Testimony of
Professor David Michaels
The George Washington University

Hearing Before the United States Congress
House Committee on the Judiciary
Subcommittee on Antitrust, Commercial, and Administrative Law

The Administrative Procedure Act at 75:
Ensuring the Rulemaking Process is Transparent, Accountable, and Effective

December 1, 2021

David Michaels, PhD, MPH
Department of Environmental and Occupational Health
Milken Institute School of Public Health
The George Washington University
950 New Hampshire Ave NW, Fourth Floor
Washington, DC 20052
dmm@gwu.edu

Testimony of
Professor David Michaels
Milken Institute of Public Health
The George Washington University

Hearing Before the United States Congress
House Committee on the Judiciary
Subcommittee on Antitrust, Commercial, and Administrative Law

The Administrative Procedure Act at 75:
Ensuring the Rulemaking Process is Transparent, Accountable, and Effective

Chairman Cicilline, Chair Jayapal, Ranking Member Buck, and Members of the Subcommittee, thank you for inviting me to testify here today. My name is David Michaels. I am an epidemiologist and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health of George Washington University. The views expressed in my testimony are my own and do not represent the views of George Washington University.

This year marks the 75th year of the Administrative Procedures Act, which governs much of the inner workings of the American regulatory system. I am honored to have been invited to provide testimony about updating the APA in light of the challenges our country faces today, including through the Stop Corporate Capture Act. Thank you for your efforts to improve the functioning of our regulatory system – the primary mechanism through which the federal government protects the health and well-being of the nation's people and environment.

I will speak from my experience as a leader in the federal regulatory system and as an academic who has extensively studied this system.

From 2009 until January 2017, I served as Assistant Secretary of Labor for Occupational Safety and Health, the longest serving Assistant Secretary in OSHA's history. From 1998 to 2001, I was Assistant Secretary for Environment, Safety and Health in the U.S. Department of Energy, charged with protecting the workers, community residents and environment in and around the nation's nuclear weapons facilities.

I am a member of the Board of Scientific Counselors of the US National Toxicology Program, appointed to this position by HHS Secretary Alex M. Azar, United States Secretary of Health and Human Services from 2018 to 2021 under President Donald J. Trump. I am also a Senior Member of the Administrative Conference of the United States and served as a Government Member from 2010-2017.

I have focused on the regulatory system, and the importance of protecting the integrity of scientific basis for public health and environmental protections through much of my academic career. I have written two books on the subject: *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health* (Oxford University Press, 2008), and *The Triumph of Doubt:*

Dark Money and the Science of Deception (Oxford University Press, 2020). The importance of these books has been widely acknowledged in the scientific community. The reviewer in the journal *Science* wrote "The Triumph of Doubt is a tour de force that examines how frequently, and easily, science has been manipulated to discredit expertise and accountability on issues ranging from obesity and concussions to opioids and climate change."[1] In the journal Nature, the reviewer called The Triumph of Doubt "a brave and important book, raising the alarm about the systemic corruption of science."[2] In recognition of my work defending the integrity of the science used in regulation, I was awarded the Scientific Freedom and Responsibility Award by the American Association for the Advancement of Science and the John P. McGovern Science and Society Award by Sigma Xi, The Scientific Research Honor Society.

In this testimony, I will comment on components of the Stop Corporate Capture Act, as well other aspects of the regulatory system that need improvement. My comments are based on my experiences directing regulatory agencies as well as my academic research.

The Need for a Stronger, More Agile Regulatory System to Maintain Our Freedom

A catalog of public health tragedies—from cigarettes and asbestos to the climate crisis and the widespread PFAS contamination of drinking water—have necessitated the growth of America's public health regulatory system. In each of these cases, corporations making a product caused damage, then turned a profit by avoiding paying for externality costs. Litigation is typically valuable in redressing the public's grievance, but it is not sufficient for changing the root issues, in part because litigation always occurs after the fact. By the time the lawsuit is filed, too many people have been sickened, or maimed, or killed—to say nothing of how the environment has been desecrated.

Our regulatory system is the response to these market failures. The objectives of the laws and the agencies empowered to enforce them is not only to stop the damage and prevent future harm; it is to maintain and strengthen the free market system. Law and regulation are the underpinnings of our economic system. They define market structure and property rights while attempting to ensure that property rights don't intrude on personal liberties. They ensure access to information and empower individuals to make economic decisions without coercion. Without the regulatory apparatus of the state, our modern economy could not exist.

We all value freedom, in particular the freedom to live the lives we choose. But this is not possible unless we are secure from being harmed by others, and in our modern world we individuals cannot bargain with the factory owner or the manufacturer of contaminated food.[3] We generally have little or no knowledge of the effects of a given exposure, or sometimes that such exposures are even occurring. It is America's elected representatives and officials who must enact and enforce laws that protect us from individual and collective harm—from violence and from robbery, but also from dangers posed by tainted food, polluted air and water, unsafe drugs, and dangerous workplace exposures.

Science underpins all of these public health and environmental regulations. The basic principle of the regulatory system holds that decisions must be made on the basis of the best evidence available at the time. Conflicted science doesn't just game our free-market system; it prevents the system from accomplishing its very purpose, which is facilitating the owners of a company to profit by producing or performing something, while not impinging on the freedom and well-being of others. We want stronger regulation not because we don't care about freedom, but because we cannot be free without the state's protection from harm. We need to know that our air is safe to breathe, that our food is safe to eat, and that we can return home from work at the end of our shifts no less healthy than when we walked out the door in the morning.

As great as the current need for public protections is, it is clear that the current system of issuing standards to protect the public's health, safety, well-being, and environment does not function well. We are a rapidly changing world, with new developments that can have significant and potentially cataclysmic effects on the population occurring with greater frequency. We need an agile regulatory system to address, to name just a few challenges, the climate crisis, COVID-19 variants, environmental injustice, massive income and wealth inequality, the affordable housing shortage, antibiotic resistant organisms, the opioid overdose epidemic, and the threats to financial stability posed by cryptocurrency.

The agency I ran, OSHA may be among the agencies with the slowest, least agile standard setting processes. This long and burdensome process is diagrammed in Appendix A. The US Government Accountability Office has estimated that it takes OSHA an average of seven years to issue a regulation,[4] although this is an underestimate, since minor regulations can be issued quickly, and significant regulations take far longer. OSHA began work strengthening the standard for workplace exposure to silica, a dust that increases risk of lung cancer and silicosis, in 1997. It was finally issued in 2016, 19 years after the start of the process, and required a tremendous effort in terms of staff time.

Just as regulations have costs and benefits, the failure to protect the public's health, safety and well-being has benefits, which generally accrue to parties profiting from actions that hurt the public. Failure to regulate also has costs: increased illness and death, or in the case of financial regulation, lower income or wealth, among people impacted by the deleterious actions not regulated.

I hope today's hearing will help jumpstart an effort to improve and strengthen the processes the federal government employs to issue the regulations the nation so badly needs. The following are my comments on aspects of the Stop Corporate Capture Act.

Addressing Conflicts of Interest in Evidence Submitted in Regulatory Proceedings

Sections 2 and 3 of the Stop Corporate Culture Act require parties submitting technical information, including scientific studies, provide conflict of interest disclosures similar to those required by scientific and medical journals.

These are valuable steps designed to protect the integrity of science that forms the underpinning of regulatory protections. At minimum, they will help distinguish those studies that have been produced by mercenary scientists for the purpose of delaying or weakening public health protections, from those that produce a more accurate and useful understanding of the effects of exposure to a given substance.

However, requiring disclosure and making this information public will only improve the quality of agency decision-making if agencies can act on the degree of objectivity of the science. The subcommittee should consider amending the legislation to add teeth to the disclosure requirements. It could do so by allowing agencies to choose to exclude conflicted science from the administrative record on which they make decisions, if they determine that the study is irreparably tainted by conflict-related concerns. Or it could exclude judicial challenges to agency actions under the APA on the grounds that the agency didn't consider important evidence if that evidence was similarly tainted.

The world's science community has long recognized that financial support of a study is associated with the study producing results favorable to the sponsor. This is known widely as the "funding effect." It is well recognized that no matter who performs the study, those studies funded by a private sponsor tend to deliver the results the sponsor wants. This was seen in the tobacco literature when the tobacco industry was still trying to promote the erroneous idea that secondhand smoke did not increase lung cancer risk. There have been so many studies documenting the funding effect in evaluating risk associated with tobacco, food products, chemicals, and pollutants that it is almost surprising when manufacturers of a product sponsor a study that does not find the results they desire.

Recognizing that conflicts of interest can influence the findings of a study, virtually every scientific and medical journal requires disclosures of who paid for studies and whether the authors have financial conflicts of interest. In virtually all leading scientific journals, every published study is accompanied by a statement by the authors of sources of their funding and their financial ties that might be perceived as posing a conflict of interest. This convention is no longer controversial or even debatable. The transparency alerts readers and regulators to look more closely at the studies, knowing that financial interests may have influenced the results.

In contrast, the federal government does not require any such disclosure when accepting public comments on proposed regulations, permits or other actions or documents.

In a commentary published in the journal *Science*, Professor Wendy Wagner and I proposed that regulatory agencies should adopt, at a minimum, requirements for research independence

comparable to those of biomedical journals (see Appendix B). Disclosure of conflicts of interest should be required for all research, regardless of whether it is federally or privately funded. Scientists should disclose whether they have a contractual right to publish their findings free of sponsor control and should identify the extent to which their work was reviewed by an affected party before publication or submission to the agency. Sponsors who submit data should similarly disclose if their investigators had the contractual right to publish without sponsor consent or influence. Finally, other parties (i.e., trade associations, unions, or public interest groups) who submit scientific results should disclose all known conflicts of interests of the scientists conducting the studies.[5]

During the period I ran OSHA, we included requests that all public comment submissions be accompanied by a disclosure of financial conflicts in the Notice of Proposed Rule Making for strengthened silica and beryllium exposure standards. This initiative was applauded in an editorial in the journal *Nature* entitled "Full Disclosure: Regulatory agencies must demand conflict-of-interest statements for the research they use"[6] a copy of which is included in Appendix C.

Disclosure of Conflicts is Not Enough

The Stop Corporate Capture Act includes similar provisions. However, while disclosure is a useful step, it is not adequate to protect the integrity of the science used in regulation. Disclosure of conflicts figures into the assessment of the scientific research as published, but it is the actual conflict that shapes the course of the research itself. Studies conducted by conflicted scientists are still entered into regulatory proceedings and based on APA requirements, agencies currently must consider them in their deliberations. This is problematic because many of the studies submitted by corporations and trade associations are not legitimate studies – research undertaken by scientists to better understand how the world works, and, in the case of public health, how to better improve the public's health. It is unfortunate that regulators even have to consider studies created by mercenary scientists paid by polluters and manufacturers of dangerous products to manufacture uncertainty about the harms associated with these products. As discussed above, I recommend this legislation be amended to enable agencies to discount or disregard studies produced by conflicted scientists if the information provided by the study is tainted by conflict of interest.

The production of studies to manufacture uncertainty about a product's harm is a component of a larger strategy to convince regulators that hazardous products are not so hazardous after all; or, at least, that there is so much uncertainty that there is inadequate convincing evidence to increase protections for members of the public exposed to that product. This strategy, often called the "tobacco playbook" or the "disinformation playbook", has been widely documented, in my books and by other researchers.[7,8,9] It was also the subject of a 2019 hearing of the House Natural Resources Subcommittee on Oversight and Investigations "The Denial Playbook: How Industries Manipulate Science and Policy from Climate Change to Public Health".[10]

The strategy actually predates Big Tobacco's attempts to convince the public and regulators that the evidence that smoking cigarettes increased lung cancer risk was inadequate. It is called the tobacco playbook because that industry was able to deploy the strategy for such a long time, so successfully, they were able to ward off public health controls for decades. The result: millions of preventable deaths.

The tobacco industry took advantage of the provisions of the Administrative Procedures Act in its successful effort to block an OSHA regulation on indoor air quality. In Appendix D, I've included a record of a conference call involving Philip Morris executives, their lawyers, and product defense consultants, discussing how they could use comments sent to a regulatory docket to overwhelm OSHA. The discussion notes that the consultant "has experts in 'deductive meta analysis' that reveals confounders and identifies the real risk involved if any.'' Understanding the regulatory process and OSHA's obligation to respond to all comments, the conspirators planned a ''line by line analysis raising scientific questions that OSHA would have to respond to. . . . [This] attack could take [OSHA] 2 to 3 years to respond to.'"[11]

Big Tobacco's experts understood they could handcuff OSHA for years by raising complex scientific questions – knowing that OSHA's failure to respond in great detail to these issues would disadvantage the agency in the inevitable legal challenge that regulated parties mount to defeat an undesirable regulation once it is issued. These delay in implementing public health precautions come with costs, of course: additional illnesses and deaths because of the years of members of the public were exposed to a hazard before the regulation was finally issued and enforced.

The tobacco playbook is now standard operating procedure for corporations trying to delay regulation. Volkswagen, for example, bankrolled efforts to dispute studies that documented the deleterious impact of diesel pollution on human health—at the same time that it secretly employed "defeat devices" to fool the Environmental Protection Agency's auto emissions testing systems into underestimating its cars' diesel engine exhaust. Battery manufacturers and smelters employ consultants to question the studies on the impact of low levels of lead exposure to children.[12] ExxonMobil and the oil industry have used many of these same consultants to claim that the evidence of the health effects of air pollutants like ozone is too uncertain to use to in setting regulatory limits. Years ago, scientists at these same fossil fuel firms actually modeled the impact of atmospheric carbon accumulation and predicted much of what we are seeing today, but that didn't stop them from funding the climate change denial machine. These are but a few of the many examples of polluters or manufacturers of dangerous products using the tobacco playbook to delay or weaken regulations designed to protect the public from the deleterious health effects of their products.[13]

In several of these examples, polluters and manufacturers of dangerous products had collected extensive evidence of the harms of their products but did not reveal them to regulators or the public. In some cases, this included studies corporations commissioned but, once the results were known, did not allow to be released. In submitting comments to regulatory dockets, the

subcommittee should consider adding a requirement that manufacturers of a product or pollutant must provide evidence in their possession on the toxic effects of exposure, if that evidence is not already in the public record.

In addition, given the history of mercenary parties slowing down the regulatory process, it would be of great value to give agencies the ability to promulgate emergency regulations based on research showing serious effects on public health without having to consider industry sponsored research while further notice and comment rulemaking is pursued.

Much of the work to manufacture scientific uncertainty about a product or pollutant is done by scientists employed by product defense firms, ones whose business model involves producing studies and reports that provide whatever conclusion the client needs – generally one that minimizes the harms caused by their client's products. These studies, which are often published in scientific journals to give them the appearance of validity, are generally commissioned to influence regulatory proceedings or defeat litigation by people who allege they were harmed by the products.

There is no question that product defense scientists have severe conflicts of interest that actually dictate the conclusions of their "research". They are being paid to produce studies that help their clients. And, in most cases, their conflicts of interest are disclosed. However, it is clear from studies of the health effects of exposure to the class of fluorinated chemicals known as PFAS, or the "forever chemicals" that have been found in drinking water sources in many parts of the country (see box), the problem is not lack of disclosure, it is that they were paid to reach a specific conclusion.

The sordid history of the studies claiming PFAS exposures are safe one of many examples of mercenary studies that have been shown to have underestimated or rejected health risks from exposure to the substances made by the clients of these product defense firms.

Given this, I believe we need to go beyond requiring disclosure of conflict to requiring that studies used in regulatory proceedings aimed at protecting the public to some extent be limited to those performed by scientists free of conflicts of interest. There is value in some basic studies performed by manufacturers to understand aspects of the effects of exposure to a product, and these are needed for regulatory purposes. However, I strongly recommend that studies done by consulting firms whose business model is producing reports to advance their clients' interest should not be admitted into the evidentiary record since they do not reflect honest science. Manufacturers of potentially dangerous products should be required to fund the research meant to investigate the risks associated with their products, but they should not control the research. Only this way can we have confidence in the findings.

CASE STUDY: CONFLICTED SCIENCE CREATED TO MAKE PFAS EXPOSURES APPEAR TO BE SAFE

The most well-known firms have developed very lucrative practices defending chemicals that are facing regulation because of their harmful properties. One recent example is the class of fluorinated chemicals known as PFAS, or the "forever chemicals" that have been found in drinking water sources in many parts of the country. Since concerns about the toxic effects of exposure first surfaced almost 20 years ago, PFAS manufacturers have hired product defense firms to make these chemicals appear to be safe. Before the studies featured in the movie "Dark Waters" found multiple toxic effects of exposure through drinking water consumption among people whose water systems were contaminated by PFOA and PFOS, two chemicals of this type released from DuPont's Teflon-producing plant in Parkersburg WV, DuPont hired product defense expert Dennis Paustenbach and ChemRisk. They produced a study that concluded that the health risk among population who drink PFAS-contaminated water was essentially negligible.[14] Subsequently, PFAS manufacturer 3M hired product defense firm Exponent to prepare a strategic literature review, which concluded: "the epidemiologic evidence does not support the hypothesis of a causal association between PFOA or PFOS exposure and cancer in humans."[15] The manufacturer also hired Gradient, another product defense firm, to provide a report for a court case (3M was sued by the State of Minnesota) in which she claimed that the state overestimated any risk and that current exposures are far below a level that could make people sick.[16] Gradient also teamed with Exponent to challenge the National Toxicology Program's decision to categorize PFAS as an immune hazard. Exponent's scientists published their evaluation in *Critical Reviews in Toxicology*, one of the favored product defense journals, asserting, not surprisingly, that "available evidence is insufficient to conclude that a causal relationship has been established between PFOA or PFOS exposure and any immune condition in humans." [17,18]

There are now many, many studies conducted by scientists <u>not</u> paid by PFAS manufacturers that have found toxic effects at very low exposure levels. As a result, it is now clear that all of these efforts to make PFAS exposures appear to be safe and to enable manufacturers to avoid regulation and pay the costs of environmental cleanup and compensation to victims, were far from accurate. Based on the overwhelming scientific evidence, EPA is finally moving toward issuing regulations that will permit exposure levels that are a tiny fraction of levels these product defense scientific firm declared to be safe.

But the mercenary efforts of the product defense firms were not wasted. Their work helped delay EPA's efforts to control exposure and delayed the imposition of cleanup costs on the polluters responsible for much of the drinking water exposures.

Who knows how many people will be sickened because they continue drink PFAS-contaminated water?

An example of this approach to research that is funded but not controlled by industry is the Health Effects Institute (HEI), a research group originally established in 1980 by EPA and the automobile industry to study the health effects of motor vehicle emissions, with each party contributing half the budget. HEI has since expanded to collaborate with more firms and industries, and it continues to produce research of great importance. Institutes like HEI are not a perfect solution. The corporations involved still wield undue influence, in that they can withdraw from HEI if they don't approve of a research project or its findings, but the model is one that can serve as the basis for future research endeavors.

However, short of requiring industry to fund but not control research, the requirement to disclose potential conflicts of interest by scientists who work in sued in regulation is an important step in protecting the integrity of studies on which to base our public health protections.

Additional Comments on the Stop Corporate Capture Act

Section 4: Disclosure of Inter-Governmental Rule Changes

Increased transparency will result in an improved regulatory process – one that shapes rules and policies that better protect the public's health and well-being. I say this having witnessed too many closed-door sessions in which public health protections are weakened because powerful forces oppose them alleging that they increase costs or are otherwise detrimental to their interests.

One example of this: In a regulatory process for strengthened OSHA shipyard safety rules involving notice and public comment, the Department of the Navy blocked the final rule when it went through inter-agency review. In closed meetings, the Navy claimed that some of the new requirements were unneeded or too expensive. Our experts did not agree with their objections and had rejected similar ones coming from private sector shipyards. But the Navy was able to use their refusal to sign-off in the inter-agency process to hold hostage a badly needed safety regulation.

If enacted, these transparency requirements would not have eliminated that discussion, or stopped the Navy from making their case that the regulation needed to be weakened. However, if the Navy's lack of commitment to the safety of their workforce had become known to the public, I believe they have withdrawn them or scaled back their considerably.

Section 9: Establishment of the Office of the Public Advocate

While regulations are meant to protect the public, they are often shaped by parties who stand to gain if the regulation is written to promote their needs over that of the public. This occurs with great regularity, driven by the tremendous imbalance of power in regulatory proceedings. Large corporations and their trade associations have essentially unlimited resources to

influence the regulatory process to achieve the outcomes they desire. While regulations are meant to protect the public, they are often shaped by parties who stand to gain if the regulation is written to promote their needs over those of the public at large.[19] proceedings. Large corporations and their trade associations have enormous financial resources to influence the regulatory process to achieve the outcomes they desire. These corporate players are often far more likely to participate in the regulatory process than public interest representatives like unions or environmental groups.[20] And studies have shown that agencies tend to be more responsive to comments posed by industry groups than their public interest counterparts.[21]

Smaller businesses also have a privileged ability to influence OSHA, EPA and Consumer Financial Protection Bureau regulations through special processes coordinated by the Small Business Administration (SBA) Office of Advocacy (although much of the work of this misnamed agency is in fact in the interest of large businesses). This office also attempts to shape proposed regulations outside the public APA notice-and-comment system through inter-agency review, giving its staff more ability to advocate for business interests than any other stakeholder representative.[22]

In contrast, the public, the party most in need of the protections that regulations provide, have relatively little voice in these proceedings. This is particularly true of poor and working people, who have neither the resources to spend on influencing regulation nor even the knowledge about how the system works. Even organized groups – unions, environmental and consumer groups – are far less resourced that corporations. Industries that want to influence environmental regulations, for example, often spend millions of dollars commissioning studies by product defense firms in order to present data that will justify weakening public health protections. Citizen groups can't do that.

This inequity of influence is in part due to the procedural requirements of the APA. Agencies need to write rules that can withstand potential litigation, and better-resources organizations can craft sophisticated legal or scientific arguments against proposed rules that—meritorious or not—agencies must spend enormous time addressing. In contrast, the APA does not require agencies to meaningfully address comments arguing for or against a regulation based on personal or anecdotal experiences. Moreover, the notice-and-comment procedures created by the APA assume equity of *access* to the regulatory process—but a producer of a hazardous product will be far more able to comment on a proposal to regulate that product than the citizens who may not know they are even being exposed to it.

The current regulatory structure allows the business community to dominate the regulatory system. The Office of the Public Advocate, as envisioned by the Stop Corporate Capture Act, is an important first step in righting this current imbalance. The Public Advocate created by the Stop Corporate Capture Act would assist individuals in their interactions with agencies, work with agencies to improve public participation, and conduct equity assessments on proposed regulations.

To be successful, this office must be generously resourced and staffed with people who understand the regulatory system so they can be effective advocates for the public interest. And it must be statutorily empowered to represent the public interest in a way that agencies must be responsive to, like the SBA Office of Advocacy. Finally, the Public Advocate should itself have the ability to comment on proposed regulations and petition agencies to take action. In this manner, the Public Advocate can not only represent underserved stakeholders in the regulatory process but channel the diffuse interests of the public.

To compliment the workings of this office, agencies need to be instructed to make significant efforts to include the impacted public in their regulatory proceedings. They should also ensure that analyses of the impact of regulations go far beyond the costs and benefits currently estimated, to promoting "public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations;" the often previously unconsidered impacts of regulation described in President Biden's Memorandum on Modernizing Regulatory Review, issued January 20, 2021.[23]

Section 10: Actions by Private Persons

The Stop Corporate Capture Act's provisions permitting a private right of action in situations where regulatory protections have failed would have tremendously useful impact on workplace safety. To be clear, this would permit a private right of action by workers not seeking compensation for individual injuries but who are attempting to enforce compliance with OSHA regulations. Currently, when workers face hazardous conditions, there is little they can do except raise the concern with their employer or complain to OSHA. Trade unions representing workers facing hazards are often able to use the bargaining or grievance process to demand safer conditions, but the vast majority of private sector workers are not represented by unions and therefore have no recourse, other than contacting OSHA, when their safety is endangered at the workplace.

OSHA, however, is limited in what it can do. The agency has enough inspectors to visit every workplace once every 160 years. Many of its standards are out-of-date and inadequately protective. Many workers are not covered by OSHA, either because of gaps in the law (millions of state and county workers in states under the authority of federal OSHA) or because they are not in the traditional employer-employee relationship (common when the law was written more than 50 years ago, such as independent contractors and gig workers). Finally, except for certain unusual circumstances, injured workers cannot sue their employer. They are barred from these suits under exclusive remedy provisions of the workers' compensation laws of every state

In addition, there have been times when OSHA has simply not done all it could do. In the first months of the COVID pandemic, when hundreds of meat workers were sickened following workplace exposure to SARS-CoV-2, OSHA failed to take steps necessary to protect these workers. The House Select Subcommittee Committee on the Coronavirus Crisis noted in its

investigations, it learned "that OSHA leadership made a 'political decision' not to issue a much-needed regulatory standard requiring meatpacking companies to take specific steps to protect workers, limiting the universe of enforcement tools OSHA had at its disposal."[24]

As a result, there have been many hazardous situations in which OSHA could not or would not require the workers' employers to abate hazards. And, except for those workers who belong to unions, these workers have had nowhere to turn.

This would change if they had a private right of action. Faced with the threat of litigation, many employers who are not deterred by an under-resourced OSHA and its low penalties, will eliminate safety hazards. And for the same reason, OSHA will be encouraged to move more quickly to insist these workers be protected. The result will be safer workplaces and fewer workers injured or killed on the job.[25]

Sections 14 and 15: Congressional Review Act

The Congressional Review Act of 1996 (CRA) does not permit an agency to issue a rule that is substantially similar rule to one that Congress has disapproved. In a period in which the need for strengthened and more agile protections is so great, this provision of the CRA potentially handcuffs agencies, blocking them from addressing the needs of the public.

The first regulation rescinded by Congress using the CRA was OSHA's 2000 rule to protect workers from ergonomic hazards. Musculoskeletal disorders (MSDs), many of which are caused by exposure to ergonomic hazards, are the most common occupational disorders, based on cases recorded by employers on their OSHA logs and reported by the Bureau of Labor Statistics. Hundreds of thousands are reported annually.

In my years running OSHA, I saw the relationship of workplace MSDs, pain, and addiction. The stories were heartbreaking. Coal miners, construction workers, and others who are injured on the job or whose muscles are battered by years of difficult work, take pain pills in order to get back to work—and get paid again. Many of these workers became addicted and eventually turned to illicit opioids and heroin, often less expensive and more easily obtainable than prescription drugs. I have no doubt that had Congress not overturned OSHA's ergonomics standard, fewer workers would have suffered MSDs and therefore avoided addiction and overdose.[26]

Opioid overdoses killed more than 100,000 Americans last year, and there appears to be no end for this tragic epidemic in sight. The Stop Corporate Capture Act creates a fast track for reinstating rules disapproved of under the CRA. If enacted, OSHA could then revisit its standard preventing MSDs, giving the nation another tool to protect the backs and limbs of workers and prevent more opioid addiction and death.

Section 16: Cost-Benefit Analysis

Analyses that compare costs and benefits of a proposed standard sound like they make sense, but are almost inevitably flawed, often resulting in the mistaken conclusion that the purported costs outweigh the benefits. It is easy, in fact too easy, to express in dollars the estimated costs of a regulation, and far more difficult to do the same for the estimated benefits of lives saved and injuries or illnesses prevented. While we have a system that assigns a dollar amount to the value of a life lost because of a hazard a regulation would prevent, we currently do not assign a monetized value to many of the effects of workplace or environmental hazards. We do not count, for example, the emotional impact on a child of losing a parent because of a workplace incident, because we have no monetary amount to assign it. The requirement of the Stop Corporate Capture Act to consider the nonquantifiable benefits to the public is an important step in addressing the acute limitations of cost-benefit analysis.

Some agencies, including OSHA, are barred by their authorizing statute from conducting formal cost-benefit analyses that compare these two estimates. However, The Regulatory Flexibility Act and various Presidential directives require executive branch agencies to estimate (but not necessarily compare) costs and benefits, making it appear that the agency has conducted a cost-benefit analysis when it has only estimated (but not formally compared) costs and benefits. To ensure the inclusion of all agencies in this provision, it will be important to address this minor difference in language.

Thank you for the opportunity to share my comments with you today. I look forward to your questions.

END NOTES

[1] Kirshenbaum S. The art of misleading the public. Science 367 (6479) 2020. doi: 10.1126/science.aba5495
[2] Lawrence F. Truth decay: when uncertainty is weaponized. Nature 578:28-29, 2020. doi: https://doi.org/10.1038/d41586-020-00273-4
[3] Singer JW. No Freedom without Regulation. New Haven: Yale Univ. Press; 2015.
[4] United States Government Accountability Office. Workplace Safety and Health: Multiple Challenges Lengthen OSHA's Standard Setting. GAO-12-330. Apr 02, 2012. https://www.gao.gov/assets/gao-12-330.pdf
[5] Michaels D, Wagner WE. Disclosure in Regulatory Science. Science 302:2073, 2003
[6] Full disclosure: Regulatory agencies must demand conflict-of-interest statements for the research they use. *Nature*. 507:7490 2014. https://www.nature.com/articles/507008a
[7] McGarity TO, Wagner WE. Bending science: How special interests corrupt public health research. Harvard University Press.: Cambridge, Massachusetts. 2008.
[8] Oreskes N, Conway E M. Merchants of doubt: How a handful of scientists obscured the truth on issues from tobacco smoke to global warming. New York: Bloomsbury Press. 2010.
[9] Reed G, Hendlin Y, Desikan A. et al. The disinformation playbook: how industry manipulates the science-policy process—and how to restore scientific integrity. J Public Health Pol (2021). https://doi.org/10.1057/s41271-021-00318-6
[10] https://naturalresources.house.gov/hearings/the-denial-playbook-how-industries-manipulate-science-and-policy-from-climate-change-to-public-health
[11] Dreyer LP. Wash Tech Conference Call. (Handwritten notes of Philip Morris in-house memorializing meeting between Philip Morris in-house counsel and Philip Morris regulatory consultants regarding proposed OSHA rulemaking.) Philip Morris document no. 2023896207. April 12, 1994. Available at: http://legacy.library.ucsf.edu/tid/cfn12a00.
[12] https://obamawhitehouse.archives.gov/omb/oira_2060_meetings_792
[13] Michaels D. The Triumph of Doubt: Dark Money and the Science of Deception. New York. Oxford University Press 2020.
[14] Paustenbach DJ, Panko JM, Scott PK, Unice KM. A methodology for estimating human exposure to perfluorooctanoic acid (PFOA): A retrospective exposure assessment of a community (1951–2003). Journal of Toxicology and Environmental Health, Part A. 70(1):28-57 2006. doi: 10.1080/15287390600748815
[15] Chang ET, Adami HO, Boffetta P, Cole P, Starr TB, Mandel JS. A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and cancer risk in humans. Crit Rev Toxicol. May;44 Suppl 1:1-81 2014. doi: 10.3109/10408444.2014.905767. Epub 2014 May 5. PMID: 24793953.
[16] Expert Report of Barbara D. Beck, Ph.D., DABT, ATS, ERT in the Matter of State of Minnesota vs. 3M Company. http://stmedia.startribune.com/documents/2124-07+2017-11-06+BARBARA+BECK+REPORT++A+11-03-2017.pdf. November 3, 2017.
[17] National Toxicology Program. Comments Regarding the Systematic Review of Immunotoxicity Associated with Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS): Prepared on behalf of 3M. https://ntp.niehs.nih.gov/ntp/about_ntp/monopeerrvw/2016/july/publiccomm/gradient20160705_508.pdf July 5, 2016.
[18] Chang ET, Adami H, Boffetta P, Wedner HJ, Mandel JS. A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and immunological health conditions in humans. Crit Rev Toxicol. 46(4):279-331 2016. doi: 10.3109/10408444.2015.1122573
[19] Olson M. The Logic of Collective Action. Cambridge, MA. Harvard University Press. 1965.
[20] Wagner WE, Barnes KY, Peters L. Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Regulations (December 7, 2010). Administrative Law Review, Forthcoming, Arizona Legal Studies Discussion Paper No 10-01, Energy Center Research Paper No. 03-10, U of Texas Law, Law and Econ Research Paper No. 190, Available at SSRN: https://ssrn.com/abstract=1531243
[21] Yackee JW, Yackee SW. A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy. The Journal of Politics 68(1):128-139 2006. https://www.jstor.org/stable/10.1111/j.1468-2508.2006.00375.x
[22] United States Government Accountability Office. Small Business Administration: Office of Advocacy Needs to Improve Controls over Research, Regulatory, and Workforce Planning Activities

GAO-14-525 Jul 22, 2014. https://www.gao.gov/products/gao-14-525

[23] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/modernizing-regulatory-review/

[24] Select Subcommittee on the Coronavirus Crisis. Coronavirus Infections and Deaths Among Meatpacking Workers at Top Five Companies Were Nearly Three Times Higher than Previous Estimates. Oct.27, 2021. https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.10.27%20Meatpacking%20Report.Final_.pdf

[25] Duff MC, McGarity TO, Shapiro S, Steinzor R, Tracy K. OSHA's Next 50 Years: Legislating a Private Right of Action to Empower Workers Center for Progressive Reform. July 2020. http://progressivereform.org/our-work/workers-rights/osha50pra/

[26] Felsen M. How Deregulation Led to the Opioid Epidemic. The American Prospect August 1, 2019. https://prospect.org/health/deregulation-led-opioid-epidemic/

APPENDICES

APPENDIX A:

The OSHA Rulemaking Process

APPENDIX B:

Michaels D, Wagner W. Disclosure in Regulatory Science. *Science* 302:2073, 2003.

APPENDIX C:

Full disclosure: Regulatory agencies must demand conflict-of-interest statements for the research they use. *Nature* 507:7490, 2014.

APPENDIX D:

Handwritten notes of Philip Morris in-house memorializing meeting between Philip Morris in-house counsel and Philip Morris regulatory consultants regarding proposed OSHA rulemaking. Philip Morris document no. 2023896207. April 12, 1994

Appendix A

THE OSHA® RULEMAKING PROCESS

Stage 1
Making the Decision: Conducting Preliminary Rulemaking Activities
12 to 36 months

- Identify health or safety hazard
- Conduct research and gather data to determine scope of problem; identify and obtain information needed for health effects analysis, risk assessment, technological feasibility analysis, and economic analysis
- Meet with internal and external stakeholders
- Identify regulatory and nonregulatory approaches
- Prepare timeline, identify resources needed including need for advisory committees
- Prepare decision papers to obtain executive approval to proceed
- List Regulatory Action on Unified Agenda/Regulatory Plan
- Establish public rulemaking docket
- Develop and publish RFI or ANPR if needed

Stage 2
Developing the Proposed Rule
12 to 36 months

- Develop health effects analysis
- Conduct preliminary risk assessment
- Develop preliminary technological feasibility analysis
- Develop preliminary economic and regulatory flexibility analysis
- Draft proposed regulatory text and preamble
- Initiate Federalism and Unfunded Mandates analysis and make preliminary determination of impact on State, local, and tribal governments
- Prepare preliminary information collection analysis
- Continue discussion with stakeholders
- Consult with ACCSH if rule affects the construction industry
- Consult with MACOSH if rule affects maritime industry
- Conduct review process required by SBREFA
- Conduct peer reviews of health effects analysis, preliminary risk assessment, and preliminary economic analysis
- Obtain all Agency and Departmental clearances
- Submit to OMB for review and clearance

Stage 3
Publishing the Proposed Rule
2 to 3 months

- Obtain approval to publish
- Plan for public hearings
- Submit to *Federal Register* for publication
- Submit preliminary Information Collection Request to OMB
- Send the proposed rule to SBA

Stage 4
Developing and Analyzing the Rulemaking Record
6 to 24 months

- Receive public comments; prepare for and hold public hearings; close the public record
- Review and analyze all written comments, exhibits, and testimony
- Prepare record summary and analysis

Stage 5
Developing the Final Rule
18 to 36 months

- Update and finalize health effects analysis
- Update and finalize risk assessment
- Update and finalize technological feasibility analysis
- Update and finalize economic and regulatory flexibility analysis
- Draft final regulatory text and preamble
- Complete Federalism and Unfunded Mandates analysis and make final determination of impact on State, local, and tribal governments
- Obtain all Agency and Departmental clearances
- Submit to OMB for review and clearance
- Prepare final information collection analysis
- Prepare rollout materials

Stage 6
Publishing the Final Rule
2 to 3 months

- Obtain approval to publish
- Submit to *Federal Register* for publication
- Submit Information Collection Request to OMB
- Send the final rule to SBA
- Submit the final rule and to Congress and GAO

Stage 7
Post-Promulgation Activities
4 to 12 months

- Develop and publish small entity compliance guide and other outreach and training materials, compliance directives, and letters of interpretation
- Respond to legal action

SOURCE OF REQUIREMENT:

= Executive Order

= Legal Requirements

= Internal Procedures

Acronym	Definition
ACCSH	Advisory Committee on Construction Safety and Health
ANPR	Advance Notice of Proposed Rulemaking
GAO	Government Accountability Office
MACOSH	Maritime Advisory Committee for Occupational Safety and Health
OMB	Office of Management and Budget
RFI	Request for Information
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act

Directorate of Standards and Guidance | Revised: October 15, 2012.

POLICY FORUM

SCIENCE AND GOVERNMENT

Disclosure in Regulatory Science

David Michaels and Wendy Wagner

There is substantial divergence between the scientific community's standards for ensuring research integrity and the ad hoc protections for researcher independence tolerated by federal regulatory agencies. The biomedical community's concern about potential conflicts of interest is addressed in the widespread (*1*, *2*) policy of journals to require that authors of submitted articles disclose financial relationships so that editors and readers can judge whether conclusions might have been influenced by those financial ties. The editors of 13 leading biomedical journals have gone further and declared that they will no longer publish articles based on studies done under contracts in which the investigators did not have the unfettered right to publish the findings (*1*).

With the increased involvement of universities in commercial enterprises and collaborations, conflicts-of-interest concerns at academic institutions have grown in importance. In response, many institutions have implemented policies that attempt to ensure independence and protect the ability of researchers to share data with fellow scientists and the public (*3*–*6*).

Research independence is also of great importance to regulators. Federal agencies charged with protecting the public's health rely out of necessity on scientific evidence submitted by private parties in determining the hazardous characteristics of products and wastes. At the same time, there is growing evidence of conflicts of interest in private research submitted for regulation. For example, there are reports of a "funding effect," with sponsorship associated with favorable findings (*3*, *7*, *8*). There are also accounts of improper sponsor control over the design and reporting of results, and sponsor suppression or termination of research showing adverse effects (*9*–*13*).

Except for limited prohibitions against the suppression of adverse effects, however, the quality and independence of private research used for regulation is subject to considerably less oversight than corresponding federally funded research. Most significantly, private research submitted for regulatory purposes escapes external scrutiny if the research or the chemical under study is claimed to be confidential business information (*14*). Most of the applications submitted to the U.S. Environmental Protection Agency (EPA) to market new chemicals, for example, contain science-relevant information that industry claims is confidential. Many of these trade secret claims do not appear to be justified (*15*). Yet without this information, it is not possible to evaluate the regulators' decisions.

Even when sponsored research is not protected as trade secrets, the data underlying privately submitted research used for regulation need not be made publicly available, as is required for its federally funded counterpart (*16*). Also in contrast to public research, private research is not subject to the scientific misconduct regulations promulgated by the U.S. Office of Research Integrity (*17*). Finally, even the "Data Quality Act", which ostensibly is an attempt to improve the quality of regulatory science through a formal complaint process, exempts a great deal of private research from its coverage (*18*).

Despite the evident value of transparency about sponsorship in regulatory science, the disclosure of sponsor influence is generally not required or even requested by federal regulatory agencies. The EPA, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration have no formal mechanisms to identify potential conflicts of interest, nor do they provide any incentive to encourage the conduct of research that is free of sponsor control. The Food and Drug Administration (FDA) has instituted a conflict policy requiring financial disclosures for safety research conducted by private parties in support of a license to market a drug or food additive (*19*). These disclosures do not, however, distinguish between research where the sponsor controls the design or reporting of the research and research where sponsors have no control.

Regulatory agencies should adopt, at a minimum, requirements for research independence comparable to those of biomedical journals. Disclosure of conflicts of interest should be required for all research, regardless of whether it is federally or privately funded. Scientists should disclose whether they have a contractual right to publish their findings free of sponsor control and should identify the extent to which their work was reviewed by an affected party before publication or submission to the agency. Sponsors who submit data should similarly disclose if their investigators had the contractual right to publish without sponsor consent or influence. Finally, other parties (i.e., trade associations, unions, or public interest groups) who submit scientific results should disclose all known conflicts of interests of the scientists conducting the studies.

Regulators should not use conflict disclosures to exclude research; they have the obligation to consider all evidence, according greater importance to studies of higher quality and relevance. Federal agencies should, however, develop policies that strongly encourage clear disclosures that counteract the strong incentives for sponsors to influence research. Only then can agencies accurately weight studies and encourage research independence.

D. Michaels is at the Department of Environmental and Occupational Health, George Washington University School of Public Health and Health Services, Washington, DC, 20052, USA. E-mail: eohdmm@gwumc.edu W. Wagner is at the University of Texas School of Law, Austin, TX 78705, USA. E-mail: wwagner@mail.law.utexas.edu

References and Notes

1. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, www.ICMJE.org (October 2001).
2. F. Davidoff *et al.*, *JAMA* **286**, 1232 (2001).
3. S. Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted the Virtue of Biomedical Research?* (Rowman & Littlefield, Lanham, MD, 2003).
4. U.S. General Accounting Office, "Biomedical research: HHS direction needed to address financial conflicts of interest" (GAO-02-89, Government Printing Office, Washington, DC, 2001).
5. M. K. Cho *et al.*, *JAMA* **284**, 2203 (2000).
6. American Assoc. of University Professors, Statement on Corporate Funding of Academic Research 2001, available at www.aaup.org/statements/
7. J. E. Bekelman *et al.*, *JAMA* **289**, 454 (2003).
8. J. Lexchin *et al.*, *BMJ* **326**, 1167 (2003).
9. D. Rennie, *JAMA* **282**, 1766 (1999).
10. S. A. Glantz *et al.*, *The Cigarette Papers* (Univ. of California Press, Berkeley, 1996).
11. G. Markowitz, D. Rosner, *Deceit and Denial: The Deadly Politics of Industrial Pollution* (Univ. of California Press, Berkeley, 2002).
12. D. Rennie, *JAMA* **277**, 1238 (1997).
13. P. Brodeur, *Outrageous Misconduct: The Asbestos Industry on Trial* (Pantheon Books, New York, 1985).
14. Code Fed. Regul. (C.F.R.) **40**, §2.201–2.310.
15. U.S. General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective* (GAO/RCED-94-103, Government Printing Office, Washington, DC, 1994).
16. Pub. L. No. 105-277, Stat. 112, 2681 (1998).
17. C.F.R. **42**, §50, A, Scientific Misconduct.
18. *Fed. Regist.* **67**, 8452 (2002).
19. C.F.R. **21,** §54.

APPENDIX C

Full disclosure

Regulatory agencies must demand conflict-of-interest statements for the research they use.

It was the 1976 film *All the President's Men*, about the uncovering of the Watergate political scandal by two *Washington Post* reporters, that popularized the phrase: "Follow the money." He who pays the piper calls the tune. Science combats the undue influence of commercial interests — or at least tries to — by using a different guideline, illustrated by a popular catchphrase from another film: "Show me the money." Give us transparency.

The selective promotion of scientific research to steer policy-making is a murkier business altogether — particularly in environmental policy-making, in which the battle for the ear of the piper between big business and the 'little guy', who is often affected by pollution or hazardous substances, is so asymmetric. The problem is not limited to climate change, which is only the most high-profile example at present.

It has been more than a decade, for example, since David Michaels, previously a public-health researcher at George Washington University in Washington DC, and Wendy Wagner, an environmental-law specialist, broached the issue in the pages of *Science* (D. Michaels and W. Wagner *Science* **302,** 2073; 2003). They warned that the evidence base of important regulatory standards is undermined by the limited scrutiny of private research submitted to regulatory bodies, and by the fact that these bodies often do not require disclosure of researchers' funding sources.

Michaels is now in a position to do something about this. In 2009, he was appointed to lead the Occupational Safety and Health Administration (OSHA), one of the US agencies he criticized in that 2003 piece.

OSHA's remit is health-and-safety standards, and the test bed for Michaels' stance is a 40-year effort to regulate exposure to silica dust. Crystalline silica dust is produced by processes such as concrete grinding and sandblasting in construction and other industries. If inhaled, it can cause silicosis — an incurable condition involving inflammation of the lungs — and lung cancer.

As part of a consultation on tougher regulation of silica exposure, OSHA asked that people submitting scientific comments to the agency should declare financial conflicts of interest. According to Michaels, this might be the first time that any federal agency has made such a request.

But even though this is a request and not a requirement, it has not gone down well in all quarters. In particular, a group of powerful US senators has come out against the idea that such a declaration should be part of federal rule-making (see page 18). They suggest that OSHA might "prejudge the substance" of comments on the basis of such disclosures.

"There is a broad consensus in favour of transparency about funding sources."

Nature — like many journals — has required such disclosures for years, and considers such opposition to be misguided. In controversial areas, these conflict statements pre-empt allegations of secrecy and bias that could distract from the central issues. And past failure to be transparent about such interests has led to scandals involving concealed or distorted evidence and ghost-writing, as has been well documented in areas from tobacco control to drug development.

The medical profession and the pharmaceutical industry, to their credit, have taken major steps towards openness. Some researchers think that conflict-of-interest disclosures should go even further than they currently do, and should detail the contractual arrangements involved, such as whether the funder had a veto on publication. In science more generally, there is a broad consensus in favour of transparency about funding sources.

Transparency is the best defence against the purchase of undue influence by those with the most financial clout. In areas where tough standards are needed to protect public health, and powerful and wealthy interests have a financial incentive to water down these standards, such transparency is more than desirable — it is essential, and history demonstrates that. Rather than challenging OSHA for requesting conflict-of-interest disclosures, US politicians should be asking why all federal agencies do not require them. After all, it is easier to the follow the money, and to make the proper decision, when all details are on full show. ■

Track and trace

Identifiers that follow researchers' work from grant to paper will make funding more effective.

More than half a million researchers have now signed up for an online science passport: a unique 16-digit identity number, with an accompanying online profile, from the Open Researcher and Contributor ID (ORCID) project. There, researchers can maintain an up-to-date record of their professional pursuits.

Already, ORCID is being integrated into the ecosystem of science: many publishers accept ORCID identifiers in their manuscript-submission processes, and funders including the Wellcome Trust and the US National Institutes of Health are accepting the identifiers to streamline grant applications. Universities and research institutions are planning to use the system to track their researchers' output throughout their careers.

So far, the ORCID website has prompted scientists to record outputs such as articles, data sets, citations, patents and media appearances. This fits in with the growing desire of institutions and funding agencies to recognize the full range of researchers' activities and impacts.

But this week, ORCID begins to request a new set of data — inputs. Researchers logging in to their profiles will be prompted to add the details of their grants, or to confirm information on grants they hold. Such information is often publicly available on the Internet, but scattered across funding-agency websites, rather than collated for individual scientists. ORCID hopes to improve tracking of the connections between the cash that funders pour into research and the results that emerge.

Another service that makes it easier to link grants in with papers out is FundRef, launched last year by the non-profit publisher alliance CrossRef. It provides a standardized format for adding funding information to the metadata of research articles published online.

The result — if such systems catch on — should be easier tracking of the efficiency of the science system. Which academics produce the most for the grants they receive, and why? What kinds of grants are most effective at prompting what types of output? That is something funders and economists would dearly like to know. They have made individual efforts, but a bigger-picture understanding has been held back by lack of connectivity across agencies.

There is perhaps a danger that scientists — so used to measuring the properties of others — will be resistant to having information recorded on themselves. (Less than one-quarter of researchers signed up to ORCID have actually listed at least one output on their profiles.) But ORCID (of which Nature Publishing Group is a partner) gives researchers control over the information that they allow to be publicly visible. Hopefully, they will embrace the opportunity to make science funding more effective and evidence-based. ■

➲ NATURE.COM
To comment online, click on Editorials at:
go.nature.com/xhunqv

APPENDIX D

Wash Tech Conference Call 4-12-94

WashTech

Kahorst
Lowe
Weinberg

SHB
Dreger
Koska
Davis

PM
Purcell

AJA

1. Wynder is quoted quite a bit → could he comment on his views of the ETS science
2. major weakness is CVD epidemiology and failure to take into account other risk factors
   A. comment that rule will eliminate all baseline cases of lung cancer & CVD which assumes no other risk factors — this undermines their "benefit" analysis of implementation of the rule
3. OSHA must respond to all comments
4. WashTech has experts in "deductive meta analysis" that reveals the confounders and identifies the real risk involved if any
5. Task 1
   A. line by line analysis raising scientific questions that OSHA would have to respond to
6. Task 2
   A. deductive meta-analysis → could do this and publish it !!
7. a line by line attack could take 2 to 3 years to respond to
8. extension could be based on the fact OSHA has <u>not</u> made available the underlying documents (400 series documents)
9. deductive meta-analysis

2023896207