PRELIMINARY ASSESSMENT OF PRUITT'S PROPOSED REGULATION TO RESTRICT EPA'S USE OF SOUND SCIENCE
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Scott Pruitt's plan to exclude the use of a broad portion of the scientific literature on human health and the environment is inconsistent with scientific practice and sound public policy.

Overview

EPA Administrator Scott Pruitt is proposing to eliminate the use of scientific studies that examine relationships between public health and environmental pollution unless the underlying data, including private information on individuals used in the studies, can be made freely available to the public.[1]

In many important examples, ethical and legal considerations restrict the ability of investigators to release for general use personal data such as dates of birth and death, personal health and lifestyle information, and location. The level of detail in these data precludes the ability to simply redact portions of the information to protect privacy. These include both completed and ongoing epidemiological studies that examine the relationship between pollutant concentrations and human health effects.

EPA regulations have relied on assessing many thousands of health-related studies of pollutants done in the last five decades, including epidemiological, human clinical, and animal toxicology studies. Even for controlled human and animal studies, where subject data might ethically be released, the underlying data may no longer be accessible years after publication. Under the new plan, sustaining some regulations might require that the most useful and influential of these studies would have to redone, at great expense in terms of time and resources. Even then, it would no longer be possible to assess the full weight of the available scientific evidence – a key guiding principle for judging the scientific integrity of the decision-making process.

The Pruitt approach disingenuously would place greater weight on the goal of transparency of scientific data, than on the need to consider the full array of well conducted and peer reviewed scientific studies of health effects of pollution, including both existing reanalysis as well as numerous replications of particularly important studies. Assessment of all relevant scientific information is essential in making sound judgements for protecting public health, and is a stated requirement in all-major environmental legislation.

A preliminary examination of the potential impacts of the Pruitt policy reveals several examples of rules and programs that might not have been possible if EPA had adopted a data transparency limitation in past regulations.[2] Among these are programs to: reduce or eliminate lead exposure to children from paint, gasoline, and drinking water; develop water quality criteria for priority toxic pollutants, including polychlorinated biphenyls (PCBs); approve the registration of pesticides for agricultural and other uses under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetics Act (FFDCA), approve increases in production volume and usage of commercial chemicals under the Toxic Substances Control Act (TSCA); promulgate air quality standards for particulate matter and possibly other air pollutants; and control certain toxic pollutants

in air, drinking water, and solid wastes. If this misguided policy had been in effect 20 years ago, the nation might have forgone programs that are preventing over 50,000 premature deaths each year.[3]

The Pruitt proposal ignores both available approaches embraced by the scientific community and the record of past EPA assessments, which reveal alternative methods for ensuring the credibility of potentially useful scientific studies. These include both reanalysis by competent third party investigators and replication of studies using different data sets and conducted by different researchers. This is the approach followed for two epidemiology studies on fine particles and mortality that were originally published in the 1990s, where the availability of underlying health data became an issue. The organizations holding the confidential health data made them available to independent, experienced third party investigators for reanalysis, under the management of the Health Effects Institute (HEI), which is jointly funded by EPA and industry.[4] More importantly, in the intervening years other investigators have published many studies that essentially replicate the original findings using different data sets.[5] The most recent of these used a Medicare database that is available for any research group that can guarantee confidentiality of the personal data.[6] This study found even larger effects of fine particles down to at levels below EPA's current standards. Yet even this powerful new study could not be evaluated under the Pruitt policy.

In summary, the Pruitt data proposal appears to be more aimed at suppressing the use of important scientific information to support regulations and cost benefit analysis, than over any valid concern that the study results should be viewed as faulty because the underlying data are not publically available. Indeed, use of the more recent scientific results on air pollution would show that the benefits of certain regulations the Agency has recently proposed to withdraw are greater than the costs, and similar to those found in the studies EPA originally used for its benefits analysis. Pruitt's new policy is neither necessary nor consistent with the nearly fifty-year responsibility of the Agency to protect public health and the environment.

The Issues: Transparency and Reproducibility

EPA Administrator Scott Pruitt is proposing to codify a new policy that would restrict EPA's use of certain scientific studies in rulemakings and regulatory impacts analyses.[1,7] In a reversal of the long-standing approach taken by EPA and other federal agency science assessments, Pruitt would not allow regulators to consider any scientific study that does not provide public access to all of their raw data, including private information on individuals included in such studies. As EPA has noted, this policy mirrors that of recent legislative proposals on the issue. This legislation and the Pruitt proposal are intended to ensure that underlying data be not only publically available, but also "reproducible." Congressional supporters of such legislation would apply these restrictions to any EPA assessment of hazard, exposure, risk, or regulatory impact assessments, or for supporting any rule or guidance.[2]

Proponents disregard the difficulties and limitations such proposals would place on the EPA's mandates to consider the broad range of available scientific information, as well as to support research that takes advantage of the best available sources of data for study. Some of the most useful information regarding health effects comes from real world (epidemiological) and laboratory (clinical) studies of human subjects, in which detailed information can be collected regarding health, lifestyle, medical status, location, and more about participants can be collected. For many relevant

epidemiology studies, ethical and legal considerations restrict the ability of investigators to release for general use personal data such as dates of birth and death, personal health and lifestyle information, and location. The level of detail in these data precludes the ability to simply redact portions of the information to protect privacy. Moreover, some of the broadest and most detailed health data come from organizations that, to protect the privacy of participants, will not allow investigators to provide the data to others.

In general, the publicly available health survey data recommended by some typically omit not only the identity of subjects, but otherwise useful details that could be used to identify them, such as location. Limiting EPA's research and review only to studies based on publically available data not only reduces the quality and scope of scientific inquiry and assessment, but also as discussed more fully below, is not necessary to ensure the integrity of the most important studies. More specific examples of the problems and limitations presented by this requirement are presented in the next section.*

Understood literally, the additional requirement that studies be "reproducible" could be interpreted in such a way as to eliminate even more environmentally relevant scientific literature from consideration. Examples of observational studies that cannot be reproduced include the class of "intervention" studies based on unique events such as a severe weather induced air pollution increase,[8] decreases in emissions caused by a strike[9] or special event restrictions,[10] and oil spills.[11] Such studies have been particularly useful in making conclusions about causal relationships between environmental pollution and effects. Other studies that are not directly reproducible include both ongoing long-term or older epidemiology studies that include pollution exposures that no longer exist.

As discussed more fully below, it is clear that neither Administrator Pruitt nor the sponsors of comparable legislation have conducted a full evaluation of unintended consequences, which might result in the loss of substantial amounts of information that have supported decisions on multiple existing regulations for air, water, solid waste, pesticides and other toxic substances, as well as conflict with existing legislative mandates and interfere with the integrity of the scientific process. For these and other reasons, a broad coalition of American science, engineering, and academic institutions[12] and others have opposed the proposed legislation.

By singling out EPA for such restrictions, these proposals display a strong distrust and ignorance of environmental science, one that seems based more on concerns about policy implications of the available results than on any real concern about transparency of science in general. For example, the EPA administrator has repeatedly challenged the broad scientific consensus regarding the likely impacts of climate change in this century, which is in conflict with his goal of expanding the extraction and use of coal and other fossil energy.[13]

The supporters of recent legislation to restrict the use of scientific information have focused specific attention and misinformation on EPA's use of two air pollution epidemiology studies in regulatory impact analyses that conclude air pollution benefits exceed costs for multiple air regulations, including the Clean Power Plan aimed at reducing carbon emissions from power plants. As discussed

* Examples of such survey data discussed below include the American Cancer Society and the Medicare database.

more fully below, they ignore that since publication in the mid 1990s, these studies were successfully reanalyzed by third party scientists, who were given access to the data, and that multiple newer studies have largely replicated the major results using a variety of alternative sources of health data. Replication of original study results by different investigators using different data has traditionally been viewed as a sufficient basis to rule out some kind fundamental bias or error in the original study. Contrary to Pruitt's implication,[1] the scientific record over the last 20 years shows there is no "crisis of replication" in air pollution epidemiology.

Preliminary assessment of potential impacts of the Pruitt Policy

This section provides a preliminary examination of the potential impacts of applying arbitrary restrictions on the use of peer reviewed scientific information for EPA regulations and risk and benefit assessments. Conducting a complete examination of such impacts should have been the first order of business, well before signaling the impending policy decision on EPA's news release page.[1] While no formal EPA analyses of such policy have been made public, the Congressional Budget Office (CBO) consulted with the Agency in their own analyses of related legislation, H.R. 1030[14] in 2015 and H.R. 1430[15] in 2017. The 2015 analysis assumed that EPA would reduce the number of studies it relied on by half, but would still need to expend $250 million/year initially in an effort to determine data availability, and where necessary pay for obtaining and disseminating it. CBO did not assess the impacts of losing influential studies where data could not be made available for various reasons.

In the 2017 analysis, CBO estimated a cost ranging from 1 million to 100 million dollars per year, depending on the approach taken by EPA in assessing studies. They determined that meeting H.R. 1430 requirements would cost EPA an average of $10,000 per study. EPA officials told CBO that the Agency would likely greatly reduce the number of studies it relied on and would not take on the cost of disseminating the underlying data.[15] The Pruitt proposal reiterates EPA's plan to focus on a more limited number of studies. Under these assumptions, CBO suggested costs could be as low as $1 million/year, but again did not assess the potential implications for existing or future regulations. An unofficial draft response to CBO questions from unidentified EPA staff strongly disagreed with the lower cost estimates, and expressed concern that the legislation would prevent EPA from using the best available science.[16] This response was not forwarded to CBO.

Nature of studies that could be excluded

Based on the proposal, the Administrator clearly would require that any study used to support a major regulation, risk or cost-benefit assessment by EPA would have to provide free access to all requests to underlying data and detailed methodology used in producing a peer reviewed publication. This restriction would eliminate use of the following:

- Human studies using data sources that contain protected private medical, lifestyle, location, and other information
- Studies that invoke confidential business information and protected intellectual property of researchers

- A potentially large number of older studies for which the original data sets were either not maintained, lost, or stored on media that can no longer be accessed
- A potentially large number of human and animal studies published by independent investigators, who could refuse to incur the time and expense required to reformat their original raw data and produce a step by step guide to their methodology beyond the summary given in their peer reviewed paper

As noted above, recent legislation and the EPA proposal would add a second overarching requirement, which is that studies EPA uses must be "reproducible." It is less clear how the Pruitt proposal, which appears modeled after the legislation, would implement that requirement. Neither the legislation nor the proposal defines "reproducible," and are in fact not clear on how broadly this goal might be applied. Taken literally, requiring studies be reproducible as well as 'transparent' would exclude the use of the following:

- Studies of the effects of natural or human-induced disasters and interventions on health and the environment
- Studies of human exposures historically high concentrations of environmental pollutants or to occupational exposures that could not ethically be reproduced

The following preliminary assessment reveals several examples of rules and programs that might not have been possible if EPA had adopted this approach in past regulations.

1) Protecting Children's Health: Regulation of Multiple Sources of Lead Exposure

Lead is a heavily-studied pollutant, and a partial regulatory success story. Many federal programs are in place, which have drastically decreased the average blood lead levels in children over decades.[17] Nonetheless, the urgent need for updated regulations has been highlighted by EPA's Children's Health Protection Advisory Committee (CHPAC) in March 2017 and by EPA's National Drinking Water Advisory Council (NDWAC) in December 2015. Under court order, EPA must propose an updated rule on lead in soil, dust and paint this year. In addition, EPA will propose an updated lead and copper rule for drinking water by 2020.

Lead exposure comes industrial sources, drinking water distribution systems, the residential environment, and more. EPA considers basic health research, epidemiologic studies, and exposure studies including how lead enters the environment and bloodstream, the relative importance of various exposure pathways, and how housing and lifestyle affect the severity of exposure and possible solutions.

Many of the foundational lead studies analyzed children with higher exposure and blood lead levels than are commonly seen today. Requiring that studies on lead be reproducible would be unethical and dangerous, as it would mean dosing children with lead to study the resultant effects, or placing them in heavily leaded environments to study the resultant blood lead levels. Requiring that all data be released in the name of transparency would be similarly unethical and would violate patient confidentiality agreements – the raw data contains confidential medical, housing,

educational, and other information. Redacting such information, even where possible, could cost researchers significant time and expense.

Such a policy shift is also unnecessary. EPA typically relies on the overall weight of evidence prior to developing regulations, rather than on individual studies. For the 2000 Risk Analysis[18] to support standards for lead in paint, dust, and soil, EPA relied on well over 300 references, including the EPA Air Quality Criteria documents for lead, which itself relied on even more studies. Some researchers already share and re-analyze data from colleagues to explore and confirm results. Some have performed meta-analyses[19] to confirm overall trends and to diminish the influence of outliers. In an ordinary assessment of scientific validity, such diligence would be sufficient to show that an association is not due to investigator bias.

Making raw data available from all studies considered would result in significant costs and limitations for risk assessment and policy decisions. These are issues EPA has not yet examined. Data may have been gathered over many years, by many different researchers, in many different countries, and may be quite vast, owned by different research teams with differing priorities and obligations, and stored in different ways. In some cases, data may have been lost to history or in unreadable storage media. One example of a possible regulatory issue would be the 2006-2008 lead air standards, which were based in part on a pooled analysis, for which two of the seven primary investigators refused to provide the raw data to the public. Even when researchers are open to sharing data, there is a significant cost to preparing the data for public consumption; this would be an especially difficult burden for investigators whose research has been done prior to this type of policy being in place.

It is especially problematic that the Pruitt policy would place EPA apart from federal partners:

- The Centers for Disease Control and Prevention (CDC) has responded nimbly to advances in lead research and, acknowledging that no safe level of lead in blood has been identified, has identified a "reference level"[20] to define especially high-risk populations and geographic areas most in need of primary prevention. Even some of the studies that the Federal government's most respected lead advisory group (CDC's Advisory Committee on Childhood Lead Poisoning Prevention) used to develop background justification[21] for the reference level could be made unavailable for EPA use under this policy. This means that EPA regulations could fail to adequately address CDC's high-risk exposures, and that EPA cost-benefit analyses could be precluded from considering some CDC health effects. State childhood lead poisoning prevention programs across the country, which rely on CDC guidance to focus their work but which may use EPA risk reduction guidance to guide their responses, may experience a disconnect.
- Both EPA and U.S. Department of Housing and Urban Development (HUD) regulate similar residential sources of lead (paint, soil, and dust). This policy shift increases the potential for disparate treatment and public confusion stemming from those situations. For example, EPA regulates lead hazards in private housing, and HUD does the same in public housing, including Federally-supported units in private buildings. While there may be policy reasons to treat these types of housing differently, the risks are currently analyzed consistently. Should this proposal be put into place, EPA would not be able to rely on as wide a range of studies as

would be available to HUD, which could result in different regulatory outcomes – even different risk statements - for similar, and possibly even adjacent, dwellings.

2) Water Quality Criteria and Fish Consumption Advisories

Under Administrator Pruitt's new policy, EPA could be forced to roll back current water quality criteria and safe levels for fish consumption for pollutants such as methylmercury and PCBs. EPA establishes water quality criteria for priority toxic pollutants that are designed to protect people who drink the water and eat the fish from a river, lake or stream. All states either adopt EPA's recommended criteria or develop their own scientifically defensible criteria as legally enforceable instream pollutant concentrations that are used to reduce or eliminate the discharge of these pollutants to the state's waters. States also use these same criteria to develop recreational fish consumption advisories based on the level of pollutants in fish that are safe to eat.

EPA has not yet examined the full impacts of implementing the new policy with regard to which criteria and advisories might be lost, but methylmercury and PCBs, the most widespread pollutants in the U.S., will most likely be affected. EPA's water quality criteria and fish consumption advisories for methylmercury are based on human health studies conducted in the Seychelles Islands, Faroe Islands, and New Zealand.[22] These studies found neuropsychological effects in children exposed in utero to methylmercury in the fish consumed by their mothers. EPA's water quality criteria and fish consumption advisories for PCBs relied on several long term studies of cancer incidence in workers who had unknowingly been exposed to PCBs.[23] EPA also based their recommendations on other studies which followed the results of accidental high dose or cumulative low dose ingestion of certain PCBs.[24] All of the methylmercury and PCB studies relied on long term and transgenerational epidemiological data including confidential patient information which could not be publicly released. In addition, none of these studies could realistically or ethically be reproduced since they derive from a unique cohort studied over a long period of time, and it would be unethical to expose people to occupational or ingested pollutants.

3) Drinking Water Standards and Health Advisories

Under Administrator Pruitt's new policy, EPA could be forced to roll back current drinking water standards and drinking water health advisories for pollutants such as arsenic and nitrate. EPA establishes legally enforceable drinking water standards and treatment techniques for all public water systems in the U.S. Over the years, standards have been promulgated for microorganisms, disinfectants, disinfection byproducts, inorganic and organic chemicals, and radionuclides. EPA also has the authority to recommend non-regulatory drinking water health advisories, which public water systems can voluntarily choose to follow. EPA has not assessed how the requirements in the new policy might affect drinking water standards and advisories. An assessment of similar legislation (H.R. 1430) by the Environmental Data and Governance Initiative (EDGI) found that the radionuclide standard would have been blocked by multiple requirements, including availability of study data and reproducibility.[2] Our preliminary look suggests that the standards for arsenic and nitrate standards will most likely be affected. EPA's drinking water standard for arsenic is based on human health studies, which document skin damage and

possible increased risk of cancer.[25] EPA's drinking water standard for nitrates is based on studies of infants exposed to nitrate in the drinking water used to prepare their formula.[26] EPA's drinking water standard for nitrates is based on studies of infants exposed to nitrate in the drinking water used to prepare their formula. The nitrate standard is set at a level to prevent infants below 6 months of age from serious illness and, if untreated death. Symptoms include shortness of breath and blue baby syndrome. Both drinking water standards rely on epidemiological data including confidential patient information as well as old data that may no longer be available for public release. In addition, none of these studies could realistically or ethically be reproduced since they derive from a unique cohort, and it would be unethical to expose people to ingested pollutants.

4) Registration of pesticides for agricultural and other uses under FIFRA and FFDCA and approval of increases in production volume and usage of commercial chemicals under TSCA

The Pruitt proposal could be implemented in a way that would be tremendously damaging to agriculture, medical care and other businesses. All of EPA's decisions relating to pesticides rest on large bodies of research and testing performed by the companies that want to sell pesticides. EPA is legally prohibited from making the pesticide companies' raw research data freely available to the general public. Much like the copyright laws that prohibit pirating videos, the purpose of this prohibition is to protect the enormous investment companies make in proving the safety of their products from being stolen by competitors. Yet, if the requirements for public disclosure of underlying data that Pruitt would place on science supporting other EPA regulations were applied to pesticide actions, EPA could not use companies' studies to show a pesticide was safe. In this case, EPA would have to ban the sale of all pesticides, including such critical products as the sterilizers and disinfectants used in hospitals; the insecticides, herbicides and fungicides that make American agriculture the most productive in the world; and the termiticides that prevent termites from destroying homes and other buildings. Rather than exclude company-generated data from pesticide decisions, the agency would most likely exempt such data from meeting the transparency requirements of the proposed rule. It is not clear, however, why or how transparency in scientific data should be required for data supporting air, water and other regulations but not for pesticide decisions.

Similar constraints on release of confidential business information apply to some TSCA decisions, which could have similar consequences—partial or complete prohibition of production and use of chemicals for commercial purposes such as in consumer products. Currently, well over 80,000 substances on the Toxic Substances Inventory could be used in U.S. commerce and estimates of up to 20,000 of those actually are in use at any point in time. Under TSCA, EPA must make a set of findings to require testing of chemicals. If a chemical meets certain criteria related to potential harm, the Administrator has to require that such testing be conducted. Under the recent Lautenberg Amendments to TSCA, EPA was given additional testing authority to implement other sections of this act or to meet the regulatory needs of another law with respect to toxicity and exposure and to use orders or consent agreements in addition to rules to implement the testing requirements under the Act.

The Pruitt proposal could largely prevent EPA from using existing information to make an "unreasonable risk finding" used to require testing, thus depriving EPA of one mechanism to obtain needed data. However, more significantly, it could cut the other way when EPA made the findings based on substantial human exposure or substantial release to the environment, or the finding that data are needed to make decisions under another regulatory authority (e.g. the Clean Air Act). If one of these findings were made, under the proposal, the EPA might be required to reject scientifically acceptable studies found in the peer reviewed literature or submitted in response to a proposed test rule or order. This might require millions of dollars of duplicative testing, because the data required under a rule or consent order would need to meet all of the agency's data requirements to be used to support risk management decisions and major rulemaking regarding the control of a chemical or cleanup of a hazardous site. Such duplicative testing could then burden industry with huge and unnecessary costs. Furthermore, the Pruitt proposal appears to violate the "Mutual Acceptance of Data Treaty" under which the U.S and other OECD member countries agreed to accept data generated according to internationally harmonized OECD test guidelines. This treaty was adopted to eliminate duplicative testing to save industry money and facilitate regulatory decision making.

5) National Ambient Air Quality Standards: Particulate Matter

The Pruitt policy and comparable legislation are antithetical to the spirit and the letter of science-based process Congress envisioned for establishing National Ambient Air Quality Standards (NAAQS) in the Clean Air Act. These standards, which address six major classes of common air pollutants, are the backbone of the U.S. air quality management system.[27] The Act specifies that new or revised NAAQS be based on scientific criteria that "*accurately reflect the latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air" [emphasis added]. Pursuant to the act, EPA's assessments of the peer-reviewed literature are reviewed by an independent committee of scientists, as well as accompanying reviews by the public.

While details of the development and review of the criteria and standards have evolved over time, in practice, EPA has endeavored to include all relevant peer reviewed scientific studies in the process, even providing provisional assessments of relevant literature that appears after the formal scientific review has been completed.[28] Over the years, tens of thousands of peer-reviewed studies of health effects, exposure, and atmospheric interactions, and monitoring have been included in reviews of criteria and standards. A requirement that the raw data and full methodologies be made available for all of them is both impractical and inconsistent with the legislative mandate and EPA's practice over the last 40 years.

EPA has relied largely on community epidemiology and controlled human studies in establishing the specific levels and averaging times for NAAQS, while using animal toxicology to provide supporting information on potential mechanisms of toxicity. For many of the reasons noted above, removing studies that could be excluded by the Pruitt restrictions would greatly reduce the availability of information that has proved to be relevant in assessing the consistency and

coherence of evidence among studies and disciplines. While this would certainly weaken the scientific basis for maintaining or strengthening the current standards, a more comprehensive evaluation of what studies remained would be necessary to determine whether a relaxation of the any of the standards would be supportable.

A key example is the basis for the standards for fine particles ($PM_{2.5}$), most recently strengthened in early 2013. Because $PM_{2.5}$ is a mixture, the most relevant information comes from community epidemiology studies relating health effects to measured concentrations. The daily standard is based on "time-series" studies of daily mortality, hospital admissions and other health effects in selected communities. The best such studies include multiple cities. Much, but not all, of the effects data for such studies is publically available. The current long-term $PM_{2.5}$ standard is based on the annual levels in short-term studies, as supported by the results of long-term cohort studies.[29,30] It is these cohort studies that have been the focus of data availability concerns, despite the fact that the first two published in the 1990's have been reanalyzed[4] and replicated by other investigators in dozens of additional studies using different cohorts.[5] EPA's integrated assessment concluded that, as of 2009, the number of large U.S. cohort studies, together with supporting evidence from other epidemiology and toxicological studies were sufficient to infer a causal relationship between long-term PM2.5 exposures and mortality and cardiovascular effects.[31]

Arbitrarily removing these cohort studies from consideration would clearly weaken the basis for the causality conclusion as well as the basis for an annual standard. Paradoxically, however, the level of current annual standard is based more on the annual averages in multi-city short-term studies than on the average concentrations cohort studies.[25] So a case could be made for keeping the current annual standard, even if compelling evidence from many long-term peer reviewed studies were to be ignored. Nevertheless, the EPA policy assessment, CASAC recommendations and final decisions clearly considered the results of an EPA risk assessment based on multi-city studies. The percent of annual incidence of mortality based on the cohort studies was an order of magnitude higher than that based on the short-term studies.[29] Arbitrary exclusion of this risk information would provide a distorted picture that could influence the decision on the margin of safety in setting the standard. It would also mean that the benefits estimated for future EPA regulations that reduce fine particles would be substantially lower than indicated by the best available scientific information, thus providing misleading cost-benefit information to the public and policymakers.

The most obvious implication of the Pruitt proposal for the current review of $PM_{2.5}$ criteria and standards would be the exclusion of any significant new cohort studies that suggest effects at lower concentrations than in previous long-term studies. A recent study of the largest cohort to date used Medicare data and found associations between $PM_{2.5}$ and ozone and premature mortality at levels well below those of the current standards for both pollutants.[6] Of course, the strengths and weakness of this new work should be fully evaluated in the review before reaching any conclusions. But excluding this peer-reviewed study from any consideration because Medicare will not allow the confidential subject information to be openly published is both unreasonable, unnecessary, and as noted above, inconsistent with the Clean Air Act.

6) Regulation of Hazardous Air Pollutants

EPA regulates certain hazardous air pollutants (HAPs) from both stationary and mobile sources. The EDGI assessment of legislation[2] noted above concluded that EPA's 2007 regulation of benzene from gasoline, passenger vehicles, and fuel containers would have been blocked by prescriptions on data availability and reproducibility. The act requires initial technology-based emissions standards for stationary sources of one or more pollutants from a list of over 180 HAPS. The act contains provisions for 'delisting' pollutants where petitioners show that "adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects." Because hazard data for many of these can come from sources that include older studies or confidential business or personal health information, it is possible that the requirement to exclude studies where raw data are not available might lead to delisting decisions that might either prevent an appropriate delisting, or give a decision-maker the latitude to delist a pollutant on the basis that no evidence of effects exists in studies passing the transparency or reproducibility tests.

7) Regulations that address accidental release and restoration programs

The EDGI assessment[2] notes two kinds of EPA actions that would have been blocked by the ill-defined requirement for "reproducibility": 1) Accidental release requirements for risk management programs under the Clean Air Act and 2) the restoration work plan and program to address the Exxon Valdez oil spill under the clean water and the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund). Both actions gather and use environmental data on the damages resulting from unique events that could not be reasonably reproduced.

A science- based approach for reanalysis and replication of the scientific studies used in regulations: how EPA used the Harvard six city[27] and ACS[28] studies in the PM NAAQS

The Pruitt plan would ignore both the available approaches embraced by the scientific community and the record of past EPA assessments, which reveal alternative methods for ensuring the credibility of potentially useful scientific studies. These include both reanalysis by competent third party investigators and replication of studies using different data sets and conducted by different researchers. This is exactly the approach followed for the two long-term epidemiology studies on fine particle and mortality,[32,33] where the availability of underlying health data became an issue in the 1990s. Contrary to some characterizations, the fact that high daily levels of particles from coal combustion could increase mortality and illness was well established through episode studies in the U.S. and Great Britain in the 1950's and 60's. The six-city study appeared in 1993 and was among the first long-term studies that had sufficient medical and lifestyle data to address potential confounding and had access to direct measurements of fine particles. However, the number of cities and subjects were limited. To check their findings, the investigators obtained a second detailed health data set that included many more cities and

participants and published the "ACS" study in 1995, which found a similar relationship between fine particles and mortality.

As noted above, in developing scientific criteria for standards, EPA considers the broad range of relevant peer reviewed literature and identifies the relative strengths, weaknesses, and uncertainties of particular studies in terms of their potential use in regulatory decision-making and risk assessment. These EPA assessments are themselves reviewed by a panel of external science advisors, selected for their recognized expertise and experience in one or more of the relevant disciplines. With the approval of its science advisors, in 1996 EPA included the ACS study in a provisional staff risk assessment. Ultimately, EPA placed limited reliance on these studies in setting the level for the $PM_{2.5}$ standard in 1997. Instead, the level of the annual standard was based mainly on annual levels in daily mortality study cities.[34]

Some groups raised concerns about gaining access to the data in public comments as well as in subsequent lawsuits. As discussed elsewhere,[35] the court later upheld EPA's consideration and use of the studies as published in the peer-reviewed literature. The investigators and the ACS had refused to release the in general due to privacy concerns regarding the subjects' lifestyle, medical data and location. Given the concerns over the need for reanalysis, however, the investigators solicited the help of the Health Effects Institute (HEI), which is jointly funded by EPA and industry. Harvard and the ACS agreed to make the data and methodology available to experienced independent third party investigators for reanalysis, who would be chosen and managed by HEI. The reanalysis of both studies was successful and published in 2000.[36] The HEI report conclusion stated: "Overall, the reanalyses assured the quality of the original data, replicated the original results and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality."[4]

In subsequent years, both Harvard and ACS continued to collect new data and eventually published new studies that included more years of data. The Harvard group found that the reduction in $PM_{2.5}$ from air pollution controls was accompanied by a reduction in mortality risk. In general, these updated studies produce results that are consistent with the earlier studies, and the more recent and complete versions have been used in EPA risk and benefit assessments.

More importantly, in the intervening years different investigators have published dozens of peer reviewed long-term studies that essentially replicate the findings from the original and more recent Harvard and ACS studies using different data sets from the U.S. and other countries.[5] These replications provide strong evidence of a significant and causal relationship between protracted exposures to fine particles and premature death. As noted above, one of the most recent of these used a Medicare data base to show a similar level of risk that continues even when excluding all PM data above the level of the current standard.[6] Significantly, these data are available for any research group that can guarantee confidentiality of the personal information. Yet even this powerful new study could not even be evaluated under the Pruitt proposal. Why isn't limited availability to qualified researchers who will guarantee confidentiality enough? There is a better way that is offered by science, and it is conducting further investigations and

advancing our understanding. Increasing transparency in *all* of science is a desirable goal. Pruitt's policy would ignore the many layers of oversight that are already in place and make it more difficult to use environmental science results in policymaking. Thus instead of achieving improved transparency at the agency, Pruitt's policy undermines the very ability of his staff to use the best available science to meet the EPA's mission of protecting public health and the environment.

For Further information:
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