Docket ID No. EPA–HQ–OA–2018–0259

COMMENTS ON PROPOSED "TRANSPARENCY" RULE
Docket ID No. EPA–HQ–OA–2018–0259

submitted via **https://www.regulations.gov**

These comments are filed on behalf of Keeper of the Mountains Foundation (KOTM), and People Concerned About Chemical Safety, INC. (PCACS), both non-profit West Virginia corporations. KOTM's address is 179 Summers Street, Suite 234, Charleston, WV 25301. PCACS' address is 1511 Pinewood Park Dunbar, WV, 25064.

In a Notice of Proposed Rulemaking dated April 30, 2018, at 83 Fed. Reg. 18768 (Notice), the Environmental Protection Agency (EPA) states that it is proposing regulations intended to insure, for science pivotal to its significant regulatory actions, that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis, and thereby implement policies favoring transparency in a robust and consistent manner. This proposal, the Notice states, will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

By way of background, the Notice states that: "The best available science must serve as the foundation of EPA's regulatory actions." Additionally, the Notice observes that Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public.

The Notice focuses, however, on decisions having economic costs:

> When EPA develops significant regulations using public resources, including regulations for which the public is likely

> to bear the cost of compliance, EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

Under the heading "Does this action apply to me?" the Notice states that, while the proposed regulation does not directly regulate any entity outside the federal government, any entity interested in EPA's regulations may be interested in this proposal, adding that:

> This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

KEEPER OF THE MOUNTAINS FOUNDATION

KOTM and PCACS do not directly conduct scientific activities or research of the type contemplated by the proposed rule. However, both KOTM and PCACS have missions that focus on the need for robust regulatory schemes to protect the citizens of the United States from the exposures inherent in a post-industrial society primarily dependent on fossil fuels, and heavily invested in chemical processes with potentially lethal emissions.

Specifically, KOTM and its officers and employees live in areas of West Virginia proximate to ongoing mountaintop removal coal mining, and coal-fired electric generation plants. As EPA noted in its proposed rulemaking for the Clean Power Plan, West Virginia is dependent on coal for 96% of its electric generation, the highest percentage dependence of any state in the nation.

A series of not less than two-dozen peer reviewed studies (See

summary attached to these comments as Exhibit A) have consistently documented the adverse health effects of exposure to particulate matter in areas adjacent to mountaintop removal coal mining and coal-fired electric plants. Those adverse health effects include increased birth defects, decreased birth weights, diminished educational attainment, increased cardio and pulmonary diseases and increased cancer rates. In addition, these studies document very substantially diminished life expectancy, on the order of a decade or more.

Larry Gibson, the founder of KOTM in 2004, lived for years on Kayford Mountain, the home of 300 ancestors buried there, and their home from a time dating back to the nineteenth century. Kayford Mountain was also the site of a 5,500 acre mountaintop removal site from the mid-1990's forward. Larry Gibson was 66 years old at the time of his death on Kayford Mountain in 2012.

PEOPLE CONCERNED ABOUT CHEMICAL SAFETY, INC.

PCACS and its officers and directors live in the so-called "Chemical Valley" bracketing the eastern and western boundaries of Charleston, West Virginia. The Chemical Valley got its initial start during World War I when the military established it (strategically beyond the range of German naval vessels) in a virtually new town named, appropriately, Nitro, West Virginia. In World War II, the government created a synthetic rubber plant in Institute, WV; that plant later became the international headquar ters of Union Carbide Corporation.

Other than Union Carbide, subsequent chemical companies with substantial operations in a relatively confined, 25-mile geographic area include, currently and historically, Dow Chemical, DuPont Chemical, Bayer CropScience, among the most conspicuous large chemical companies; virtually all chemical companies of any size

have, or have had, installations in the Chemical Valley. The availability of cheap and abundant ethane from Marcellus shale and other natural gas fields in the region has lead to a substantial increase in West Virginia's chemical sector over recent years, which is likely to continue to expand in the future.

PCACS, formerly known as "People Concerned About MIC" began in Institute, West Virginia, by professors at what was then known as West Virginia State College, an historic Black college, around which a highly educated African American community of teachers, students and their family members located and grew. Institute, was the headquarter's site of Union Carbide immediately following the December 1984 release of methylisocyanate (MIC) at a Union Carbide plant in Bhopal, India, the largest industrial accident in human history, killing tens of thousands of persons overnight. For twenty-seven years following the 1984 Bhopal disaster, MIC was manufactured in exactly one place on the planet – the 440 acre chemical complex in Institute, W. Va., operated in sequence by Union Carbide, Rhome Peulonc, Aventis and, in 2008, by Bayer CropScience. The citizens of Institute went to bed every night wondering if they too would be victims of instantaneous chemical annihilation.

In August 2008, a portion of the MIC facility at Bayer CropScience's chemical complex exploded, killing two employees on site and releasing an undetermined amount of MIC because all perimeter metering devices had been turned off. A civil action against the operators of the MIC chemical facility in 2008, filed in 2011 by a founding member of PCACS for the wrongful death of his wife, was dismissed on grounds of untimeliness, without reaching the merits.

On February 6, 2011, residents of Institute, W. Va. and members of People Concerned About MIC who later incorporated PCACS, commenced litigation in the United States District Court, against

Bayer CropScience, owner of the MIC facility which exploded in 2008, had been rebuilt and was about to restart. The citizen plaintiffs obtained a temporary restraining order halting the restart of the MIC facility unless and until Bayer CropScience implemented the recommendations for improved safety identified in a January 2011 report by the US Chemical Safety Board (CSB), following CSB's investigation of the 2008 explosion. On the eve of a court hearing on issuance of a preliminary injunction, Bayer CropScience announced that it would immediately and permanently terminate all production, transportation and storage of MIC.

The foregoing narrative background is intended to make clear that the Directors, Officers and staffs of KOTM and PCACS are directly affected by safety regulations promulgated by the EPA and other agencies of the federal and state government. As such, they are treat seriously issues pertaining to the soundness of the science underlying government regulations, and support any good faith proposal to improve those regulations in a manner likely to improve health outcomes.

At the same time, KOTM and PCACS acknowledge that they bring more than marginal skepticism to EPA's "transparency" rulemaking, proposed by an administration who has announced its hostility to the EPA's statutory mandate, and aggressively delayed or repealed multiple regulations, final and proposed, intended to improve the nation's health and environment. The laundry list of EPA actions undoing the work of the last half centur increases daily.

Moreover, it cannot go unnoted that the so-called "transparency" rule is a restatement, in regulatory format, of the so-called "Honest Act," legislation proposed by the Chairman of the House Science Committee, retiring Texas Congressman Lamar Smith. Chairman Smith's major claim to fame has been his highly public and

vitriolic harassment of scientists, in particular those involved in the promulgaton of the regulations of the EPA. Important and likely fatal to this rulemaking, Chairman Smith's "Honest" act has been repeatedly rejected by the United States Congress despite many opportunities to obtain enactment. *F.D.A. v. Tobacco Company*, 529 U.S. 120, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000).

Still, no serious observer could be against "transparency" in science, particularly where it is proffered as a way of making regulatons better able to protect the citizens of the United States?

EPA's Notice states, reassuringly, that it is prospective only, suggesting that it is not proposed to be used to undo regulatory enactments of the past, particularly those pertaining to regulaton of particulate matter. Simultaneously, however, the Notice requests comments regarding the long standing National Ambient Air Qualifty Standards (NAAQS) program. That program – the bed rock of the EPA's implementation of the Clean Air Act – will face:

> future significant regulatory actions …based on the administrative record from previous reviews—particularly where the governing statute requires repeated review on a fixed, date-certain cycle.

How, EPA's "transparency" rulemaking Notice asks, , should the proposed rule apply to the previous NAAQS record? Indeed, how, if – as is the case – the strictures currently proposed were not followed in the now decades old rulemakings?

Is it too far a stretch to imagine that the current EPA administrators would use those purported historic deficiencies as a pretext for dismounting the entire edifice of the Clean Air Act?

Nothing in the aggressive de-regulation of industry by the current EPA provides any reassuance that the foundations of generations

of existing regulation are not being set up for unceremonious disintegration in the name of a new found concern about the integrity of science, a science heretofore villified by industry advocates and opponents of regulations designed to protect the citizens of the US, regardless of the diminution on profits associated with those regualations.

Having stated their broad concerns, KOTM and PCACS support the broad proposition that rulemaking must be based uon sound science, and further support a good faith effort to develope understanding of such science based upon reproducible data.

We conclude this prefatory comment with the observation that the Administrative Procedure Act, and a healthy jurisprudence developed over a half-century of judicial review, already require that rulemakings be supported by "substantial evidence." The EPA retains the option of allowing the community of science in all its many categories and subcategories to continue the ongoing, decade long commitment to evolving – and improving – standards of "reproducibility."

PROPOSED § 30.1

What is the purpose of this subpart?

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

COMMENT:

KOTM and PCACS support the stated purpose of the proposed regulation in §30.1. We note that, in other parts of the Notice, the purpose is stated as making the data underlying regulatory science

understandable by the public. Candidly, it is not realistic to expect the general public, in a highly developed, modern industrial economy, to possess a level of educational attainment sufficient to comprehend the underlying science of all significant regulatory undertakings, particularly the underlying statistical skills necessary to analyze substantial bodies of data. Although it may not be possible to make complex data understandable, it is demonstrably the case that industry subject to regulation can exploit ambiguities and uncertainties in data, not to foster public understanding but the opposite, to foster highly exploitable public confusion.

PROPOSED § 30.2

What definitions apply to this subpart?

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

> ***Dose response data and models*** means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal *regulatory science* that drives the size of benefit/cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.
>
> **COMMENT:**
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> What level of uncertainty, or margin or error, in any scientific data, will be sufficient to impose costs on industry? How certain must the aimed for improvements in health and

the environment be in order to justify cost increases on business. What level of cost increases will be acceptable for intended benefits. Where the cost of compliance with a proposed regulation are readily identifiable, but the quantity and quality of health benefits are less identifiable, what ratio of costs to benefits will pass muster under the proposed rule?

KOTM and PCACS observe that too rigid a formula may have the effect of deferring innovation in regulatory science, by making what was achievable in past experience, a confining restraint on what may in fact be otherwise unknowable benefits, i.e., benefits that can only be known by what is candidly recognized as a regulatory experiment.

Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant *regulatory decisions.*

COMMENT:

There is no mechanism in the regulation for assuring that the science drives the decision. Therefore, there is no means for judging the term pivotal. Without transparent consideration of all the information available, and public comment on whether all pertinent information was considered, it is pointless to promulgate rules on the availability of the information.

PROPOSED § 30.3
How do the provisions of this subpart apply?

The provisions of this subpart apply to *dose response data and*

models underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

COMMENT:

The question posed is not answered by the regulatory proposal. That is, no clear information is stated in the Notice as to HOW the provisions of the subpart will be applied.

PROPOSED § 30.4
What requirements apply to EPA's use of studies in taking final action?

EPA shall clearly identify all studies (or other *regulatory science*) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

COMMENT:

Identifying studies and making them available to the public may be, at least superficially, easily attainable objectives. Less clear is how the public is going to be expected to understand whether all pertinent data was included and comment on highly technical discussions of statistical data and analyses.

PROPOSED§ 30.5
What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

When promulgating *significant regulatory actions*, the Agency shall ensure that *dose response data and models* underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''*publicly available in a manner sufficient for independent validation''* when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

(a) Data (where necessary, data would be made available subject to access and use restrictions).

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

COMMENT:

Releases necessary to allow the "public to understand" are simply not going to happen. For the reasons stated, public educational attainments are not at a level needed to insure understanding. Alternatively, releases necessary to allow competent scientists, with access to statistical and other tools of scientific assessment, are possible. The problem presented by the proposed standard of understanding is that simple public confusion becomes a basis for setting aside a regulation. And how is the public confusion to be ascertained? By public surveys? By assessing comments received from the public?

PROPOSED § 30.6
What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

COMMENT:

How will EPA decide, on a case-by-case basis, what default assumptions, including assumptions of a linear, no-threshold dose response, are appropriate?

What if the *sensitivity of the modeled results to alternative assumptions* is itself not subject to scientific consensus.

Won't any regulated industry potentially subject to a proposed regulation, be able to exaggerate the impacts of assumptions, based on disputed sensitivity, to effectively diminish in the public mind, the cost/benefit ratio of a proposed regulation.

Will such an industry-inspired public confusion be sufficient to establish the procedural inadequacy of a proposed regulation?

PROPOSED §30.7:

What role does independent peer review in this section?

EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein. Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications.

COMMENT:

The pragmatic impact of rule 30.7 is straight forward. EPA proposes to set itself up as the ultimate arbiter of science and, effectively, censor all future peer review studies conducted by the specialists in a given area.

Although the April 30, 2018 EPA Notice pays lip service to the so-called "reproducibility" crisis facing science, and in footnote 12 references several serious discussons of "reproducibility, the Notice does not observe that those footnoted discussions have proceeded deliberately and carefully over literally years. EPA's April 30, 2018 proposal has a thirty-day comment period, after which EPA will be free, procedurally, to act.

In "A Manifesto for Reproductive Science," referenced at https://www.nature.com/articles/s41562-016-0021, the author discusses the multi-year concern of the entire scientific community, including studies in 2015 and 2016, as part of the matters leading to its publication in January, 2017.

"Why Most Published Research Findings Are False," is itself a 2005 commentary, referenced at http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 and observes that "Selecting the performance of large-scale studies based on narrow-minded criteria, such as the marketing promotion of a specific drug, is largely wasted research."

Those "marketing" studies are largely conducted by private, for-profit, companies out to prove the efficacy of their company's product as a means to enhanced profits. This is the same research community the EPA Noticc suggests is immune to claims of bias.

Moreover, the April 30, 2018 Notice does not propose to adopt transparency rules similar to those advanced by the National Institute of Health (NIH) or the Natinal Institute of Neurological Disorders and Strokes (NINDS), developed over most of the last decade.

The cited "reproducibility crisis" is not something science has ingored. To the contrary, science has for most of the last decade recognized the presence of "confirmation bias" and other factors inherent in any scientific inquiry. Importantly too, science has seriously addressed the topic, appropriately by the filed affected, and without the overriding if indirect mendace of governmental agents and the private, for-profit entities exercising influence over them at a particular moment in our countriy's political history

The reality is that science, not subject to the suffocating and chilling overhang of governmental censorship, is far more likely to develop a robust protocol for enhancing and assessing reproducibility than is a government agency subject to the fickle influence of private industry and its paid representatives who are in the business of producing doubt with respect to any proposal that implies increased cost to, or potentially diminished market share for, the industry affected by a particular EPA proposal.

UNADDRESSED INTEGRITY IN SCIENCE ISSUE:

Reproducibility v. Producibility

KOTM is particularly sensitive to the "reproducibility crisis" the EPA Notice purports to address. However, from the viewpoint of KOTM, the public concern of reproducibility should be assessed along side its parallel – the "producibility crisis." Rather than review and consider studies available to it, the EPA has often

swept them aside, failing to consider the legitimate concerns raised by these scientific inquiries.

The summary of health studies attached as **Attachment A** references in many places particulate matter in its various sizes and concentrations. Every attempt to bring these matters to the attention of EPA is met by resistance, relying upon a single 2005 study claiming that PM is not detectible. **See Attachment B**. However, two studies of PM (**Attachments C and D**) in the contexts of a highway during rush hour, and an adjacent residential neighborhood, have been simply disregarded by EPA, who continues to rely on the now outdated 2005 study, even after studies (**Attachments E and F**) have totally replicated the later studies.

Moreover, KOTM is aware that the current administration has withdrawn funding from the National Academies of Sciences, Engineering and Medicine for a study tentatively titled "Potential Human Health Effects of Surface Coal Mining Operations in Central Appalachia." See NAS Press Release dated August 21, 2017 (**Attachment G**). See also, *Trump administration halts study on coal mining's impact on health*, August 21, 2017 The Roanoke Times, http://www.roanoke.com/business/news/trump-administration-halts-study-on-coal-mining-s-impact-on/article_bf9a6a04-ad9e-5fe2-a0cb-177c2c9cccca.html (last visited May 25, 2018). That study sought to do what the proposed rule would seem to support – a transparent assessment of the scientific literature that demonstrates the health effects of Mountain Top Removal coal mining, furthering our concern about the language in this proposal being used to achieve the opposite.

Similarly, PCACS has requested a copy of the Agency for Toxic Substances and Disease Registry (ATSDR) assessment of a class of toxic chemicals that has contaminated water supplies near

military bases, chemical plants and other sites from New York to Michigan to West Virginia. The assessment was scheduled to be released previously but was, reportedly, blocked after a January 30, 2018 email forwarded by James Herz of the Office of Management and Budget in which an unidentified White House employee reportedly stated: *"The public, media, and Congressional reaction to these numbers is going to be huge*" and "*The impact to EPA and [the Defense Department] is going to be extremely painful. We (DoD and EPA) cannot seem to get ATSDR to realize the potential public relations nightmare this is going to be*," all as reported in a May 14, 2018 article published by politico.com at https://www.politico.com/story/2018/05/14/emails-white-house-interfered-with-science-study-536950 (last visited May 16, 2018).

On May 22, 2018, the Department of Health and Human Services denied the request for the ATSDR study on the grounds that:"*ATSDR's Toxicological Profile for Perfluoroalkyl Substances has not been approved for release to the public*." See **Attachment H.**

PCACS is not insensitive to the potential for public embarrasment of political appointees. But the obvious question is why the study is not ready? Is it because agency scientists are scrupulously running checks on the statistical bases for the conclusions in the study? Or is it because the release of the study would cause a predicable – and politically inconvenient – demand for enhanced regulatory response from an administration committed to the destruction of the EPA as an effective regulatory body? Thinking people want to know!

KOTM and PCACS applaud the stated goals of EPA's Notice regarding the proposed "transparency" rule. As commenters they suggest that concerns for "reproducibility" and "producibility" be treated in tandem as the EPA continues its quest for truth.

Respectully submitted,

KEEPER OF THE MOUNTAINS FOUNDATION
PEOPLE CONCERNED ABOUT CHEMICAL SAFETY, INC.

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