

INSIGHTS



PERSPECTIVES

SCIENCE AND REGULATION

Congress's attacks on science-based rules

Proposed laws based on false premises could undermine science for the public interest

By A. A. Rosenberg,^{1,*†} L. M. Branscomb,^{2,*} V. Eady,^{3,*} P. C. Frumhoff,^{4,*} G. T. Goldman,¹ M. Halpern,¹ K. Kimmell,⁴ Y. Kothari,¹ L. D. Kramer,^{5,*} N. F. Lane,^{6,*} J. J. McCarthy,^{7,*} P. Phartiyal,¹ K. Rest,⁴ R. Sims,^{*} C. Wexler¹

There is a growing and troubling assault on using credible scientific knowledge in U.S. government regulation that will put science and democracy at risk if unchecked. We present five examples, and the false premises on which they are based, of current attempts in the U.S. Congress in the supposed pursuit of transparency and accountability but at the expense of the role of science in policy-making.

Over the past century, the federal government has striven to protect public health, safety, and the environment. Many statutory mandates require administrative agencies to craft regulations informed by credible, legitimate, and salient scientific assessments (*1, 2*) that prescribe actions and obligations of government entities, private sector enterprises, and individuals to protect the public interest. The federal laws that create these science-based mandates—such as the Clean Air Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act—are perceived as inconvenient and expensive by some corporate actors. Consequently, congressional leaders are pressured to render these long-standing and well-regarded

laws ineffective by undermining their scientific foundations (*3*).

This should raise alarm among all scientists. Each year, thousands of experts from academia, industry, and government serve on agency advisory panels and boards, peer-review panels, and National Academies' study committees. Many more conduct research relevant to important public policy decisions. The regulations that result from these scientific inputs have led to profound improvements in air and water quality, protections for workers and the public, and environmental safeguards (*3*).

Regrettably, five major bills have recently advanced in the U.S. Congress that would transform the scientific advisory process. Four passed the House of Representatives

POLICY

ILLUSTRATION: DAVIDE BONAZZI



Five major bills have recently advanced in the U.S. Congress that would severely limit the scientific advisory process.

last year but failed to advance in the Senate. Four of the five bills were reintroduced and three passed the House this year; with the fourth likely to pass soon. All have Senate sponsors. Although effective advocacy by scientists has helped stymie their progress thus far, any of these bills could be attached to must-pass legislation, and some presidential candidates are already embracing them as necessary reforms.

The bills employ insidious, albeit creative, approaches to weaken the ability of science to inform federal rule-making. One approach is to shift regulatory decisions from career employees in federal agencies working with experts to politicians in Congress vulnerable to special-interest influence. The Regulations from the Executive in Need of Scrutiny (REINS) Act, which backers say will

make regulatory agencies more accountable and reduce undue burdens on businesses, requires joint congressional approval within 70 legislative days for any new or updated major rule with an annual economic impact of \$100 million or more. If either chamber fails to act, the agency cannot move forward with the rule until the next Congress convenes and jointly approves the rule. The act suggests no criteria for Congress in evaluating a rule. Agencies, on the other hand, must adhere to specific statutory requirements—including basing decisions on science in many cases—and must defend their decisions in court. Given the current gridlock on Capitol Hill, few regulatory protections would survive both houses of Congress. Rather than increasing accountability—which of course is a worthwhile goal—the proposed mechanism for approval would, in effect, prevent science-based rules from ever being implemented.

A second approach is to tie up federal agencies in additional and redundant bureaucracy, even as their budgets decrease. This will make efficient rule-making even more difficult if not impossible. The Regulatory Accountability Act, with a stated goal of reducing costs to business, passed the House

in February, and imposes more than 70 new requirements on development, analysis, and public engagement processes that agencies must follow in updating or creating new rules (4). This includes additional formal administrative hearings that would give regulated industry and others the opportunity to directly challenge and cross-examine the agency on the science underlying its cost-benefit analysis. The act makes the least costly approach the default option for new public health and safety regulations even if it is less protective, a change from current laws which typically prioritize public health protection over cost. The act also gives the White House Office of Management and Budget the power to override independent scientific advice on the costs, benefits, and risks of proposed regulations, enabling implementation of regulations that might not reflect the best available science as required by statute.

Or take the Sound Science Act. Introduced in the House last year and likely to resurface in the current Congress, the legislation is ostensibly designed to improve the scientific basis for regulations. The bill requires agencies to hold additional public comment periods specifically on all scientific findings throughout the process and each time a new finding is considered. Furthermore, agencies must give “greatest weight to information that is based on experimental, empirical, quantifiable, and reproducible data.” But, as scientists know well, and as AAAS (American Association for the Advancement of Science, which publishes *Science*) has noted (5), some good science cannot be easily subjected to reproducible experiments. Should modeling studies be excluded? Is qualitative information not to be considered? The decision about how to weigh different types of information should be a scientific decision, not a political mandate. Although, in many cases, such weighting may be appropriate, this decision should be left to technical experts who understand how to interpret the data. Otherwise, decisions might not be based on the best understanding of the scientific evidence.

A third approach is to limit the information that regulators can use. The Secret Science Reform Act, passed by the House in February 2015, mandates that the Environmental Protection Agency (EPA) may only put forward a regulation if all of the data, models, methods, and other information in the science studies used in its development are publicly available, accessible, and reproducible. Supposedly, the data are required so that the “public” can analyze the data for themselves, although, in practice, it is likely that special interest groups will hire scientists to reanalyze the data to cast doubt on results that are not to their liking in order to delay the regulatory process. Although

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scrutiny of the science used in rule-making is important, this act would drain time and resources from rule-making processes that already include expert peer review, the release of summarized data, and ample opportunities for public and stakeholder input.

Although greater access to data can be a laudable goal, confidential health records, confidential business information, or protected intellectual property should not be disclosed. And although the bill carefully states that it does not require the release of confidential information, the EPA is prohibited from moving forward with a regulation unless all data are public. So although EPA is charged with protecting public health, say with regard to ozone or mercury emissions from power plants, it may not utilize any studies that analyze confidential public health data as a basis for action. This restriction applies to any actions the agency might take from rule-making to guidance, standard-setting, or scientific assessment of toxic substances. In other words, the EPA may not act on the basis of data it is legally restricted from releasing; therefore, it may not act.

A fourth approach is to change the composition and operation of the science advisory process itself. The EPA Science Advisory Board Reform Act, passed by the House this year, would set a quota for state, local, and tribal government officials and clarify that industry experts with ties to a regulated industry are not barred from advisory board membership, while barring independent scientists from serving if they have received an EPA grant within the last 3 years (and preventing their acceptance of an EPA grant for 3 years after they serve). Concurrently, the legislation makes it difficult for board members to discuss their scientific views that are not already published. Procedurally, the board is required to solicit and respond in writing to public comments on the state of the science and may not place time limits on that process. In reporting back to the EPA, the board must ensure that the views of the public are reflected and encourage dissenting members to report their views. Taken together, these changes give political and legal operatives greater influence over the advisory board while marginalizing independent scientists, as well as greater opportunity for frivolous and resource-consuming challenges to the board's findings.

Procedurally and monetarily, any of these proposals, if enacted, will delay and complicate an already complex regulatory process. The Congressional Budget Office estimated that the Secret Science Reform Act alone could cost EPA \$250 million annually at a time when its mandate has increased and its budget has been cut (6).

The bills described above are based on three false premises. The first premise is that regulations put forward by federal agencies reflect agency and executive branch "overreach." In reality, the rule-making process provides many opportunities to check such overreach, including by the judiciary.

The second premise is that corporations need more opportunity to influence the scientific information used in rule-making. But many industries already support technically proficient scientists and skilled advocates in every step of the process to argue their perspectives (7). By comparison, community groups and many civil society organizations can never match corporate resources for influencing government.

The third premise is that regulations only impose costs on industry, and public benefits are negligible. Yet just 10 rules proposed in the last 5 years are estimated to result in saving more than 10,000 lives and preventing 300,000 cases of disease, illness, or injury annually (8). Nine of the 10 rules—including actions on protecting workers from silica exposure, controlling mercury

"The bills use insidious... approaches to weaken the ability of science to inform federal rule-making."

pollution, and preventing salmonella contamination in eggs—are estimated to have monetized social benefits that substantially exceed monetized compliance costs even though many benefits cannot be monetized (9). Further, it is important to recognize that risk-mitigation costs not borne by industry will not evaporate but will become a public burden.

Attacks on the science advisory process as the foundation of regulatory action have a profound, chilling effect on the willingness of scientists to contribute to the process of advancing critical health, safety, and environmental protections. Restrictions on expert participation, requirements for multiple rounds of public comments, and procedural hurdles will subject the advisory process to greater industry and political influence and discourage independent scientists from participating in advisory activities. Many scientists are honored to serve the public as independent experts to inform the policy process, and most do so without compensation. As barriers for participation rise, their willingness to engage will plummet. The end result may be that mostly experts paid by special interests will serve.

The scientific community needs to push back. Elected officials respond to constituents, and there are scientists in every congressional district. With leadership from professional societies and scientific organizations, scientists across the country should tell their members of Congress how much they value the opportunity to engage in informing policy and how important it is that these attacks on the process are defeated.

The present system is far from perfect, but there are better solutions to ensure that science advice remains reflective of the evidence and resistant to special interest manipulation. To that end, with leadership from professional societies, science-based organizations, and academic institutions, better pathways must be created for independent scientists to share their expertise. This includes providing greater training for early career scientists on the advisory process and creating career-based incentives and time for them to participate. It also includes institutionalizing professional recognition for work and activity that informs policy-making. Public service should be a central component of what it means to be a scientist.

Further, public trust in science increases when we all have access to the same base of evidence. To that end, we must improve and fully implement conflict of interest and disclosure standards and strengthen peer review while increasing the public accessibility of scientific information. The stakes are high, as our collective well-being and the strength of our democracy depend on our success. ■

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10.1126/science.aab2939

LETTERS

Edited by Jennifer Sills

Science in Congress: Good-faith debate

A. A. ROSENBERG *et al.*'s Policy Forum "Congress's attacks on science-based rules" (29 May, p. 964) unfortunately adopts a common political gambit: Endorse desirable policy goals, but denounce efforts to advance them without offering better alternatives.

Rosenberg *et al.* target five bills that they claim would "weaken the ability of science to inform federal rule-making." The authors declare that "public trust in science increases when we all have access to the same base of evidence," but they assail bills that would require agencies to disclose the data, models, and methods on which their proposed rules rely. They laud the concept of "using credible scientific knowledge in U.S. government regulation," but criticize legislation that would require agencies to give greatest weight to experimental, empirical, quantifiable, and reproducible data. They say "we must strengthen peer review," but oppose bills that would largely codify the Environmental Protection Agency's leading practices for scientific advisory panels. They call increasing accountability "of course... a worthwhile goal," but decry efforts to do so.

In a good-faith political debate, the constructive response to bills that promote good ideas in a flawed way is to suggest ways to correct the flaws. While the Secret Science Reform Act does not clearly prohibit agencies from issuing rules based on data that are legally confidential, it is ambiguous about whether agencies can proceed in that

case. So let's clarify it. Does a requirement to "give greatest weight" to empirical data mean that "modeling studies [must] be excluded?" Presumably, it means that model results should receive less weight, but that could be made explicit.

Rosenberg *et al.* clearly prefer regulatory decisions to be made by "career employees in federal agencies working with experts," among whom they no doubt count themselves. But efforts to make that process more transparent, participatory, or accountable should not "raise alarm among all scientists." Such efforts would promote democracy, not "put [it] at risk."

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Science in Congress: Unnecessary conflict

IN THEIR POLICY Forum "Congress's attacks on science-based rules" (29 May, p. 964), A. A. Rosenberg *et al.* charge that there is an assault on using credible scientific knowledge to inform U.S. government regulations. To make this claim, they use false premises to attack constructive criticisms of how the U.S. Environmental Protection Agency (EPA) obtains and uses scientific advice. Although Rosenberg *et al.* are loath to admit it, that process can be improved, and the proposed legislation could help.

Many highly qualified scientists are employed in academic, government, and private organizations, yet most EPA committees consist almost exclusively of academic scientists. The Policy Forum fosters a "science versus industry" conflict that does not serve the public good. Public corporations have as much interest in regulations being based on

credible science as do academic and government institutions. Corporations recognize that the costs of meeting regulations are borne by their customers or shareholders. Scientists from all sectors, including industry, bring unique perspectives to advisory committees that advance the use of credible science to inform regulatory decisions.

Rosenberg *et al.* suggest that the proposed legislation will marginalize independent scientists. To the contrary, the proposed legislation will encourage the kind of independent advice that all committee members should be offering. I agree with the authors that "public trust in science increases when we all have access to the same base of evidence." Thus, I strongly support efforts that will make critical databases that undergird regulatory decisions available to scientists beyond the original investigators for replication and extended analyses. Alternative analyses and interpretations help advance science and increase confidence in the use of all the analyses to inform regulatory policies. Looking to the future, I urge that we move beyond the "science versus industry" attitudes of the past and focus on how best to use science to inform regulatory decisions and advance society.

Roger O. McClellan

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Science in Congress: Deceptive statistics

IN THEIR POLICY Forum "Congress's attacks on science-based rules" (29 May, p. 964), A. A. Rosenberg *et al.* attempt to make a case that only technical experts should be granted the privilege of decision-making on technical issues. They write that decisions on data weighting "should be left to technical experts who understand how to interpret the data."

That is a revealing statement in light of the numerous journal articles just in the past year on the corruption of "p-hacking" (1), misinterpretation of data and statistical significance (2), retractions of research because of data mismanagement and fraud, and inability to replicate experimental results (3). The misuse of statistical significance in null hypothesis significance testing led the journal *Basic and Applied Social Psychology* in February to ban it from all future submissions (4).

Rosenberg *et al.* justify their insular call for experts to be in control because "otherwise, decisions might not be based on the best understanding of the scientific evidence." There is a huge assumption hiding



in that sentence: that the scientific evidence is accurate. The literature suggests this is often not the case.

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Response

CONRAD MISSES THE key point of our argument: The bills we highlight are fundamentally flawed because they are based on a series of false premises about how agencies use science to make policy.

Taken together, these bills pervert the idea of a more “transparent, participatory, or accountable” regulatory process by sidelining independent science and scientists and creating redundant bureaucratic hoops that hamstring the ability of agencies to protect the public. Simply tweaking their language cannot achieve the goal of improving the process.

Conrad also misrepresents the true intent of these bills: to shut down or block regulations that sponsors, and those who support their campaigns, don’t like. Collectively, the bills shift analysis and decision-making authority from subject-matter experts to politically motivated generalists.

McClellan, who has worked closely with the chemical industry throughout his career, notes that there are highly qualified scientists in industry, government, and academia that can usefully contribute to the policy process. We agree. But we disagree that these bills take the right approach or can be made to do so with some minor modifications to the language.

Evans calls attention to incidents of bias and misuse of statistics, which can occur in any study that requires technical analyses. He actually helps to make our point: The process of assessing science for the purpose of developing the best policies needs to be in the hands of independent scientists. Attempts to distort this process by including analysts who have an agenda are dangerous for society.

Can the process be improved? Absolutely. But only by encouraging the full participation of the science community rather than solely through industry lobbying efforts. We must begin from a rational starting point by recognizing that while enormous public health, safety, and environmental benefits have come from regulatory processes, a better connection between truly independent science and the policy-making process will result in still greater benefits for the public

and for industry. We and our colleagues in science organizations, academia, and civil society are ready to fully engage in making those improvements. Are elected officials willing to work with us?

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TECHNICAL COMMENT ABSTRACTS

Comment on “Phylogenomics resolves the timing and pattern of insect evolution”

K. Jun Tong, Sebastián Duchêne, Simon Y. W. Ho, Nathan Lo

Misof et al. (Reports, 7 November 2014, p. 763) used a genome-scale data set to estimate the relationships among insect orders and the time scale of their evolution. Here, we reanalyze their data and show that their method has led to systematic underestimation of the evolutionary time scale. We find that key insect groups evolved up to 100 million years earlier than inferred in their study.

Full text at <http://dx.doi.org/10.1126/science.aaa5460>

Response to Comment on “Phylogenomics resolves the timing and pattern of insect evolution”

K. M. Kjer, J. L. Ware, J. Rust, T. Wappler, R. Lanfear, L. S. Jermini, X. Zhou, H. Aspöck, U. Aspöck, R. G. Beutel, A. Blanke, A. Donath, T. Flouri, P. B. Frandsen, P. Kapli, A. Y. Kawahara, H. Letsch, C. Mayer, D. D. McKenna, K. Meusemann, O. Niehuis, R. S. Peters, B. M. Wiegmann, D. K. Yeates, B. M. von Reumont, A. Stamatakis, B. Misof

Tong et al. comment on the accuracy of the dating analysis presented in our work on the phylogeny of insects and provide a reanalysis of our data. They replace log-normal priors with uniform priors and add a “roachoid” fossil as a calibration point. Although the reanalysis provides an interesting alternative viewpoint, we maintain that our choices were appropriate.

Full text at <http://dx.doi.org/10.1126/science.aaa7136>

LETTERS

Edited by Jennifer Sills

Editor's note

ON 20 MAY, in response to questions about the validity of the methods and data in the 2014 Report by M. J. LaCour and D. P. Green, *Science* published online an Editorial Expression of Concern on the Report. On 28 May, *Science* released online an Editorial Retraction of the paper. Articles first published online are typically published in print a few weeks after online posting. Because of the rapid chain of events in this case, both the Editorial Retraction and the Editorial Expression of Concern are printed here. The Editorial Retraction is *Science*'s final decision on this paper and supersedes the earlier Editorial Expression of Concern.

Marcia McNutt
Editor-in-Chief

Editorial retraction

SCIENCE, WITH THE concurrence of author Donald P. Green, is retracting the 12 December 2014 Report "When contact changes minds: An experiment on transmission of support for gay equality" by Michael J. LaCour and Donald P. Green (1). On 19 May 2015, author Green requested that *Science* retract the paper because of the unavailability of raw data and other irregularities that have emerged in the published paper. *Science* is urgently working toward the appropriate resolution, while ensuring that a fair process is followed. In the meantime, *Science* is publishing this Editorial Expression of Concern to alert our readers to the fact that serious questions have been raised about the validity of findings in the LaCour and Green paper.

The reasons for retracting the paper are as follows: (i) Survey incentives were misrepresented. To encourage participation in the survey, respondents were claimed to have been given cash payments to enroll, to refer family and friends, and to complete multiple surveys. In correspondence received from Michael J. LaCour's attorney, he confirmed that no such payments were made. (ii) The statement on sponsorship was false. In the Report, LaCour acknowledged funding from the Williams Institute, the Ford Foundation, and the Evelyn and Walter Haas Jr. Fund. Per correspondence from LaCour's attorney, this statement was not true.

In addition to these known problems, independent researchers have noted certain statistical irregularities in the responses (2). LaCour has not produced the original survey data from which someone else could independently confirm the validity of the reported findings.

Michael J. LaCour does not agree to this Retraction.

Marcia McNutt
Editor-in-Chief



Antibiotics have been found in pork in China.

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Published online 28 May 2015
DOI: 10.1126/science.aac6638

Editorial expression of concern

IN THE 12 December 2014 issue, *Science* published the Report "When contact changes minds: An experiment on transmission of support for gay equality" by Michael J. LaCour and Donald P. Green (1). On 19 May 2015, author Green requested that *Science* retract the paper because of the unavailability of raw data and other irregularities that have emerged in the published paper. *Science* is urgently working toward the appropriate resolution, while ensuring that a fair process is followed. In the meantime, *Science* is publishing this Editorial Expression of Concern to alert our readers to the fact that serious questions have been raised about the validity of findings in the LaCour and Green paper.

Marcia McNutt
Editor-in-Chief

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Published online 20 May 2015
DOI: 10.1126/science.aac6184

Antibiotics crisis in China

THE EMERGENCE OF antibiotic-resistant pathogens has become a global public health crisis. A new and serious crisis is emerging in China: Antibiotics have polluted the food and drinking water supply. Antibiotics are detectable in the residential

tap water of Chinese homes (1). Urban water supplies present multiclass antibiotic residues, including those of fluoroquinolones (broad-spectrum antibiotics whose use is discouraged except in treating serious bacterial infections). Antibiotic residues have been found in foods, including pork (2), aquatic products (3), vegetables (4), and milk (5). For instance, the Shanghai Food and Drug Administration found 7.7% of aquatic products to be unacceptable for human consumption because of antibiotic residues (6). Antibiotic residues are also found in vegetable samples, especially those grown in manure-amended soil (7). In one study, 47% of raw milk samples from 10 provinces of China were found positive for antibiotic residues (5).

At least three factors are responsible for this new antibiotic-related crisis in China. First, the country is the largest producer and consumer of antibiotics, reaching about 210,000 tons of antibiotics annually (8). Antibiotics are misused and discharged into the environment, where they pollute crop-producing soil and groundwater and rivers that are sources of drinking water, such as the Yangtze River (7). Second, an important source of antibiotics in food is antibiotic residues present in the agricultural and livestock industries (9). In China, about 97,000 tons of antibiotics [46% of all antibiotics used in the country (8)] are used in its livestock to prevent disease and improve production (8). In addition to residues present in livestock food products, misuse of antibiotics results in 29,000 to 87,000 tons of antibiotic residues annually in livestock waste, which is used as manure soil amendment for crop production, thereby causing contamination of agricultural products with antibiotics (10). Third, a main reason for this emerging crisis is the lack of effective supervision over the production, use, and disposal of antibiotics. For instance, one of

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First Name James Last Name Enstrom

Email jenstrom@ucla.edu Yes, I would like to hear about AAAS's future initiatives.

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Question for Rush Can AAAS Board Members undertake an assessment of the concerns of many scientists regarding a distinct bias of Science magazine in certain controversial areas, like climate science and environmental regulatory policy?

From: jfahrenkamp@science-int.co.uk
Sent: Monday, August 24, 2015 3:42 AM
To: jenstrom@ucla.edu
Cc: jfahrenkamp@science-int.co.uk
Subject: Decision on your Science Manuscript aad2566

24-Aug-2015
Retired Research Faculty
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Dear Dr. Enstrom,

Manuscript number: aad2566

Thank you for submitting your manuscript "Particulate Matter Does Not Cause Premature Deaths" to Science. Because your manuscript was not given a high priority rating during the initial screening process, we have decided not to proceed to in-depth review. The article is a resubmission of manuscript aad0615 ("Transparent Science is Necessary for EPA Regulations"), which we returned to you on 3 August; the two submissions are very similar in substance, and we have reexamined and confirmed the basis for our earlier decision. It is simply a fact that every day we reject many research and commentary submissions because of stringent space requirements and the need to keep the journal to a manageable size. Furthermore, most articles in our Perspectives section are invited, leaving limited room for uninvited contributions. In the context of other articles under consideration we did not find your submission to be competitive. I am sorry to disappoint you again.

We wish you every success when you submit the paper elsewhere.

Sincerely,

Julia Fahrenkamp-Uppenbrink, Ph.D.
Senior Editor
Science

August 17, 2015

Julia Fahrenkamp-Uppenbrink, Ph.D.
Senior Editor & Perspectives Editor
Education: Ph.D., University of Cambridge
Areas: Perspectives in physical sciences and ecology, chemistry, climate, science policy, history of science
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Dear Dr. Fahrenkamp-Uppenbrink,

I am submitting the attached manuscript “Particulate Matter Does Not Cause Premature Deaths” for consideration as a *Science* Perspective. The Abstract for this manuscript is:

“A 2014 *Science* Policy Forum stated: “With the estimated benefits of PM reductions playing such a central role in regulatory policy, it is critical to ensure that the estimated health benefits are based on the best available evidence.” We challenge the “\$1.7 trillion” claim that EPA’s fine particulate matter (PM_{2.5}) regulations are beneficial because they prevent thousands of “premature deaths” annually. We present strong evidence that PM_{2.5} does not *cause* premature deaths in the U.S.: the major increase in U.S. life expectancy since 1970 is not due to reductions in PM_{2.5}; there is no established etiologic mechanism by which PM_{2.5} causes premature death; misrepresentation (falsification) of PM_{2.5}–death findings has undermined their credibility; prominently cited American Cancer Society “secret science” data cannot be independently analyzed. Transparent science, as required by the Secret Science Reform Act, is as essential for determining the value of EPA regulations as it is for the research published by *Science*.”

For a full understanding of this submission, it is important that you read the manuscript and this cover letter. In addition, we have provided Supplementary Material, which contains one publication by each of the nine co-authors, in co-author order (71 total pages). These nine publications are all relevant to the contents and background of the manuscript. The names, email addresses, and websites for the co-authors are shown below.

As I explained in my August 10, 2015 email message to Editor-in-Chief McNutt (see below), *Science* has extensively covered the importance of PM_{2.5}-related deaths (references 3, 4, 14, 15, and more dating back to 1997), but it has never published a critique of the PM_{2.5} -death relationship. We make a very strong case that there is no *causal* relationship and that scientific misconduct (falsification and unethical use of data) has occurred. The misconduct dates back at least to 2000 and involves the willful collaboration of several EPA-favored scientists. The extensive irrefutable evidence we have presented (particularly in references 10, 12, and 13) is certainly worthy of peer review by *Science*.

The first two co-authors (Enstrom and Young) are primarily responsible for the writing of the manuscript and we are both long-term AAAS members. I am a 40-year AAAS member, who was once nominated to be an AAAS Fellow, and Dr. Young is an AAAS Fellow. The other co-authors, some of whom have a history as AAAS members, provided input from seven different perspectives and we all support the contents of the manuscript. We are a diverse group of experienced, accomplished, and independent scientists and physicians. We have expertise in the

following relevant disciplines: epidemiology, statistics, toxicology, medicine, environmental economics, environmental law, environmental physics, particle physics, and anthropology. The first five authors have recently spoken and/or written on the subject of this Perspective (see Reference 10 and elsewhere).

We are sure that most AAAS members support transparent science in the way we do and we hope that our viewpoint on PM2.5-related deaths and the need for transparent science can be published in *Science*. We are willing to clarify any aspect of this manuscript that you do not understand and we are willing to make modifications that improve it.

Thank you very much for your consideration.

Sincerely yours,



James E. Enstrom, Ph.D., M.P.H.
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From: Marcia McNutt <mmcnutt@aaas.org>
Sent: Monday, August 10, 2015 12:29 PM
To: James E. Enstrom <jenstrom@ucla.edu>
Subject: Re: Reconsider Decision on Science Manuscript aad0615

Dear Dr. Enstrom:

I looked into the history of this submission and discussed it with the Editor. As you can perhaps appreciate, we need to be consistent in how we handle various types of content that we receive. In the case of your submission, on one hand the essay was presented as an alternative view to the Rosenberg et al. PF. We have already published quite a few letters to the editor that express alternate viewpoints and support for the Secret Science Act. If you have additional points that have not already been made in any of the letters we have already published, our Letters editor would be pleased to consider publishing an additional letter from you.

On the other hand, there were some elements of your policy forum submission that were only marginally connected to the Rosenberg piece, and were instead discussing the public health impacts of PM2.5. That issue needs to be submitted as a research article and reviewed as such, rather than as a policy forum. That would be a rather different sort of submission.

I hope this explanation helps you decide in what direction to take your manuscript.

Marcia McNutt

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From: "James E. Enstrom" <jenstrom@ucla.edu>
Date: Monday, August 10, 2015 at 5:59 AM
To: Marcia McNutt <mmcnutt@aaas.org>
Subject: Reconsider Decision on Science Manuscript aad0615

August 10, 2015

Marcia K. McNutt, Ph.D.
Editor-in-Chief, *Science*
mmcnutt@aaas.org

Dear Editor-in-Chief McNutt,

I request that you reconsider the August 3, 2015 rejection by Editor Brad Wible of the July 20, 2015 *Science* Policy Forum Manuscript aad0615 "Transparent Science is Necessary for EPA Regulations". Because of the strength of the evidence that it contains, I request that the manuscript undergo full in-depth review. If you have not done so, I request that you briefly examine the manuscript itself (<http://www.scientificintegrityinstitute.org/PFPaper072015.pdf>), the detailed cover letter (<http://www.scientificintegrityinstitute.org/PFLetter072015.pdf>), the 71-page supplement (<http://www.scientificintegrityinstitute.org/PFSupp072015.pdf>), my June 4, 2015 email message to you (<http://www.scientificintegrityinstitute.org/McNuttWSJ060415.pdf>), and the outstanding credentials of the nine co-authors (as stated on their personal websites).

Reference 10 of the manuscript contains overwhelming and indisputable evidence of scientific misconduct (falsification) by major investigators who have published key epidemiologic research on the relationship between PM2.5 and mortality. Reference 12 contains clear evidence that the research of these same investigators has violated a 1982 ACS confidentiality statement to CPS II research subjects. This evidence warrants in-depth peer review by *Science*.

For the record, *Science* has never published a major article which challenges the claim the air pollution (particularly PM2.5) currently *causes* "premature death" in the United States, particularly in California. However, *Science* has published several major articles which promote the dangers of air pollution, including the August 21, 1970 article on "Air Pollution and Human Health" (<http://www.sciencemag.org/content/169/3947/723.full.pdf>), the February 14, 1992 article on "Valuing the Health Benefits of Clean Air" (<http://www.sciencemag.org/content/255/5046/812.full.pdf>), the April 18, 2014 Policy Forum on "Particulate Matter Matters" (<http://www.sciencemag.org/content/344/6181/257.full.pdf>), and the May 29, 2015 Policy Forum on "Congress's Attacks on Science-based Rules" (<http://www.sciencemag.org/content/348/6238/964.full.pdf>).

In the interest of objectivity and integrity regarding an environmental science issue of national significance, *Science* should peer review this manuscript. Please let me know your decision.

Thank you very much.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
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Particulate Matter Does Not Cause Premature Deaths

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National Association of Scholars

August 17, 2015

An extensive 2011 U.S. Environmental Protection Agency (EPA) cost-benefit report estimates the annual costs required to meet 1990 Clean Air Act (CAA) Amendment regulations to be about \$65 billion in 2020. The annual economic benefits of these regulations are estimated to be about \$2 trillion in 2020, based primarily on EPA-projected reductions in air pollution-related premature deaths and illness (1). This report has been challenged because the benefits are unproven and depend upon several questionable and unverified assumptions. Among these are assumptions that a linear, no-threshold, *causal* relation exists between fine particulate air pollution ($PM_{2.5}$) and total mortality and that additional life expectancy gained at a median age of about 80 years should be valued at about \$80,000 per month. These assumptions are essential because \$1.7 trillion (85%) of the \$2.0 trillion total benefit estimate is attributable to reductions in premature deaths due to reductions in $PM_{2.5}$. Using discrete uncertainty analysis with plausible alternative assumptions, Cox found that the costs of CAA amendments actually exceed their benefits (2).

Dominici et al. have stated: “With the estimated benefits of PM reductions playing such a central role in regulatory policy, it is critical to ensure that the estimated health benefits are based on the best available evidence. If the estimates are biased upward (downward), then the regulations may be too stringent (lenient).” (3). Because of the urgent need to verify the health benefits of EPA regulations, Congress is enacting the Secret Science Reform Act (SSRA) (4). The SSRA would “prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible.”

Based on the data and research findings that are currently available without the SSRA, we challenge the validity of the annual \$1.7 trillion health benefit attributed to reductions in PM_{2.5}. Specifically, we present four types of evidence that PM_{2.5} does not *cause* premature deaths.

1) The major increase in U.S. life expectancy since 1970 is not due to reduction in PM_{2.5}. In 2009 Pope claimed that from 1980 to 2000 a decrease of 10 µg/m³ of PM_{2.5} was associated nationally with a 0.61 year increase in life expectancy based on a correlation involving 51 U.S. metropolitan areas (USMAs) (5). This association was vigorously contested by four independent analyses because the underlying data was available, as would be required by the SSRA. Enstrom found no association whatsoever in 11 California counties (5). Krstic found that the national association claimed by Pope lost statistical significance with the removal of one USMA (Topeka, KS) and that the correlation between changes in PM_{2.5} and life expectancy had so much scatter that it explained almost none of the association (6). Young showed that there was no association in the Western U.S., thereby supporting Enstrom, and showed that the national association was much stronger with income than with PM_{2.5} (7). Cox found no significant association between reductions in PM_{2.5} and total mortality rate between 2000 and 2010 in 483 counties in the 15 most populated states, including California (8). The inconsistencies and weaknesses found in the association means that Pope did not prove the hypothesis that a reduction in PM_{2.5} *causes* an increase in life expectancy. However, since 1970, the year that EPA was established, health-related factors other than air pollution have had a major impact on increasing the longevity of Americans. The total annual age-adjusted death rate in the U.S. has declined by 40% from 12.226 deaths/1000 in 1970 to 7.319 deaths/1000 in 2013. The death rate in California has declined by 45% from 11.370 deaths/1000 in 1970 to 6.301 deaths/1000 in 2013. Life expectancy from birth has increased from 70.8 years in 1970 to 78.8 years in 2013 in the U.S. and from 71.7 years in 1970 to 80.8 years in 2013 in California (9).

2) No plausible etiologic mechanism by which PM_{2.5} *causes* premature death is established. It is implausible that a never-smoker’s death could be *caused* by inhalation over an 80 year lifespan of about one teaspoon (~5 grams) of invisible fine particles as a result of daily exposure to 15 µg/m³. This level of exposure is equivalent to smoking about 100 cigarettes over a lifetime or 0.004 cigarettes per day, which is the level often used to define a never-smoker. The notion that PM_{2.5} *causes* premature death becomes even more implausible when one realizes that a person who smokes 0.2 cigarettes/day has a daily exposure of about 750 µg/m³. If a 10 µg/m³ increase in PM_{2.5} actually *caused* a 0.61 year reduction in life expectancy, equivalent to the claim of Pope, then a 0.2 cigarettes/day smoker would experience about a 45-year reduction in life expectancy, assuming a linear relationship between changes in PM_{2.5} and life expectancy. In actuality, never-smokers and smokers of 0.2 cigarettes/day do not experience any increase in

total death rate or decrease in life expectancy, in spite of a 50-fold greater exposure to PM_{2.5} (10). Furthermore, hundreds of toxicology experiments on both animals and humans have not proven that PM_{2.5} at levels up to 750 µg/m³ *causes* death. Finally, the small relative risks of death and other biases and weaknesses of the PM_{2.5} epidemiologic studies do not meet the standards of causality set by the 2011 Federal Judicial Center Reference Manual on Scientific Evidence (11). The legal standard for causality in epidemiologic studies is a large relative risk (RR ≥ 2.0), not the small relative risk (RR ~ 1.1) typically found in PM_{2.5}-mortality studies.

3) Misrepresentation of PM_{2.5}-death findings has harmed the credibility of epidemiology. The PM_{2.5}-mortality relationship has been contested since 1993 because this small risk could be due to well-known biases, such as, confounding variables and the ecological fallacy. In spite of these biases, several major PM_{2.5} investigators continue to assert that selected positive findings prove that PM_{2.5} *causes* death and they continue to ignore or dismiss null PM_{2.5} results. Enstrom prepared a detailed November 15, 2013 document (5000 words of text with 77 URLs) which describes many misrepresentations and exaggerations (12). In particular, Pope and others have ignored null PM_{2.5} findings in California. Serious concerns about the PM_{2.5}-mortality relationship in California were expressed at a February 26, 2010 Symposium on “Estimating Premature Deaths from Long-term Exposure to PM2.5” by the California Air Resources Board (CARB). Vastly different viewpoints were expressed by scientists like Enstrom and Pope. Although this Symposium could have led to better understanding and cooperation among PM_{2.5} investigators, it did not. For instance, three Symposium attendees (Pope, Jerrett, and Krewski), published extensive findings in their October 28, 2011 CARB report showing that there was an overall null relationship between PM_{2.5} and mortality in California, if one averaged the results from all nine of their models. This null finding agrees exactly with the null findings of Enstrom and others. However, in their subsequent September 1, 2013 *AJRCCM* paper, “Air Pollution and Mortality in California,” they selectively published the positive findings found in one model, but omitted the null findings of the eight other models in their 2011 report.

4) The American Cancer Society actively supports “secret science” PM_{2.5} epidemiology. Since 1995 ACS has repeatedly allowed its 1982 Cancer Prevention Study (CPS II) data to be selectively used for PM_{2.5} epidemiology research. However, ACS has refused to release the CPS II data or allow analysis that addresses the legitimate concerns raised by qualified critics of this “secret science” research. ACS is well aware of the scientific controversy generated by the original 1995 Pope *AJRCCM* paper and subsequent papers that have been used by EPA as a primary justification for its PM_{2.5} regulations. The demand for CPS II data access has increased as PM_{2.5}-related regulations have gotten stricter, more expensive, and more implausible. While ACS refuses any independent access to its CPS II data, because of alleged concerns about subject confidentiality, it has repeatedly allowed Pope and his collaborators to violate a confidentiality pledge made to CPS II subjects. When personal questionnaire data was collected from CPS II subjects upon enrollment in late 1982, ACS informed them with this exact sentence: “We will **never** release information about any particular person and will not release addresses to any agency for any purpose, whatsoever” (13). Both the September 1, 2013 *AJRCCM* paper and the new January 2, 2015 *Circulation Research* paper by Pope include findings based on linking the home address of each study subject to a geographically estimated PM_{2.5} concentration, in violation of the 1982 agreement.

Our evidence that PM_{2.5} does not *cause* premature deaths invalidates the \$1.7 trillion annual benefit that EPA attributes to reductions in PM_{2.5} and supports Cox's findings that the economic costs of EPA CAA Amendment regulations exceed the resulting health benefits. Because the scientific and economic stakes are high for America, there is an urgent need for transparency and reproducibility in the science and data underlying EPA regulations, as required by the SSRA. The data access requirement in the SSRA is very similar to the one *Science* has for its research papers and to the one recently recommended by the editors of 30 major journals, including *Science* (14). Even an environmental organization that objects to the SSRA, the Union of Concerned Scientists, realizes that "public trust in science increases when we all have access to the same base of evidence" (15).

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(<http://www.sciencemag.org/content/348/6238/964.full.pdf>)

OPINION

REVIEW & OUTLOOK

Scientific Fraud and Politics

A press release from the Union of Concerned Scientists recently hit our desk titled "Science Leaders Decry Congressional Attacks on Science and Science-Based Policy." It flagged an op-ed in the journal *Science* that laments "a growing and troubling assault on the use of credible scientific knowledge."

Hmmm. Is this about science, or politics?

Since the scientists brought it up, which is the greater threat to their enterprise: the Republicans who run Congress, or the most spectacular scientific fraud in a generation, which was published and then retracted by the journal *Science*?

Last year UCLA political science grad student and maybe soon-to-be Princeton professor Michael LaCour released stunning findings from a field trial on gay marriage called "When Contact Changes Minds." He found that a 20-minute conversation with a house-to-house canvasser could convert huge numbers of opponents into supporters, at least if the canvassers explained they were gay and told personal stories.

The study quickly became a media sensation, the most talked-about poli-sci paper in years, and it led gay-rights activists including some working on the Ireland referendum to retool their voter outreach.

The problem is that Mr. LaCour stands accused of faking everything from start to finish. Ph.D. candidates at Berkeley David Broockman and Josh Kalla tried but failed to replicate Mr. LaCour's results. They then noticed unusual statistical irregularities in Mr. LaCour's survey panel. He now says he pulled a Hillary Clinton and deleted his raw data. But the canvassing firm he claimed to have employed has never heard of the project—and there is no proof anyone was ever contacted, much less changed their minds.

Mr. LaCour denies wrongdoing and in a response paper assailed the motives of Messrs. Broockman and Kalla, whose violations of academic decorum include their decision to go public and "bypass the peer-review process." That would be the same process that failed to catch Mr. LaCour's

non-findings at *Science* magazine.

The larger question is why anyone invested Mr. LaCour's paper with the authority of "science." Experience and common sense suggest that persuading people to reconsider their opinions is difficult. An uninvited nag carrying on about politics on the front porch sounds like

one of the less successful approaches.

Then again, the study flattered the ideological sensibilities of liberals, who tend to believe that resistance to gay marriage can only be the artifact of ignorance or prejudice, not moral or religious conviction. Mr. LaCour's purported findings let them claim that science had proved them right.

Similar bias contaminates inquiries across the social sciences, which often seem to exist so liberals can claim that "studies show" some political assertion to be empirical. Thus they can recast stubborn political debates about philosophy and values as disputes over facts that can be resolved by science. President Obama is a particular aficionado of this bait and switch.

As for those supposedly "anti-science" Republicans, they stand accused by *Science* magazine of trying to introduce more transparency and accountability to federal science grants. The House GOP is also guilty of attempting to spend more on the harder sciences, passing a bill last month that allocates money for the National Science Foundation by directorate—for example, boosting engineering spending by 13.2% over 2015 and biology by 12.6%. Money for the social and behavioral sciences declines by 44.9%.

Scientific misconduct does seem to be mercifully rare, but a lesson of the LaCour retraction is to show more humility amid the illusion of scientific omniscience and to be more skeptical of studies that carry heavy political freight. That goes for the profusion of foods that are purported to cause or prevent cancer, and macroeconomic literature that claim to document a stimulus "multiplier."

Meanwhile, *Science* magazine editors who rebuke politicians might have more authority if their own science wasn't so political.

From: Marcia McNutt <mmcnutt@aaas.org>
To: "James E. Enstrom" <jenstrom@ucla.edu>
Subject: Re: Request to Discuss AAAS & SSRA & PM2.5 Misconduct
Date: Fri, 5 Jun 2015 15:37:39 +0000

Dear Dr. Enstrom:

You would need to contact the AAAS office of Public Policy to reverse the AAAS position on the Secret Science bill. I have no control over that. It is not part of the journal *Science*. You would need to contact the AAAS Board of Directors to ask them to conduct such an assessment. I do not sit on the Board. I have never heard of them conducting an assessment of this sort, ever. I do not believe that they have the mechanism or resources to do it. The NAS would be your best bet.

Sincerely,

Marcia McNutt

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From: "James E. Enstrom" <jenstrom@ucla.edu>
Date: Friday, June 5, 2015 at 12:38 AM
To: Marcia McNutt <mmcnutt@aaas.org>
Subject: Request to Discuss AAAS & SSRA & PM2.5 Misconduct

June 5, 2015

Dear Dr. McNutt,

I appreciate your quick response to my email message. However, I do not want the editors at Science to consider another retraction equivalent to the LaCour and Green retraction. First, I want that AAAS/Science to reconsider its objections to the Secret Science Reform Act and to take a clear position in favor of access to the data underlying the PM2.5-mortality relationship, a subject that Science has written about since 1997. Second, I want the AAAS Board of Directors to assess my evidence of scientific misconduct in PM2.5 epidemiology, much of which involves

the University of California. Third, I want to make clear that the points made in the April 11, 2015 Lancet Comment apply to PM2.5 epidemiology. Ideally, I would like to briefly discuss these three important issues with you, either in person or over the phone, when I am in Washington, DC, next week. Please let me know if a discussion is possible.

Thank you very much for your consideration.

Sincerely yours,

Jim Enstrom
(310) 210-7145

At 02:47 PM 6/4/2015, you wrote:

Dear Dr. Enstrom:

If you would like the editors at *Science* to consider a retraction, could you please provide us with the citation for the paper you believe needs to be retracted, the report from the university where the research was conducted requesting retraction, or a request from the study's senior author(s) requesting retraction? Thank you.

Sincerely,

Marcia McNutt

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From: "James E. Enstrom" <jenstrom@ucla.edu>
Date: Thursday, June 4, 2015 at 5:19 PM
To: Marcia McNutt <mmcnutt@aaas.org>
Cc: Geri Richmond <richmond@uoregon.edu>, "Carlos J.Bustamante" <carlosb@berkeley.edu>, Michael Gazzaniga <michael.gazzaniga@psych.ucsb.edu>, "Elizabeth F.Loftus" <eloftus@uci.edu>, Chris Carter <chris.carter@ucdc.edu>
Subject: Important Request re AAAS & 'Secret Science Reform'

June 4, 2015

Marcia K. McNutt, Ph.D.
Editor-in-Chief, Science
mmcnutt@aaas.org

Dear Editor-in-Chief McNutt,

On May 28, 2015, [Science retracted](#) the December 12, 2014 paper by Michael LaCour and Donald Green because, in part, the underlying data is not available to independently confirm the paper's findings. Science requires [Data and Materials Availability](#) for the papers that it publishes. Science has written extensively between [July 25, 1997](#) and [August 9, 2013](#) about the use of the relationship between fine particulate air pollution (PM2.5) and mortality to justify costly EPA regulations and the lack of access to the data underlying this relationship.

Because this 'secret science' data has never been available for independent analysis, Congress has introduced the [Secret Science Reform Act](#) to "prohibit the Environmental Protection Agency from proposing, finalizing, and disseminating regulations or assessments that are based upon science that is not transparent or reproducible." However, [AAAS](#) has written at least three letters to Congress raising objections to an act which requires access to underlying data. I request that AAAS reconsider its objections to this act and take a clear position in favor of access to the data underlying the PM2.5-mortality relationship. During the past ten years I have assembled extensive evidence that scientific misconduct has occurred in PM2.5 epidemiology and on December 1, 2014, I submitted [65 pages](#) of such evidence to EPA (<http://www.scientificintegrityinstitute.org/JECP120114.pdf>). On February 17, 2015, I submitted [72 pages](#) of similar evidence to the UCLA Vice Chancellor for Research (<http://www.scientificintegrityinstitute.org/Economou021715.pdf>). My evidence is far more extensive than the [27 pages](#) of evidence that supported the retraction of the LeCour and Green paper.

I request that you and the AAAS Board of Directors examine my evidence, much of which involves UCLA Professor [Michael Jerrett](#), who is at the same university as LaCour. The stakes are high for both scientific integrity and the U.S. economy. The PM2.5-mortality relationship is currently being used as a major justification for many major EPA regulations, most recently EPA's Clean Power Plan. The CPP has been estimated to cost up to \$479 billion over the next 15 years and a strong case can be made that it is not scientifically or economically justified. I will be giving a talk about "EPA's Clean Power Plan and PM2.5-related Co-benefits" on June 11, 2015 at the [Tenth International Conference on Climate Change](#) in Washington, DC. You and others from Science and AAAS are welcome to attend my presentation.

Last Friday I sent the email message below to most of the scientists involved with PM2.5 epidemiology misconduct and no one has yet responded. I hope that Science and AAAS will take my evidence of misconduct seriously. In any case, I am going to use this evidence to support the April 11, 2014 [Lancet Comment](#) of Editor Richard Horton, who stated, in part, "The case against science is straightforward: much of the scientific literature, perhaps half, may simply

be untrue . . . science has taken a turn towards darkness."

Thank you very much for your consideration of this important matter.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
UCLA and Scientific Integrity Institute
<http://www.scientificintegrityinstitute.org/>
jenstrom@ucla.edu

Date: Fri, 29 May 2015 11:00:16 -0700
To: "James E. Enstrom" <jenstrom@ucla.edu>
From: "James E. Enstrom" <jenstrom@ucla.edu>
Subject: Important Request re ICCC-10 & PM2.5 Premature Deaths

May 29, 2015

Dear EPA-related Scientist,

I am giving a June 11, 2015 talk entitled "EPA's Clean Power Plan and PM2.5-related Co-benefits" at the Tenth International Conference on Climate Change in Washington, DC (<http://climateconference.heartland.org/>). I am going to present evidence of scientific misconduct by you of the type described in the April 11, 2015 Lancet Comment by Editor Richard Norton on "A lot of what is published is incorrect" ([http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60696-1.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60696-1.pdf)). My evidence is described in the Clean Power Plan comments that I submitted to EPA on December 1, 2014 (<http://www.scientificintegrityinstitute.org/JECPP120114.pdf>).

I am sending this message in order to give you an opportunity to respond to my above evidence, either by attendance at my talk or by an email message to me before my talk. At least let me know your answer (YES or NO) to these two questions: 1) do you believe that PM2.5 currently causes premature deaths in the U.S.? and 2) do you believe that EPA should continue to defy the Secret Science Reform Act of the U.S. Congress? Unless you respond otherwise, I will assume that your answer to both questions is YES. Finally, please let me know if you are concerned about the Lancet Comment.

Thank you very much for your consideration.

Sincerely yours,

James E. Enstrom, Ph.D., M.P.H.
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