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August 13, 2018

**VIA ELECTRONIC SUBMISSION**

Elizabeth Kopits  
National Center for Environmental Economics, Office of Policy  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D. C. 20004

**RE: ANPRM Regarding Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process; (Docket ID EPA-HQ-OA-2018-0107)**

Dear Ms. Kopits:

**I. Introduction**

The U.S. Chamber of Commerce (“Chamber”) offers these comments in response to the U.S. Environmental Protection Agency’s (“EPA,” or “Agency”) June 13, 2018, Advanced Notice of Proposed Rulemaking (“ANPRM”) entitled, “Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process.”

**II. Background**

The U.S. Chamber of Commerce has long advocated for increased transparency and openness in the regulatory process at the U.S. Environmental Protection Agency. The EPA has historically misinformed and misled the public by using inconsistent and opaque analytical and communication methods regarding costs and benefits. The Agency has not been transparent in how they have used those findings to inform its regulatory policy. (See Enclosures)

EPA should concentrate on improving the transparency and consistency of benefit-cost analysis for Clean Air Act (CAA) rules first. While multiple EPA regulatory programs contain problems in transparency and consistency of cost-benefit analysis, the most serious and persistent problems arise from regulations relating to the CAA. Rules promulgated under the CAA, most notably the National

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Ambient Air Quality Standards (NAAQS) are often the most costly and controversial of EPA's rulemakings, and neither the benefit-cost analyses that inform them nor the way EPA uses the analysis as a policymaking tool are clear.<sup>1</sup>

Developing and instituting sound regulatory policy requires understanding costs and benefits, and ensuring that the benefits are worth the costs. This means ensuring that the inputs and outputs to the analysis are clear, consistent, and replicable, and presented in a way that thoroughly informs the public. The EPA should present cost-benefit analyses clearly. EPA has frequently failed to meet these standards when producing analyses to support its CAA rules. EPA's over-reliance in recent years on "incidental benefits" or co-benefits from fine particulate matter (PM2.5) to justify virtually every new air regulation casts serious doubt on the transparency and accountability of the federal regulatory process.<sup>2</sup> Developing clear standards with public input and participation can potentially curtail such practices.

The Chamber and its members strongly support continued efforts to improve U.S. air quality. Recently released EPA data show that emissions of criteria air pollutants have declined 67 percent since 1980, all while the nation's economy and population have both grown substantially. We are proud of this success and look forward to collaborating in support of continued improvements, but must do so in a manner that ensures that EPA addresses longstanding flaws in the cost-benefit analyses developed to inform the regulatory process.

### **III. Major Problems with EPA Analyses that the Agency Should Remedy**

#### *A. EPA cost-benefit estimates used to justify regulations are inconsistent and often contain methodological deficiencies*

Many methodological problems plague EPA's analyses and substantially reduce their transparency and utility. EPA often uses poor or incomplete data for both cost and benefit estimates, though the deficiencies in benefits estimates

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<sup>1</sup> See, for instance, U.S. Chamber of Commerce, [Truth in Regulating: Restoring Transparency to EPA Rulemaking](#), or U.S. Chamber of Commerce, [Regulatory Indifference Hurts Vulnerable Communities](#).

<sup>2</sup> See NERA Economic Consulting, *An Evaluation of the PM2.5 Health Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations*, (December, 2011) available here: [http://www.nera.com/content/dam/nera/publications/archive2/PUB\\_RIA\\_Critique\\_Final\\_Report\\_1211.pdf](http://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf).

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are generally many times more impactful. Another problem is the lack of transparency in how EPA handles uncertainty in cost and benefit estimates, particularly with respect to health benefits estimates for CAA rules.

EPA does not appropriately use all of the relevant scientific information on the human health effects of pollutants, particularly PM<sub>2.5</sub> and ozone, to inform CAA health benefits estimates or estimates of the economic value of emissions reductions. EPA uses a non-transparent, subjective, non-quantitative methodology to determine the studies it will use to estimate health effects. This selection process biases the results of EPA's analyses and makes the benefits estimates appear substantially more certain than they are in reality, by ignoring any contradictory evidence and failing to present the underlying uncertainty in a quantitative manner. EPA should institute new standards requiring the agency to consider available evidence, using a "weight-of-the-evidence" estimation methodology, and employing quantitative methodologies to incorporate, estimate, and present the relevant uncertainties.

EPA could greatly improve its analyses of costs by always listing a year-by-year expectation of predicted compliance costs over the first 15 or 20 years of the regulation, and by always presenting both annualized costs as well as the Net Present Value (NPV) of costs. In addition, EPA should seek more data and information on cost uncertainties. In general, EPA should work more closely with industry, particularly in highly regulated industry sectors, to develop accurate, up-to-date cost estimation tools that reflect the state-of-the-art tools used within the sector for investment and planning decisions. In the past, industry has been willing to provide EPA with data and tools on cost considerations but the agency has not used them, relying instead on flawed, outdated information and methodologies that systematically misrepresented costs.

*B. EPA uses incidental, or co-benefits, inappropriately to justify standards that are not supported by a more transparent economic analysis*

A major problem with many of EPA's CAA rulemakings is that the agency uses its statutory authority to address specific pollutants to regulate other, often-unrelated pollutants that different statutes appropriately address. EPA calls these indirect regulated emissions reductions "co-benefits" of regulation. The problem arises when EPA designs regulations *specifically* to

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produce co-benefits, rather than to address the pollutants covered under the relevant statute. In recent years, EPA has used the co-benefits of PM<sub>2.5</sub> reductions to justify costly regulations that did little to reduce directly regulated pollutants.<sup>3</sup> According to EPA cost-benefit analyses of rules finalized between 2000 and 2016, 97.2% of all claimed benefits were from PM<sub>2.5</sub> reductions, and the vast majority of all PM<sub>2.5</sub> reductions over that time period were claimed as co-benefits arising from non-PM regulations.

The consideration of direct benefits and incidental benefits jointly works to obscure the policy decisions of regulators in terms of transparency and accountability. A well-designed regulation should address an identified problem in the most cost-effective means possible, reducing the targeted pollutant through the most direct, minimally burdensome means.<sup>4</sup> EPA should drastically reduce its use of co-benefits to justify non-PM rules. The agency should develop regulatory guidance on they use the benefits of indirectly regulated emissions reductions in standards setting decisions. EPA should commit to setting standards based on the costs and benefits of directly regulated pollutants, and only then considering the additional benefits. This ensures that co-benefits are, in fact, incidental rather than the focus of regulatory action.

EPA should only count health benefits of indirectly regulated pollutants when reductions occur above the NAAQS limit. Once EPA sets a standard for PM<sub>2.5</sub> (or ozone) that meets the statutory requirements under the NAAQS as protective of human health and welfare with an adequate margin of safety, it should not claim that the policy generates additional benefits when indirectly regulating the pollutant under other statutes. This restriction preserves the preference for directly regulating pollutants via the statutory provisions designed by Congress to address the specific concerns relative to those pollutants. Doing so enhances the transparency and openness of the regulatory process and ensures that the public has every opportunity to participate in a rulemaking.

*C. EPA does not communicate how it uses benefit-cost analysis to inform policies and standard setting in a clear and consistent manner*

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<sup>3</sup> See U.S. Chamber of Commerce, [Truth in Regulating: Restoring Transparency to EPA Rulemaking](#), which covers multiple examples of EPA's use of co-benefits to justify overly stringent rulemakings that have high costs and little to no benefits from directly regulated pollutants under relevant authorizing statutes.

<sup>4</sup> As directed in E.O. 12866, Sec. 1 b(5).

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EPA’s presentation of the results of benefit-cost analyses that accompany rulemakings is often opaque. The EPA does not effectively summarize the results of benefit-cost analyses or explain in a clear and concise manner what they mean. In addition, the EPA frequently presents results in a deceptive manner. For example, EPA often claims in health benefits estimates under the CAA that a regulation will save “X” number of lives. The truth is that the regulation will reduce risks for exposed populations, often in a very non-uniform manner geographically, and often these risk reductions are very minute and occur over long time spans. This presentation biases the public to action in support of the regulation, because the average person perceives “thousands of lives saved” very differently than the reality of minutely reduced risks across millions of individuals over many years that often only affect certain sub-populations in certain specific circumstances. EPA should endeavor to present analysis that informs its regulations in a clear, but clinical manner that reduces the potential for creating bias.

EPA should also clearly explain to the public exactly how it uses the output of cost-benefit analyses in its decisions. The Agency should develop a clear, binding framework in which it fully discloses precisely what role analyses played in the rulemaking.

#### **IV. Questions Raised by EPA in the ANPRM**

Below, the Chamber provides responses to a specific questions posed by EPA regarding transparency and consistency of cost-benefit analyses in the ANPRM.

- B. 1. ***What would increased consistency look like?***
  - a. *Given statutory constraints, how could EPA more consistently adhere to existing guidance on benefit-cost analysis principles, definitions and analytical techniques whether across the entire agency or specific programs? For example, to what extent, if any, should EPA develop a regulatory action that commits the Agency to following its existing peer-reviewed guidance documents on risk assessment and Guidelines for Preparing Economic Analysis when developing future rulemakings?*

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While adoption of certain agency-wide operating principles may be valuable, EPA should address the consistency of economic analysis within each individual statute rather than try to create a one-size-fits-all rulemaking. Statute-specific rulemakings will allow EPA to tailor the requirements to specific regulatory requirements. EPA can achieve enhanced consistency and specificity *within* statute-specific rulemakings due to the similar missions of the various regulatory requirements within single statutes.

EPA can and should focus on increasing consistency in the *quality* of the analysis across agency programs rather than adopting or adhering to a one-size-fits-all approach that would cover all agency programs. EPA can seek a qualitative increase in consistency in the overall rigor and objectivity of the information presented throughout all of the Agency's rulemakings. This includes greater transparency in the identification and analysis of all assumptions and uncertainties. EPA would achieve such consistency by adopting statute-specific rules that address specific issues that arise within rulemakings.

Making one-size-fits-all standards across statutes for the sake of consistency would reduce the effectiveness of the standards because it would require too broad a perspective. The types of analysis and issues faced in fashioning uniform analytical standards are most consistent within statute. Expanding the effort more broadly necessarily limits it to very broad, high level issues that while important, tend to have less impact in performing an appropriate benefit-cost analysis, or fix persistent existing problems. For example, EPA could achieve greater consistency in the disclosure of assumptions and inputs to models, or adopt requirements for sensitivity analyses to understand the range of uncertainties in such models. Statute-specific rules, however, would also allow EPA to require how they should achieve this within the context of the specific types of models, assumptions, and uncertainties that affect the regulatory process specific to the statute. Statute-specific rulemakings would likely also result in a stronger legal basis.

With respect to improving adherence to EPA's own internal guidance on risk assessment and economic analysis, EPA should select important elements from existing EPA and OMB guidance that are

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appropriate to include in a statute-specific rulemaking.<sup>5</sup> As a general matter, guidance documents are usually too detailed for a rulemaking context. Specific examples of requirements that could be included in rulemakings include:

- (1) The presentation of annual and Net Present Value (NPV) costs and benefits.
- (2) The systematic identification and evaluation of all major relevant studies.
- (3) The appropriate identification and assessment of all major model uncertainties.
- (4) The preference for relying on studies that are replicable.
- (5) The presentation of costs and benefits to U.S. citizens as required by OMB Circular A-4.
- (6) The application of discount rates as directed in OMB Circular A-4.

b. *Should EPA consider adopting uniform definitions of specific terms used in statutes – e.g., “cost,” “benefit,” “economic factors,” “reasonable,” “appropriate,” and “weight of scientific evidence” - and specifying ex ante how they will be factored into subsequent regulatory decisions? How should EPA approach the scope of the uniformity of these definitions (e.g., within a particular regulatory program; within statute; across statutes)?*

While EPA should seek greater consistency in the definition of key terms and in the objectivity and rigor of analysis, EPA should *not* seek to develop and apply rigid definitions across all agency programs given the range and complexity of many regulatory contexts. EPA should develop statute-specific rulemakings on cost-benefit analyses, starting with the Clean Air Act, which focus on the specific regulatory authorities under the statute. Statute-specific rulemakings will allow the Agency to develop definitions that more precisely apply to the regulation. Over-generalization could reduce the effectiveness of EPA’s rulemakings and lead to conflicts. Attempting to expand definitions sufficiently to ensure that a one-size-fits-all approach does not present conflicts will reduce the effectiveness of the rulemaking.

Where the statutes are silent with regard to the consideration of costs, EPA should consider costs and benefits consistent with Supreme

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<sup>5</sup> E.g. OMB Circular A-4.

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Court decisions in *Michigan v. EPA*<sup>6</sup> and *Entergy v. Riverkeeper*.<sup>7</sup> In both decisions, the Court affirmed that the EPA should use cost-benefit analysis in standard setting within the relevant, statute-specific language. EPA should start a rulemaking from the position of using appropriate analysis as a guiding principle and walk back such usage only as the statute requires. Such an interpretation is consistent with E.O. 12,866, that required that significant regulatory actions be submitted for review to the Office of Information and Regulatory Affairs in the Office of Management and Budget.

Although a one-size-fits-all rule governing the inclusion of costs and benefits in decisions may not be appropriate, greater uniformity and rigor in the development of benefit and cost information should lead to more consistent and efficient outcomes. Improving the quality and consistency of the process under which the Agency assesses costs and benefits will ensure that the Agency is dedicating limited private and public sector resources to reducing meaningful risks.

- c. *To what extent should standard benefit-cost analysis principles (e.g., setting a standard to maximize net benefits) guide the selection of specific statutorily required metrics and thresholds (e.g., “reasonableness”) against which to measure the effects of a proposed regulation?*

This rulemaking cannot override individual statutory requirements or act as a “super-mandate” without legislative authority. Where there is discretion in the statute, EPA should conduct and present a transparent and rigorous analysis of the benefits and costs for each regulatory option, and select options that address statutory requirements while minimizing costs.

One of the key deficiencies in EPA’s benefit-cost analyses has been a failure to consider, measure, and quantify relevant uncertainties and incorporate them into its economic analysis. This failure has led the agency to overstate the certainty of health benefits from various standards promulgated under the CAA. Given the many uncertainties in estimating benefits and costs, EPA should avoid the imposition of bright-line

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<sup>6</sup> *Michigan v. Environmental Protection Agency*, 576 U.S. \_\_\_ (2015).

<sup>7</sup> *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208 (2009).

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decision criteria, such as maximizing net benefits. These uncertainties suggests that EPA should avoid a rules-based standards setting approach (especially for CAA rules).

- d. *What improvements would result from a general rule that specifies how the Agency will factor the outcomes or key elements of the benefit-cost analysis into future decision making? For example, to what extent should EPA develop a general rule on how the Agency will weigh the benefits from reductions in pollutants that were not directly regulated (often called “co-benefits” or “ancillary benefits”) or how it will weigh key analytical issues (e.g., uncertainty, baseline assumptions, limited environmental modeling, treatment of regulating multiple pollutants within one regulatory action) when deciding the stringency of future regulations? In addition, frequently scientific understanding is not adequate either to should these potentially important but non-quantified and/or non-monetized effects be included in decision making?*

This consideration is vital to conducting a rulemaking specifically on CAA regulatory analysis protocols. As noted above, EPA should not impose one rule with regard to how it will consider benefits and costs under all existing statutory provisions, and it may lack the legal authority to do so cleanly. In addition, issues like the use of co-benefits and the treatment of uncertainty, especially with respect to health benefits, are CAA specific issues that EPA should not attempt to address via a one-size-fits-all rulemaking. However the agency should focus so heavily on improving the analysis of health effects estimates, because they are used across a very wide range of CAA rules, underlie so much of the agency’s rulemaking, and account for the vast majority of all of the agency’s claimed costs and benefits.

EPA touts the health effects of PM2.5 in a cavalier fashion in cases where PM2.5 effects may be only incidental benefits or co-benefits. This tendency means EPA has doubled down on the inherent lack of transparency and uncertainty built into the Agency’s handling of health benefits. It would be appropriate for EPA to address this particular issue in a rulemaking that carries across various regulations that use PM2.5. It is too central an issue to CAA rulemaking *not* to address with a broad rulemaking.

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Before attempting to fully quantify cost and benefit information, EPA should first identify the key uncertainties that are likely to affect the resulting estimates using sensitivity analyses. Once EPA has identified the key uncertainties, EPA should quantitatively evaluate the subset of uncertainties that significantly affect the final cost, risk and benefit estimates using an integrated uncertainty analysis. This type of sophisticated, quantitative risk and uncertainty analysis should underlie EPA's biggest and most costly rulemakings.

EPA does not transparently assess all scientific studies used to inform the analysis nor does it then consider the totality of evidence in an open manner, which affects how EPA presents and considers uncertainties. The Agency should develop general criteria for evaluating the quality and design of peer reviewed studies regardless of study conclusions or funding. By ignoring many studies, or discounting them in the evaluation, and then choosing only limited studies to use as "endpoints" for estimation purposes, EPA ignores potentially important information and biases the process of developing and estimating health effects using subjective criteria like "expert opinion" when data-driven, transparent methodologies would be more appropriate.

EPA should employ a "weight-of-the-evidence" approach that allows the agency to consider all available evidence and properly present the wide variance in study outcomes. EPA should further consider using Bayesian estimation techniques for risk analysis that properly portray the underlying uncertainty that exists and more readily allow the agency to continue updating prior estimates as new information becomes available. This approach is a more scientifically valid methodology and means the agency would produce better benefit-cost analyses, consider uncertainty when formulating policy, and better inform the public about potential regulatory outcomes.

It is critical to identify and evaluate uncertainties surrounding baseline assumptions when assessing benefits and costs. The baseline should accurately reflect expected emission levels that would occur in the absence of regulation. This requires up-to-date and realistic assumptions regarding industry growth, technology innovation, fuel use, federal, state and local controls and enforcement. Under- or over-estimating baseline emissions can heavily influence the need and cost-effectiveness of new

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controls. EPA should make a quantitative assessment of the uncertainties around baseline emissions so the Agency can estimate a potential range of emissions and the expected baseline. The number and uncertainty of factors affecting the expected baseline makes predictions difficult, even more so when predicted beyond a short time. EPA must systematically address this shortcoming.

The role of incidental or co-benefits in EPA's economic analyses is also important. The consideration of co-benefits has often distorted and confused the main purpose of the underlying statutory provision. For example, the 2012 Mercury and Air Toxics Standard (MATS) rule justified the regulation of mercury from electric generation units using co-benefits that represented over 99 percent of the claimed health benefits.<sup>8</sup> EPA has greater discretion to limit the role of co-benefits in final regulatory decisions because they are ancillary to the objective of regulatory activity. If the co-benefits are a concern, EPA can and should regulate them directly, allowing the agency to better identify the most cost-effective solution.

The EPA should also review limiting PM2.5 and ozone co-benefits to reductions above the NAAQS standard. The CAA requires EPA to set the NAAQS at a level that is protective of human health and welfare with an adequate margin of safety, and the agency must review these standards every five years. The agency should not claim additional substantial co-benefits when regulating other pollutants if they have already set a standard under NAAQS.

- e. *To what extent would it be helpful for EPA to require consideration of cumulative regulatory costs and benefits of multiple regulations during the rulemaking process, including how such consideration may affect the design or implementation of a regulation (i.e., longer or different compliance timeframes)?*

If multiple rules are likely to affect the same industry/sector within a short time period, then it makes sense to consider the cumulative impact of those regulations. If multiple rules are expected, EPA should consider more efficient, cost-effective rules that meet the law's requirements.

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<sup>8</sup> 77 Fed. Reg. 9,304 (February 16, 2012).

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EPA should also consider cumulative costs when imposing additional rules on heavily regulated industries. EPA should consider offsetting the cost of new regulation by eliminating regulations that are unnecessary or yield little improvement in environmental protection. EPA should also assess the cumulative impact of its regulations on the competitiveness of an industry and its ability to grow.

Related to this, EPA should consider job loss or displacement from regulation. EPA should properly conduct the analysis that is statutorily required under Sec. 321(a) of the CAA and examine the impact of its regulations on employment.<sup>9</sup> This consideration is important when EPA evaluates its cost-benefit analysis process, as rules that cause job losses or loss in income may produce offsetting health effects. EPA has never considered the drawback of job loss, despite the fact that it may substantially offset the claimed health effects benefits. EPA should follow the provision of the Clean Air Act requiring EPA’s Clean Air Scientific Advisory Committee (CASAC) to “advise the Administrator of any *adverse public health, welfare, social, economic, or energy effects* which may result from various strategies for *attainment and maintenance of such national ambient air quality standards.*” To date, CASAC has not offered such advisement, nor has EPA requested it.

In addition, typical EPA Regulatory Impact Analysis cost estimates are limited to direct compliance costs only. This narrow analysis fails to capture the substantial indirect impacts imposed on ultimate end-users, underestimating overall regulatory costs. EPA should undertake whole-economy modeling that is able to capture such effects.<sup>10</sup>

**B. 2. *What would improved transparency look like?***

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<sup>9</sup> EPA is required to consider employment effects as part of the original enabling legislation under the Clean Air Act. 42 USC 85:III § 7621: “(a) Continuous evaluation of potential loss or shifts of employment - The Administrator shall conduct continuing evaluations of potential loss or shifts of employment which may result from the administration or enforcement of the provision of this chapter and applicable implementation plans, including where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from such administration or enforcement.”

<sup>10</sup> [https://www.uschamber.com/sites/default/files/documents/files/3.10.16-comments\\_to\\_epa\\_on\\_sab\\_economy-wide\\_modeling\\_panel\\_teleconference.pdf](https://www.uschamber.com/sites/default/files/documents/files/3.10.16-comments_to_epa_on_sab_economy-wide_modeling_panel_teleconference.pdf)

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- a. *How might the documentation of how EPA considered costs and benefits in a regulatory decision be improved from current practices?*

EPA should improve the documentation and presentation of how they use cost-benefit analysis in rulemaking and of how they conducted the analysis itself. In general, the agency presents long and often complex regulatory impact analyses (RIAs) as standalone documents. The RIAs can be difficult to follow and in some cases, the agency presents the analysis with little transparency. EPA may present risks or health effects as simple outputs of black box models that the public cannot assess. Equally troublesome is the agency's lack of transparency in explaining to the public precisely what the results of the analysis mean and how they were interpreted and used.

In its RIAs, EPA should more transparently:

- (1) Select, evaluate and rank studies for use in risk assessment (including describing relevant studies that it chose not to use, and why).
- (2) Conduct sensitivity analysis of the key uncertainties.
- (3) Quantitatively evaluate each major uncertainty at each stage of estimating risks and benefits.
- (4) Assess and report the results of different models used.
- (5) Gather up-to-date cost data, including retrofit, design and revamping costs.
- (6) Assess weight-of-evidence.
- (7) Present full probability distributions, including central estimates and ranges of risks and benefits.
- (8) Document cost estimates based on vendor pricing and actual cost data.
- (9) Examine the potential range and uncertainty of cost estimates in a rigorous manner.

EPA should endeavor to document via narrative a step-by-step process that it uses in each rule when presenting cost-benefit analysis and explaining how it informs regulatory standards. The public should know when and how EPA considered costs, benefits, and uncertainties, and how they used these factors in setting standards.

EPA should also present both Value of a Statistical Life (VSL) and Value of a Statistical Life Year (VSLY) in all instances where the Agency uses these concepts to estimate health effects benefits. The current

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method of presenting only VSL is misleading, potentially leading the public to believe that health benefits of CAA regulations are greater than they actually are. If EPA presents both estimates and the difference between the two estimates is large, the public needs to know this and know why. Presenting both estimates adds to the robustness of EPA's health effects estimates and improves the public's understanding of a complex, technically challenging subject. More information, better presentation, and a more fulsome disclosure of the relevant uncertainties is vital.

- b. *In what ways can EPA increase transparency about the decision-making process in cases where the decision was based on information that is barred from release by law?*

EPA must comply with all statutory requirements protecting confidential data. EPA should investigate the potential of increasing transparency through the application of de-identification protocols and other procedures to anonymize data, allowing the Agency to make it available for use in verification, replication, and other studies.

Research institutions have successfully coded the data to reduce the risk of re-identification to a minimal level. For example, the Health Effects Institute (HEI) recently funded a new controlled human pollutant exposure study on older adults, known as the Multicenter Ozone Study in older Subjects (MOSES). In releasing the study, HEI fulfilled its longstanding commitment to make as much data from their studies available as possible by making the data and study materials available to any interested researcher.<sup>11</sup>

- B. 3. *To what extent would requiring a systematic retrospective review element in new regulations help to provide ongoing consistency and transparency in how regulatory decision making will adapt over time to new information? Such a requirement might provide a more regular and systematic approach to ex-post (i.e.***

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<sup>11</sup> The MOSES database is available on the Harvard Dataverse repository. Material (primarily blood samples) are available through a brief application process. All relevant documents and links, including forms to request specimens, can be found at [www.healtheffects.org/announcements/making-moses-data-and-specimens-available](http://www.healtheffects.org/announcements/making-moses-data-and-specimens-available). The database resides at <https://dataverse.harvard.edu/dataverse/MOSES> and was prepared for public use with assistance by statisticians at Westat.

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*after regulations have been promulgated and become effective) evaluation of the costs and benefits of EPA regulations, as compared with the periodic regulatory reviews the EPA has historically conducted.<sup>13</sup> This might help identify needed revisions, inform future regulatory approaches, and improve methods of ex ante analysis.*

Because EPA has never done a meaningful retrospective review of costs and benefits, it would likely need to work out the methodology and obtain useful data. EPA should explore this option and evaluate its utility by formulating a case study, potentially on a PM2.5 rulemaking.

EPA should rule out a retrospective review that focuses only on emissions reductions to validate benefits. Systematic reviews that focus merely on the amount of pollution reduced, while helpful, do not address whether the reductions improved public health or welfare.

Retrospective reviews of the cost of historical regulations could be helpful in assessing the accuracy of EPA's estimating procedures. The Agency should structure reviews carefully to include the full compliance costs of regulations, starting with the planning phase.

- a. *What are the opportunities and challenges associated with issuing regulations to require retrospective analysis and the concomitant need to collect data in order to conduct a meaningful retrospective analysis? Would it be more challenging under some provisions of key environmental statutes? If so, which ones?*

Retrospective reviews may be challenging and resource intensive, so EPA should evaluate them first as a case study to determine utility and needs. Instead of attempting retrospective reviews of all regulations, EPA should work with OMB to determine a subset of rulemakings where retrospective reviews can yield valuable information. Given the significant role of PM2.5 reductions in EPA's benefit estimates, EPA should determine whether retrospective reviews can show the estimated reductions in premature mortality that were used to justify the rules.

- b. *What criteria should EPA use to determine when retrospective review is needed? For example, should selection criteria be tied to the estimated*

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*impacts of the regulation, the degree of uncertainty at the time of ex ante analysis, the extent to which retrospective analysis will be feasible/successful?*

In determining whether a retrospective review is worthwhile, EPA should consider whether the review will be effective and what it will cost.

In deciding whether a review will be effective, EPA should determine whether it can define and easily assess a metric that can estimate the regulation's effect on public health or environmental criteria. Simply measuring how many tons or pounds of a pollutant have been reduced may be uninformative. EPA should focus on high-cost, high-benefit rules or rules that heavily impact one industry if it decides to pursue this course of action.

- c. *How specific should prospective plans for such a review be? For example, should plans specify the methodology that will be used, the coverage or scope of the analysis, the data that will be used and data collection plans?*

EPA may consider requesting that regulated entities keep track of all costs incurred by rule compliance. It may be easier to track prospective costs than retrospective ones. However, EPA should carefully select the rules for which the collection of such cost data is valuable for estimating analysis accuracy.

Unless there is a clear value to the collection of the data in providing cost insights or its effectiveness, EPA should not impose prospective review requirements.

**C. Potential for issuing regulations to govern EPA's approach in future rulemakings**

**EPA requests comment on opportunities and challenges associated with promulgating regulations to govern EPA's approach to cost and benefit considerations in future rulemakings. EPA is soliciting comment on whether and how best to develop such regulations.**

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***C. 1 What are the most pressing economic or legal considerations that should be taken into account when deciding the appropriate level of specificity (all activities, by statute, by specific statutory provision) at which to formulate regulations?***

EPA should proceed with issuing proposed and final rules on a statute-specific basis. Doing so will ensure that the resulting requirements for risks, benefits, and costs reflect the requirements, and that they address those provisions. EPA should clearly adhere to all existing statutory requirements in designing any subsequent rule. EPA should focus specifically on the CAA as a starting point for this effort.

EPA should assess legal procedures and challenges through the procedural requirements and challenges that arise during rulemaking for a single-statute-specific requirement: the Clean Air Act. EPA should evaluate the CAA first, as it is the most in need of reform due to a lack of transparency in that benefits estimation. EPA should set the basic principles of transparency the agency uses when conducting analysis for RIAs. The rulemaking should *not* prescribe individual requirements or be too rigid, and should set clear standards for good, transparent analysis of rules under the CAA.

***C. 2. What are the opportunities and challenges with issuing regulations to govern EPA's practice when statutory provisions do not mention costs or imply these are factors to be considered alongside benefits and other factors when setting pollution standards?***

Consistent with Supreme Court decisions in *Michigan v. EPA* and *Entergy Corp. v. Riverkeeper*, EPA should evaluate benefits and costs even when the statutory text does not mandate this. This will ensure that EPA considers a full range of factors in its regulatory decisions, recognizing that both public and private sector resources have important opportunity costs. An exclusive consideration of benefits could result in a disproportionate allocation of resources to address one health or environmental concern.

EPA's primary objective in issuing this rule should be to improve the metrics for how the Agency assesses and presents risks, benefits, and costs.

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However, given the differences in statutory text from one provision to another, EPA should avoid imposing a one-size-fits-all rule, such as “maximize net benefits,” in how EPA should consider and apply the benefit-cost evaluation in making regulatory decisions.

***C. 3. How can EPA best promote more consistency and predictability while still leaving room for consideration of regulatory context and for flexibility to adapt to new information and methodological advances?***

EPA should strive for greater consistency in how they assess and present risks, benefits and costs, but the Agency should leave some discretion in how they consider such information in making regulatory decisions. The predictability and enhanced consistency will come from the increased rigor, objectivity and transparency in developing and presenting estimates. This will be helpful for the public and for agency decision makers.

EPA can incorporate advances in the assessment of risks, benefits and costs over time by amending the rule as needed. In this way, the public can be informed and participate in the evolution of EPA’s techniques. A notice-and-comment process for the inclusion of new methodological advances may also elicit additional helpful ideas and viewpoints.

***C. 4. In cases where current EPA practice reflects prior judicial decisions, a change in course may come with significant burden to the Agency. Is there a way to address this concern in regulations governing the consideration of costs and benefits?***

If there are judicial decisions affecting how EPA interprets a given provision, EPA must act in a manner consistent with the judicial order. However, judicial orders rarely lock in an Agency’s technical or scientific understanding of an issue. Anytime EPA improves its understanding of the science supporting its risk, benefit, or cost estimates, the Agency runs the risk of potential inconsistencies with prior regulatory decisions or judicial decisions.

EPA cannot address this concern by obscuring changes from view or by preventing any changes in practice. Science is always changing and EPA should constantly be looking for ways to increase the accuracy and objectivity of its analysis.

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A rulemaking process provides the public and all stakeholders a chance to understand the basis for any change and its implications for subsequent rules. If the science supports the changes and they increase objectivity, then EPA should consider petitions to reopen judicial decisions or prior regulations. Those petitions are likely to be limited given that most affected entities will have already invested substantial resources to comply with regulations or judicial decrees.

***C. 5. Are there ways to improve consistency and transparency using methods other than a regulatory approach (e.g., additional guidance)? What are the opportunities and challenges associated with these approaches?***

EPA has an inconsistent record in adhering to Administration guidance and its own internally produced guidance. Since there is no judicial review or enforcement mechanism, there is no way to assure consistency in analysis over time based on guidance alone. This unpredictability has hurt regulatory decisions and undermined public participation and confidence in EPA rulemaking.

A rulemaking process adds clarity and establishes an expectation of compliance. If EPA identifies instances in a specific regulatory action where the application of specific elements of the rulemaking are not appropriate, EPA can simply propose amending the underlying rule simultaneously with any proposed action. The rulemaking process would alert the public and interested stakeholders to the change and would require EPA to explain and defend why the change is necessary. This is substantially better than EPA's current process for changing methodology and guidance.

***C. 6. Are any of the opportunities and challenges identified above specific to a particular statute or statutes? If so, please provide examples.***

Regulations under the Clean Air Act provide some of the greatest opportunities to address inconsistencies and lack of transparency in risk, benefit, and cost estimates due to the complexity of the regulations and the high cost and benefit estimates.

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**V. Conclusion**

The Chamber supports EPA's efforts to enhance transparency and consistency in its regulatory process. EPA should conduct statute-specific rulemakings and begin by focusing on improving analysis under the CAA in order to address the agency's biggest challenges. Limiting the scope of the regulatory benefit-cost analysis rulemaking should enable the agency to effectively address various issues that are specific to the CAA and minimize potential legal hurdles to conducting a one-size-fits-all rulemaking.

Additionally, EPA should focus on three specific factors affecting the benefit-cost analysis of CAA rules. First, EPA should revise the way the agency handles the uncertainty in estimating both costs and benefits. EPA should focus on how it uses scientific evidence to inform quantitative estimates of health benefits. EPA should immediately stop using opaque, subjective methodologies to select "endpoints" for estimating health effects and should instead institute an approach that incorporates all relevant evidence. EPA should also use Bayesian analytical techniques to model the broad range of potential health effects and better present uncertainty in its estimates.

If EPA desires to lower emissions of NAAQS pollutants, such as PM<sub>2.5</sub> and ozone, it should do so directly through the NAAQS. EPA should curtail the use of co-benefits as a justification for raising standards on PM<sub>2.5</sub> and ozone emissions via rulemakings authorized to regulate other pollutants. EPA should focus its rulemakings on directly regulated pollutants. EPA should limit any co-benefits to reductions in levels above the NAAQS limit the agency sets as protective of human health and welfare.

EPA should also improve the way it presents the results of cost-benefit analyses to the public. EPA should explain the results of the analysis succinctly and clearly. EPA should present relevant uncertainties to the public and explain what they mean. Finally, EPA should explain to the public precisely how and when the Agency used the results of the benefit-cost analysis.

By fixing the problems in cost-benefit analysis that have affected EPA's rulemakings in the past, the agency can improve the transparency and

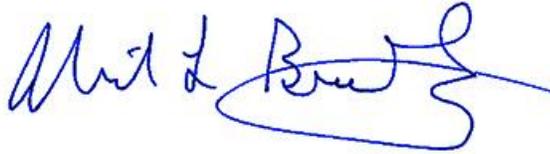
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consistency of its CAA regulations. Doing so will improve the public's understanding of what the agency's rules do, and do not, achieve. By eliminating some of the biases that have crept into EPA's regulatory process through subjective models, EPA will potentially increase participation in notice-and-comment rulemaking and ultimately incorporate more data and information in the process.

Sincerely,

A handwritten signature in blue ink, appearing to read "Neil L. Bradley", with a large, stylized flourish at the end.

Neil L. Bradley

ENCLOSURES (10)