is, as OMB drafted the rule, the nonprofit has no right to request reimbursement.

Mrs. BIGGERT. Well, doesn't the—under FOIA the reimbursement under the cost for collecting the data goes to the Treasury? So there's the problem, is how would that recipient get the reimbursement. I think that probably OMB would contend that it would take a legislative fix for that.

Mr. BASS. That's right.

Mr. THURSTON. So, if that's the case, this is an unfunded mandate.

Mrs. BIGGERT. Well, we'll look at that.

I would like to thank all of the panelists. I certainly agree with Mr. Shelton that this is a very complex issue. I don't know if it was diabolical or planned, but the way that the chairman set up the two panels in having more or less the pro and con, as I listened I thought, well, I like that and I like that, so I think I realized by having the way that the panels were set up, how complex an issue it is and how much study is necessary. I feel like we need to write a term paper on this to really have the time to sit down and really synthesize all of the information that you have all given us. I think that this is one of the best or the two panels that I have ever heard at one of these meetings, and really this substance that you have brought us I really appreciate.

And, with that, this subcommittee hearing is adjourned.

[Whereupon, at 1:10 p.m., the subcommittee was adjourned.]

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